Ventura County Health Care System Oversight Committee
Administrative Policies - Summary of Changes
April 29, 2026

#	Title	Review Period	Summary of Changes
1	L.BB.06 Safe-T-Vue® Temperature Indicators	Biennial	Biennial review. Minor edit(s)
2	L.BB.10 Refrigerator and Freezer Alarm Testing	Biennial	Biennial review. Minor edit(s)
3	L.BB.100 Critical Supplies and Services	Biennial	Biennial review. Minor edit(s)
4	L.BB.17 Blood Bank Specimen Identification, Labeling and Rejection	Biennial	Biennial review. Minor edit(s)
5	L.BB.23 Polyethylene Glycol Additive-Gamma PeG™	Biennial	Biennial review. Minor edit(s)
6	L.BB.24 Quality Control of 3% Surgiscreen Cells Using PEG	Biennial	Biennial review. Minor edit(s)
7	L.BB.26 Repeat Testing of Donor Blood	Biennial	Biennial review. Minor edit(s)
8	L.BB.29 Cold Antibody Identification	Biennial	Biennial review. Minor edit(s)
9	L.BB.30 Post Rh Immune Globulin Panel	Biennial	Biennial review. Minor edit(s)
10	L.BB.36 Check Type - ABO/Rh Confirmation	Biennial	Biennial review. Minor edit(s)
11	L.BB.38 Blood Bank Critical Values/Deviation from Standard Operating Procedures	Biennial	Biennial review. Minor edit(s)
12	L.BB.40 Positive Direct Antiglobulin Test Investigation	Biennial	Biennial review. Minor edit(s)
13	L.BB.49 Biological Product Deviation Reports	Biennial	Biennial review. Minor edit(s)
14	L.BB.56 Selected Cell Panel	Biennial	Biennial review. Minor edit(s)
15	L.BB.58 Lo-Ion Enhancement Medium	Biennial	Biennial review. Minor edit(s)
16	L.BB.60 Storage and Transportation of Blood Products	Biennial	Biennial review. Minor edit(s)
17	L.BB.62 Cryoprecipitated Antihemophilic Factor (AHF)	Biennial	Biennial review. Minor edit(s)
18	L.BB.69 Thawed Plasma – 5 Day	Biennial	Biennial review. Minor edit(s)
19	L.BB.71 Blood Bank Type and Screen/Crossmatch	Biennial	Biennial review. Minor edit(s)
20	L.BB.76 Ordering, Storage, and Return of Blood Components	Biennial	Biennial review. Minor edit(s)
21	L.BB.78 Blood Bank Correlation of Methods	Biennial	Biennial review. Minor edit(s)
22	L.BB.91 MTS™ Diluent Quality Control	Biennial	Biennial review. Minor edit(s)
23	L.BB.92 Red Cell Antigen Typing	Biennial	Biennial review. Minor edit(s)
24	L.BB.94 In-Vivo Crossmatch	Biennial	Biennial review. Minor edit(s)
25	L.BB.95 FMH Rapid Screen	Biennial	Biennial review. Minor edit(s)
26	L.BB.96 Quality Control of Blood Bank Reagents	Biennial	Biennial review. Minor edit(s)
27	L.BB.97 Verification of Functional Calibration on Serological Centrifuges	Biennial	Biennial review. Minor edit(s)
28	L.06 Terms of Accreditation by the College of American Pathologists	Biennial	Biennial review. Revised policy with latest practices.
29	L.16 Laboratory Employee Orientation	Biennial	Biennial review. Revised policy with latest practices.
30	L.26 Laboratory Quality Control	Biennial	Biennial review. Revised policy with latest practices.
31	L.33 Laboratory Analyzer and Equipment Utilization	Biennial	Biennial review. Revised policy with latest practices.
32	L.BB.102 Safe-T-Vue® 6 and Safe-T-Vue® 10 Quality Control	Biennial	Biennial review. Revised policy with latest practices.
33	L.BB.75 Supplying Blood in Blood Transport Coolers	Biennial	Biennial review. Revised policy with latest practices.
34	L.SPH.48 HCG Urine Qualitative - Medline hCG Combo	Biennial	Biennial review. Revised policy with latest practices.
35	L.CYT.1 Cytology Specimen Procurement - Introduction	Biennial	Migrated from binder to PolicyStat. Reviewed. Changed owner
36	L.CYT.10 Cerebral Spinal Fluid (CSF)	Biennial	Migrated from binder to PolicyStat. Reviewed. Changed owner
37	L.CYT.11 Criteria for the Rejection of Surgical Pathology and Cytology Specimens	Biennial	Migrated from binder to PolicyStat. Reviewed. Changed owner
38	L.CYT.12 Improperly Labeled Cytology Specimens	Biennial	Migrated from binder to PolicyStat. Reviewed. Changed owner
39	L.CYT.13 Accession Numbers and Reporting Non-Gyn Cytology and Cell Buttons	Biennial	Migrated from binder to PolicyStat. Reviewed. Changed owner
40	L.CYT.14 Cytology Specimens That May Be Contaminated With M. tuberculosis or Other Highly Infectious Organisms	Biennial	Migrated from binder to PolicyStat. Reviewed. Changed owner
41	L.CYT.15 Body Fluid, Cyst Fluid, Urine, and Cerebrospinal Fluid Processing	Biennial	Migrated from binder to PolicyStat. Reviewed. Changed owner

#	Title	Review Period	Summary of Changes
42	L.CYT.16 Cytospin 2	Biennial	Migrated from binder to PolicyStat. Reviewed. Changed owner
43	L.CYT.17 Bronchial Esophageal and Gastric Washings Processing	Biennial	Migrated from binder to PolicyStat. Reviewed. Changed owner
44	L.CYT.18 Sputum Specimen Processing	Biennial	Migrated from binder to PolicyStat. Reviewed. Changed owner
45	L.CYT.19 Histogel Cell Block Procedure	Biennial	Migrated from binder to PolicyStat. Reviewed. Changed owner
46	L.CYT.2 Specimens Which May be Excluded from Routine Submission to the Cytology Department	Biennial	Migrated from binder to PolicyStat. Reviewed. Changed owner
47	L.CYT.20 Preparation, Labeling, and Storage of Reagents	Biennial	Migrated from binder to PolicyStat. Reviewed. Changed owner
48	L.CYT.21 Papanicolaou Staining Procedure	Biennial	Migrated from binder to PolicyStat. Reviewed. Changed owner
49	L.CYT.22 Non-GYN Staining Procedure	Biennial	Migrated from binder to PolicyStat. Reviewed. Changed owner
50	L.CYT.24 Laboratory Performance Improvement	Biennial	Migrated from binder to PolicyStat. Reviewed. Changed owner
51	L.CYT.26 Quality Assurance for Pathology and Non-Gynecological Cytology	Biennial	Migrated from binder to PolicyStat. Reviewed. Changed owner
52	L.CYT.27 Sending Pathology/Cytology Material to Outside Institutions, consultants, or other Entities	Biennial	Migrated from binder to PolicyStat. Reviewed. Changed owner
53	L.CYT.28 Biohazard and Contaminated Waste Disposal	Biennial	Migrated from binder to PolicyStat. Reviewed. Changed owner
54	L.CYT.29 Handling Highly Infectious Specimens	Biennial	Migrated from binder to PolicyStat. Reviewed. Changed owner
55	L.CYT.3 After-Hours Instructions for Cytology/Histology Specimen Handling	Biennial	Migrated from binder to PolicyStat. Reviewed. Changed owner
56	L.CYT.31 Outside Slides	Biennial	Migrated from binder to PolicyStat. Reviewed. Changed owner
57	L.CYT.34 Communication of Significant or Unexpected Cytological Findings	Biennial	Migrated from binder to PolicyStat. Reviewed. Changed owner
58	L.CYT.35 Cytology Assessment Record	Biennial	Migrated from binder to PolicyStat. Reviewed. Changed owner
59	L.CYT.36 Cytology Workload Policy	Biennial	Migrated from binder to PolicyStat. Reviewed. Changed owner
60	L.CYT.37 Quality Management	Biennial	Migrated from binder to PolicyStat. Reviewed. Changed owner
61	L.CYT.38 Submitting Pap Smears to Quest	Biennial	Migrated from binder to PolicyStat. Reviewed. Changed owner
62	L.CYT.39 Specimen Rejection Criteria	Biennial	Migrated from binder to PolicyStat. Reviewed. Changed owner
63	L.CYT.4 Sputum Collection and Handling	Biennial	Migrated from binder to PolicyStat. Reviewed. Changed owner
64	L.CYT.40 Gastric Washings	Biennial	Migrated from binder to PolicyStat. Reviewed. Changed owner
65	L.CYT.5 Material Obtained at Bronchoscopy or Endoscopy	Biennial	Migrated from binder to PolicyStat. Reviewed. Changed owner
66	L.CYT.6 Body Cavity Fluids (Pleural, Peritoneal, Pericardial)	Biennial	Migrated from binder to PolicyStat. Reviewed. Changed owner
67	L.CYT.7 Urinary Tract Specimens	Biennial	Migrated from binder to PolicyStat. Reviewed. Changed owner
68	L.CYT.9 Image Guided Thyroid Fine Needle Aspiration	Biennial	Migrated from binder to PolicyStat. Reviewed. Changed owner
69	L.HIST.01 Specimens Exempt from Pathology Examination	Biennial	Migrated from binder to PolicyStat. Reviewed. Changed owner
70	L.HIST.03 Collection and Handling of Tissue Specimens	Biennial	Migrated from binder to PolicyStat. Reviewed. Changed owner
71	L.HIST.04 Specimen Identification	Biennial	Migrated from binder to PolicyStat. Reviewed. Changed owner
72	L.HIST.05 Accessioning Surgical Specimens	Biennial	Migrated from binder to PolicyStat. Reviewed. Changed owner
73	L.HIST.06 Outside Slides	Biennial	Migrated from binder to PolicyStat. Reviewed. Changed owner
74	L.HIST.07 Preparation of Tissues	Biennial	Migrated from binder to PolicyStat. Reviewed. Changed owner
75	L.HIST.09 Processing Tissue	Biennial	Migrated from binder to PolicyStat. Reviewed. Changed owner
76	L.HIST.11 Special Stain Techniques	Biennial	Migrated from binder to PolicyStat. Reviewed. Changed owner
77	L.HIST.13 Policy For Retaining Tissue Obtained From Surgery	Biennial	Migrated from binder to PolicyStat. Reviewed. Changed owner
78	L.HIST.14 Sending Pathology, Cytology, and Autopsy Material to Outside Institutions, Consultants, or Other Entities	Biennial	Migrated from binder to PolicyStat. Reviewed. Changed owner
79	L.HIST.17 Calculus (Stone) Analysis	Biennial	Migrated from binder to PolicyStat. Reviewed. Changed owner
80	L.HIST.18 CT-Guided Biopsies and Fine Needle Aspirate (FNA)	Biennial	Migrated from binder to PolicyStat. Reviewed. Changed owner

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81	L.HIST.19 Special Preparation for Electron Microscopy	Biennial	Migrated from binder to PolicyStat. Reviewed. Changed owner
82	L.HIST.23 Formaldehyde and Vapor Concentration Monitoring	Biennial	Migrated from binder to PolicyStat. Reviewed. Changed owner
83	L.HIST.24 Intra-Operative Frozen Sections	Biennial	Migrated from binder to PolicyStat. Reviewed. Changed owner
84	L.HIST.26 Special Handling of Highly Infectious Cytology and Surgical Pathology Specimens	Biennial	Migrated from binder to PolicyStat. Reviewed. Changed owner
85	L.HIST.27 Biohazard and Contaminated Waste Disposal for Surgical, Cytology, Autopsy, Blood, Body Fluid, and all Other Material	Biennial	Migrated from binder to PolicyStat. Reviewed. Changed owner
86	L.HIST.28 Frozen Section Technique for Tissues Infected by the AIDS Virus	Biennial	Migrated from binder to PolicyStat. Reviewed. Changed owner
87	L.HIST.29 Handling Specimens from Patients: Blood and Body Fluid Precautions	Biennial	Migrated from binder to PolicyStat. Reviewed. Changed owner
88	L.HIST.30 Handling of Tissues Containing Radioactive Material (I.E. Sentinel Lymph Nodes, Breast Biopsies, Prostatic "Seeds")	Biennial	Migrated from binder to PolicyStat. Reviewed. Changed owner
89	L.HIST.31 Handling of Shared Specimens	Biennial	Migrated from binder to PolicyStat. Reviewed. Changed owner
90	L.HIST.33 Criteria For Identifying Deaths Appropriate for Autopsy	Biennial	Migrated from binder to PolicyStat. Reviewed. Changed owner
91	L.HIST.34 Hospital Death Procedure	Biennial	Migrated from binder to PolicyStat. Reviewed. Changed owner
92	L.HIST.36 Fetal Deaths, Stillborn Infants, and Infant Deaths	Biennial	Migrated from binder to PolicyStat. Reviewed. Changed owner
93	L.HIST.37 Autopsy Protocol	Biennial	Migrated from binder to PolicyStat. Reviewed. Changed owner
94	L.HIST.39 Special Handling of Tissue in the Histology Lab of Autopsy, Surgical Tissue and Cytology Specimens in Which Creutzfeldt-Jakob Disease is Suspected	Biennial	Migrated from binder to PolicyStat. Reviewed. Changed owner
95	L.HIST.40 Cleaning Autopsy/Pathology Grossing Area	Biennial	Migrated from binder to PolicyStat. Reviewed. Changed owner
96	L.HIST.41 Specific Section Policies	Biennial	Migrated from binder to PolicyStat. Reviewed. Changed owner
97	L.HIST.45 Dissemination of Information when the Clinical History Submitted with a Specimen is Markedly Different from the Histologic Findings	Biennial	Migrated from binder to PolicyStat. Reviewed. Changed owner
98	L.HIST.46 Interdepartmental Consultations	Biennial	Migrated from binder to PolicyStat. Reviewed. Changed owner
99	L.HIST.48 Reflective Communication of Information Concerning Specimen tests and patient Care by the On-Call Physician	Biennial	Migrated from binder to PolicyStat. Reviewed. Changed owner
100	L.HIST.49 Interdepartmental Consultations About Proficiency Testing	Biennial	Migrated from binder to PolicyStat. Reviewed. Changed owner
101	L.HIST.50 Referral for Proficiency Testing Samples to Another Laboratory	Biennial	Migrated from binder to PolicyStat. Reviewed. Changed owner
102	L.HIST.51 Tissue Sample Quality Control Including Corrective Action	Biennial	Migrated from binder to PolicyStat. Reviewed. Changed owner
103	L.HIST.52 Quality of Formalin	Biennial	Migrated from binder to PolicyStat. Reviewed. Changed owner
104	L.HIST.53 Cleaning Surgical Pathology Grossing Area and Instruments	Biennial	Migrated from binder to PolicyStat. Reviewed. Changed owner
105	L.HIST.54 Decontamination of Cryostat	Biennial	Migrated from binder to PolicyStat. Reviewed. Changed owner
106	L.HIST.55 Cleaning Flotation Bath	Biennial	Migrated from binder to PolicyStat. Reviewed. Changed owner
107	L.HIST.56 Disposal of Used Glass Slides and Paraffin Blocks	Biennial	Migrated from binder to PolicyStat. Reviewed. Changed owner
108	L.HIST.57 Storage Retrieval/Pickup	Biennial	Migrated from binder to PolicyStat. Reviewed. Changed owner
109	L.HIST.58 Cross-Contamination in Histology	Biennial	Migrated from binder to PolicyStat. Reviewed. Changed owner
110	L.HIST.59 Cancer Protocols	Biennial	Migrated from binder to PolicyStat. Reviewed. Changed owner
111	L.HIST.60 Synoptic Reporting	Biennial	Migrated from binder to PolicyStat. Reviewed. Changed owner
112	L.HIST.62 Procedure for Reporting Gross Findings in the Surgical Pathology Reports	Biennial	Migrated from binder to PolicyStat. Reviewed. Changed owner
113	L.HIST.65 Manually Adding Charges to AP Reference Laboratory Testing	Biennial	Migrated from binder to PolicyStat. Reviewed. Changed owner
114	L.HIST.67 Gram Stain for Bacteria in Tissue	Biennial	Migrated from binder to PolicyStat. Reviewed. Changed owner
115	L.HIST.68 Kinyoun's Acid-Fast Stain (AFB)	Biennial	Migrated from binder to PolicyStat. Reviewed. Changed owner
116	L.HIST.69 Grocott Methenamine Silver Nitrate (GMS) Stain	Biennial	Migrated from binder to PolicyStat. Reviewed. Changed owner

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117	L.HIST.70 Alcian Blue, pH 2.5	Biennial	Migrated from binder to PolicyStat. Reviewed. Changed owner
118	L.HIST.71 Periodic Acid-Schiff (PAS)	Biennial	Migrated from binder to PolicyStat. Reviewed. Changed owner
119	L.HIST.72 Mayer's Mucicarmine Stain for Staining Mucins of Epithelial Origin	Biennial	Migrated from binder to PolicyStat. Reviewed. Changed owner
120	L.HIST.73 Stains for Pigments and Minerals: Iron Stain	Biennial	Migrated from binder to PolicyStat. Reviewed. Changed owner
121	L.HIST.75 Gomori's Method for Reticulum Fibers	Biennial	Migrated from binder to PolicyStat. Reviewed. Changed owner
122	L.HIST.76 Monochromatic Blue Stain of Organism and Tissue	Biennial	Migrated from binder to PolicyStat. Reviewed. Changed owner
123	L.CYT.23 Staining Non-Gyn Specimens to Avoid Cross-Contamination	Biennial	Migrated from binder to PolicyStat. Reviewed. Changed owner and other edits
124	L.HIST.35 Processing a Death	Biennial	Migrated from binder to PolicyStat. Reviewed. Changed owner and other edits
125	L.HIST.38 Autopsy Consent	Biennial	Migrated from binder to PolicyStat. Reviewed. Changed owner and other edits
126	L.HIST.43 Quality Assurance for Pathology and Non-Gynecological Cytology	Biennial	Migrated from binder to PolicyStat. Reviewed. Changed owner and other edits
127	L.HIST.47 Quality Management For Surgical Pathology and Autopsy	Biennial	Migrated from binder to PolicyStat. Reviewed. Changed owner and other edits
128	L.HIST.74 Masson's Trichrome Method for Connective Tissue	Biennial	Migrated from binder to PolicyStat. Reviewed. Changed owner and other edits
129	L.1.1 Statement Of Accountability	Biennial	Migrated from binder to PolicyStat. Reviewed. Formatting
130	L.101 Amplified Gc/Chlamydia (Genital Swab and Urine)	Biennial	Migrated from binder to PolicyStat. Reviewed. Formatting
131	L.MIC 7.09 STERILE BODY FLUIDS SUBMITTED IN BACTALERT BLOOD CULTURE BOTTLES	Biennial	Migrated from binder to PolicyStat. Reviewed. Formatting
132	L.MIC.2.1 Biofire RP2.1	Biennial	Migrated from binder to PolicyStat. Reviewed. Formatting
133	L.102 Cortisol and Cortisol Stimulation Test	Biennial	Migrated from binder to PolicyStat. Reviewed. Minor edit(s)
134	L.103 Cortisol and ACTH Stimulation Test	Biennial	Migrated from binder to PolicyStat. Reviewed. Minor edit(s)
135	L.104 Cystic Fibrosis	Biennial	Migrated from binder to PolicyStat. Reviewed. Minor edit(s)
136	L.105 Fetal Fibronectin	Biennial	Migrated from binder to PolicyStat. Reviewed. Minor edit(s)
137	L.106 HIV Testing	Biennial	Migrated from binder to PolicyStat. Reviewed. Minor edit(s)
138	L.107 Rapid HIV-1/2 Antibody Test in Whole Blood OraQuick® Advance™ Rapid HIV-1/2 Antibody Test	Biennial	Migrated from binder to PolicyStat. Reviewed. Minor edit(s)
139	L.109 Neonatal UA and Neonatal Urine Glucose	Biennial	Migrated from binder to PolicyStat. Reviewed. Minor edit(s)
140	L.111 Bordetella Pertussis by PCR	Biennial	Migrated from binder to PolicyStat. Reviewed. Minor edit(s)
141	L.113 Processing Induced Sputum for PCP	Biennial	Migrated from binder to PolicyStat. Reviewed. Minor edit(s)
142	L.114 Stool Collection and Handling	Biennial	Migrated from binder to PolicyStat. Reviewed. Minor edit(s)
143	L.115 Specimen Collection: Urine	Biennial	Migrated from binder to PolicyStat. Reviewed. Minor edit(s)
144	L.116 24 Hour Urine Collection	Biennial	Migrated from binder to PolicyStat. Reviewed. Minor edit(s)
145	L.60 Laboratory Chemical Hygiene Plan	Biennial	Migrated from binder to PolicyStat. Reviewed. Minor edit(s)
146	L.78 Isolation: Phlebotomy Application	Biennial	Migrated from binder to PolicyStat. Reviewed. Minor edit(s)
147	L.81 Specimen Collection Tubes	Biennial	Migrated from binder to PolicyStat. Reviewed. Minor edit(s)
148	L.92 Blood Collection Techniques: Venipuncture	Biennial	Migrated from binder to PolicyStat. Reviewed. Minor edit(s)
149	L.93 Venipuncture: Winged Blood Collection Sets	Biennial	Migrated from binder to PolicyStat. Reviewed. Minor edit(s)
150	L.95 Capillary Specimen Collection Heel Puncture	Biennial	Migrated from binder to PolicyStat. Reviewed. Minor edit(s)
151	L.MIC.8.0 Quality Control	Biennial	Migrated from binder to PolicyStat. Reviewed. Minor edit(s)
152	L.108 Malaria (Parasite) Smears	Biennial	Migrated from binder to PolicyStat. Reviewed. No changes
153	L.68 Phlebotomist Responsibilities: General	Biennial	Migrated from binder to PolicyStat. Reviewed. No changes
154	L.69 Trauma Response	Biennial	Migrated from binder to PolicyStat. Reviewed. No changes
155	L.70 Orientation Checklist	Biennial	Migrated from binder to PolicyStat. Reviewed. No changes
156	L.71 Phlebotomy Competency Assessment	Biennial	Migrated from binder to PolicyStat. Reviewed. No changes
157	L.72 Phlebotomy Supply and Ordering	Biennial	Migrated from binder to PolicyStat. Reviewed. No changes

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158	L.73 Patient Identification	Biennial	Migrated from binder to PolicyStat. Reviewed. No changes
159	L.74 Patient Interactions: Age Specific/Special Considerations	Biennial	Migrated from binder to PolicyStat. Reviewed. No changes
160	L.75 Patient Interaction	Biennial	Migrated from binder to PolicyStat. Reviewed. No changes
161	L.76 Minimum Volumes for Nursery Draw	Biennial	Migrated from binder to PolicyStat. Reviewed. No changes
162	L.80 Specimen Labeling Requirements: General	Biennial	Migrated from binder to PolicyStat. Reviewed. No changes
163	L.85 Send Out Tests	Biennial	Migrated from binder to PolicyStat. Reviewed. No changes
164	L.91 Venous Blood Specimen Collection	Biennial	Migrated from binder to PolicyStat. Reviewed. No changes
165	L.CGL 1.2 Coagulation Reference Ranges	Biennial	Migrated from binder to PolicyStat. Reviewed. No changes
166	L.CGL 1.3 Critical Results - Coagulation Department	Biennial	Migrated from binder to PolicyStat. Reviewed. No changes
167	L.CGL 1.4 Canceling & Reordering Tests for Unacceptable Specimens - Coagulation Department	Biennial	Migrated from binder to PolicyStat. Reviewed. No changes
168	L.CGL 1.5 Disseminated Intravascular Coagulopathy (DIC)	Biennial	Migrated from binder to PolicyStat. Reviewed. No changes
169	L.CGL 2.1 Daily Quality Control – Sysmex® CS2500 (PT & PTT)	Biennial	Migrated from binder to PolicyStat. Reviewed. No changes
170	L.CGL 2.2 Daily Quality Control Sysmex CS2500 (D-dimer, Fibrinogen, and Heparin, Anti-Xa)	Biennial	Migrated from binder to PolicyStat. Reviewed. No changes
171	L.CGL 2.3 Running Patient Specimens – Sysmex CS2500	Biennial	Migrated from binder to PolicyStat. Reviewed. No changes
172	L.CGL 2.4 Coagulation Testing Review Criteria	Biennial	Migrated from binder to PolicyStat. Reviewed. No changes
173	L.CGL 3.1 High Hematocrit (HCT) Correction	Biennial	Migrated from binder to PolicyStat. Reviewed. No changes
174	L.CGL 3.2 Coagulation Results and Clot Curve Interpretations	Biennial	Migrated from binder to PolicyStat. Reviewed. No changes
175	L.CGL 4.1 Maintenance Protocol CS2500	Biennial	Migrated from binder to PolicyStat. Reviewed. No changes
176	L.CGL 5.1 New Lot Quality Control & Reagents PT, PTT, Fibrinogen - (Lot Rollover) Sysmex CS2500	Biennial	Migrated from binder to PolicyStat. Reviewed. No changes
177	L.CGL 5.2 Calibration and New Lot Change Fibrinogen, D-Dimer & Heparin, Anti-XA Reagent	Biennial	Migrated from binder to PolicyStat. Reviewed. No changes
178	L.CGL 5.3 Platelet Poor Plasma Verification - Centrifuges	Biennial	Migrated from binder to PolicyStat. Reviewed. No changes
179	L.CGL 5.4 Intra-Instrument Comparisons – Sysmex CS2500	Biennial	Migrated from binder to PolicyStat. Reviewed. No changes
180	L.MIC 1.14 Disease Reporting to Assess Potential Bioterrorism Events	Biennial	Migrated from binder to PolicyStat. Reviewed. No changes
181	L.MIC 1.15 Bioterrorism Recognition	Biennial	Migrated from binder to PolicyStat. Reviewed. No changes
182	L.MIC 1.16 Brucellosis in the Context of Bioterrorism	Biennial	Migrated from binder to PolicyStat. Reviewed. No changes
183	L.MIC 1.17 Clinical Laboratory Bioterrorism Readiness Plan	Biennial	Migrated from binder to PolicyStat. Reviewed. No changes
184	L.MIC 1.18 Safe Work Practices	Biennial	Migrated from binder to PolicyStat. Reviewed. No changes
185	L.MIC 1.19 Microbiology Safety	Biennial	Migrated from binder to PolicyStat. Reviewed. No changes
186	L.MIC 1.20 Biosafety Levels	Biennial	Migrated from binder to PolicyStat. Reviewed. No changes
187	L.MIC 1.21 Biological Safety Cabinet	Biennial	Migrated from binder to PolicyStat. Reviewed. No changes
188	L.MIC 1.22 Taxonomic Changes of Microorganisms	Biennial	Migrated from binder to PolicyStat. Reviewed. No changes
189	L.MIC 1.23 Miscellaneous Antimicrobial Susceptibility Testing and Unusual Organism Isolation	Biennial	Migrated from binder to PolicyStat. Reviewed. No changes
190	L.MIC 10.1 VITEK® 2 Identification Card Systems	Biennial	Migrated from binder to PolicyStat. Reviewed. No changes
191	L.MIC 10.2 VITEK® 2 Antimicrobial Susceptibility Tests (AST)	Biennial	Migrated from binder to PolicyStat. Reviewed. No changes
192	L.MIC 10.3 VITEK MS PRIME	Biennial	Migrated from binder to PolicyStat. Reviewed. No changes
193	L.MIC 3.5 Cepheid SARS/FLU/RSV Assay	Biennial	Migrated from binder to PolicyStat. Reviewed. No changes
194	L.MIC 4.1 Making Smears on Slides	Biennial	Migrated from binder to PolicyStat. Reviewed. No changes

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195	L.MIC 4.3 Quantitative Cultures of Wound Tissues	Biennial	Migrated from binder to PolicyStat. Reviewed. No changes
196	L.MIC 4.4 Quantitative Culture of Bronchoalveolar Lavage (BAL) and Protected Brush Specimens (PBS)	Biennial	Migrated from binder to PolicyStat. Reviewed. No changes
197	L.MIC 4.5 Cystic Fibrosis Specimen Processing	Biennial	Migrated from binder to PolicyStat. Reviewed. No changes
198	L.MIC 5.1 Gram Stain	Biennial	Migrated from binder to PolicyStat. Reviewed. No changes
199	L.MIC 5.2 Sputum Quality Evaluation	Biennial	Migrated from binder to PolicyStat. Reviewed. No changes
200	L.MIC 5.4 Direct Examination of Stool Specimens	Biennial	Migrated from binder to PolicyStat. Reviewed. No changes
201	L.MIC 5.5 Direct Microscopic Examination of Mycology Specimens	Biennial	Migrated from binder to PolicyStat. Reviewed. No changes
202	L.MIC 5.7 Wet Mount	Biennial	Migrated from binder to PolicyStat. Reviewed. No changes
203	L.MIC 6.1 Blood Parasite Detection	Biennial	Migrated from binder to PolicyStat. Reviewed. No changes
204	L.MIC 6.2 Assessing Percent Parasitemia of Positive Malarial Smear	Biennial	Migrated from binder to PolicyStat. Reviewed. No changes
205	L.MIC 6.3 AFB Culture Handling, Processing, and Transport	Biennial	Migrated from binder to PolicyStat. Reviewed. No changes
206	L.MIC 6.4 Fungal Culture Handling, Processing and Transport	Biennial	Migrated from binder to PolicyStat. Reviewed. No changes
207	L.MIC 7.03 Unloading & Preliminary Work Up of BacT/Alert Positive Bottles	Biennial	Migrated from binder to PolicyStat. Reviewed. No changes
208	L.MIC 7.04 Blood Cultures-Conventional Handling	Biennial	Migrated from binder to PolicyStat. Reviewed. No changes
209	L.MIC 7.05 Blood Culture for Malasezzia furfur	Biennial	Migrated from binder to PolicyStat. Reviewed. No changes
210	L.MIC 7.06 Blood Culture Contamination Rate Quality Assurance	Biennial	Migrated from binder to PolicyStat. Reviewed. No changes
211	L.MIC 7.07 Handling of Probable Contaminants	Biennial	Migrated from binder to PolicyStat. Reviewed. No changes
212	L.MIC 7.10 CULTURE OF SUSPECTED CONTAMINATED BANKED BLOOD, PLASMA AND OTHER INFUSED FLUIDS	Biennial	Migrated from binder to PolicyStat. Reviewed. No changes
213	L.MIC 7.12 Cystic Fibrosis Culture	Biennial	Migrated from binder to PolicyStat. Reviewed. No changes
214	L.MIC 7.13 Ear Cultures	Biennial	Migrated from binder to PolicyStat. Reviewed. No changes
215	L.MIC 7.14 Eye Cultures	Biennial	Migrated from binder to PolicyStat. Reviewed. No changes
216	L.MIC 7.15 Genital Cultures	Biennial	Migrated from binder to PolicyStat. Reviewed. No changes
217	L.MIC 7.17 Gonococcus Screen	Biennial	Migrated from binder to PolicyStat. Reviewed. No changes
218	L.MIC 7.18 Sinus Cultures	Biennial	Migrated from binder to PolicyStat. Reviewed. No changes
219	L.MIC 7.20 Catheter Tip Cultures	Biennial	Migrated from binder to PolicyStat. Reviewed. No changes
220	L.MIC 7.22 Quantitative Cultures of Wound TIssues	Biennial	Migrated from binder to PolicyStat. Reviewed. No changes
221	L.MIC 7.24 Candida auris Surveillance Screen	Biennial	Migrated from binder to PolicyStat. Reviewed. No changes
222	L.MIC 7.25 Methicillin Resistant Staphylococcus Aureus Admission Screening by Culture	Biennial	Migrated from binder to PolicyStat. Reviewed. No changes
223	L.MIC 7.26 Group B Streptococcus Cultures	Biennial	Migrated from binder to PolicyStat. Reviewed. No changes
224	L.MIC 7.27 Throat Culture for Gonorrhoeae	Biennial	Migrated from binder to PolicyStat. Reviewed. No changes
225	L.MIC 7.28 Respiratory Tract Cultures	Biennial	Migrated from binder to PolicyStat. Reviewed. No changes
226	L.MIC 7.29 Quantitative cultures of BAL and PBS	Biennial	Migrated from binder to PolicyStat. Reviewed. No changes
227	L.MIC 7.30 Yeast ID Scheme	Biennial	Migrated from binder to PolicyStat. Reviewed. No changes
228	L.MIC 8.10 Compressed Gas Regulators and Handling of Cylinders	Biennial	Migrated from binder to PolicyStat. Reviewed. No changes
229	L.MIC 8.11 Calibration of Microscope with an Ocular Micrometer	Biennial	Migrated from binder to PolicyStat. Reviewed. No changes
230	L.MIC 8.4 Use of Kwik Stik Microorganisms	Biennial	Migrated from binder to PolicyStat. Reviewed. No changes
231	L.MIC 8.5 Stock Culture Maintenance	Biennial	Migrated from binder to PolicyStat. Reviewed. No changes
232	L.MIC 8.6 Unavailability of QC Organisms	Biennial	Migrated from binder to PolicyStat. Reviewed. No changes
233	L.MIC 8.7 General Instrument Maintenance	Biennial	Migrated from binder to PolicyStat. Reviewed. No changes
234	L.MIC 8.8 Verification of Procedures and Instrumentation	Biennial	Migrated from binder to PolicyStat. Reviewed. No changes

Ventura County Health Care System Oversight Committee
Administrative Policies - Summary of Changes
April 29, 2026

#	Title	Review Period	Summary of Changes
235	L.MIC 9.2 E test Daptomycin	Biennial	Migrated from binder to PolicyStat. Reviewed. No changes
236	L.MIC.2.2 Meningitis Encephalitis Panel	Biennial	Migrated from binder to PolicyStat. Reviewed. No changes
237	L.MIC.2.3 Film Array GI Panel	Biennial	Migrated from binder to PolicyStat. Reviewed. No changes
238	L.MIC.2.4 Biofire Blood Culture Identification	Biennial	Migrated from binder to PolicyStat. Reviewed. No changes
239	L.MIC.7.01 Blood Culture Collection	Biennial	Migrated from binder to PolicyStat. Reviewed. No changes
240	L.MIC.7.11 CSF Cultures	Biennial	Migrated from binder to PolicyStat. Reviewed. No changes
241	L.MIC.7.21 Skin, Soft Tissue, and Wound Cultures	Biennial	Migrated from binder to PolicyStat. Reviewed. No changes
242	L.MIC.8.1 Handling of Microbiology Supplies, Reagents, Disks, Media and ID Kits	Biennial	Migrated from binder to PolicyStat. Reviewed. No changes
243	L.MIC.8.2 Reagent Preparation	Biennial	Migrated from binder to PolicyStat. Reviewed. No changes
244	L.UA 1.1 Specimen Rejection, Acceptability and Stability Criteria - Urinalysis	Biennial	Migrated from binder to PolicyStat. Reviewed. No changes
245	L.UA 3.1 Urine Eosinophil's	Biennial	Migrated from binder to PolicyStat. Reviewed. No changes
246	L.UA 3.4 Cerebrospinal and Serous Fluids Cell Count- IRIS iQ200	Biennial	Migrated from binder to PolicyStat. Reviewed. No changes
247	L.UA 4.1 Maintenance Protocol UA Bench (Au-11)	Biennial	Migrated from binder to PolicyStat. Reviewed. No changes
248	L.UA.4.2 Maintenance Protocol – IRIS (Arkray AX-4030 and iQ Elite)	Biennial	Migrated from binder to PolicyStat. Reviewed. No changes
249	L.118 Quality Management System Clinical Laboratory Ventura County Medical Center Santa Paula Hospital	Biennial	Migrated from binder to PolicyStat. Reviewed. Revised policy with latest practices
250	L.86 Laboratory Test Add-On	Biennial	Migrated from binder to PolicyStat. Reviewed. Revised policy with latest practices
251	L.98 Blood Collection By Skin Puncture	Biennial	Migrated from binder to PolicyStat. Reviewed. Revised policy with latest practices
252	L.LIS.04 User Authentication, User Authorization Privileges, Unauthorized Software Installation, and Intake Procedure	Biennial	Migrated from binder to PolicyStat. Reviewed. Revised policy with latest practices

Status **Active** PolicyStat ID **19747355**

Origination	3/18/2010
Last Approved	2/9/2026
Effective	2/9/2026
Last Revised	2/9/2026
Next Review	2/9/2028
Owner	Kathrina Barcena: Supervisor-Blood Bank, Laboratory Services
Policy Area	Laboratory Services - Blood Bank

L.BB.06 Safe-T-Vue® Temperature Indicators

COPY

PRINCIPLE:

Safe-T-Vue® is a nonreversible temperature indicator that changes color from white to red when the safe temperature for blood has been reached or exceeded. The indicators are designed to attach directly to the blood bag or product being transported or stored.

SPECIMEN COLLECTION:

N/A

MATERIALS/EQUIPMENT:

1. Safe-T-Vue® 6
2. Safe-T-Vue®10
3. Refrigerator to maintain temperature sensitive blood products between 2°C and 4.5°C and storage of Safe-T-Vue® indicators.

Guidelines:

Step	Description
1	Safe-T-Vue® blood temperature indicators will be placed on all red blood cells and thawed plasma issued in a blood transport cooler.
2	• Safe-T-Vue® 6 – placed on all blood products issued in a blood transport cooler for temporary storage for up to 4 hours. These units can be returned to the blood bank for reissue if the indicator color is still white. (Example: ER, OR, ICU)

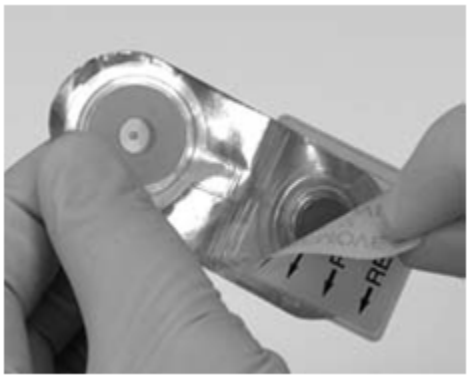
Step	Description
	• Safe-T-Vue® 10- placed on all blood products issued in a blood transport cooler for transport to a ward for immediate transfusion. Unit(s) most likely will be transfused and not returned. Units can be returned for reissue if the indicator color is still white. (Example: Hematology/Oncology Infusion Department or Dialysis)

CALIBRATION:

N/A

CALCULATIONS:

N/A

Step	Action	Comment
1	Store indicator boxes of Safe-T-Vue® 6 and Safe-T-Vue® 10 in refrigerator at temperatures below 5°C for 24 hours prior to use.	All received indicator boxes will be stored in the blood product refrigerator upon receipt.
2	Remove one unit of red blood cells or thawed plasma to be issued and monitored and one Safe-T-Vue® 6 or 10 temperature indicator from the refrigerator at the same time and place blood bag on lab bench. • **Safe-T-Vue® 6 -** for red blood cells and thawed plasma that require temporary storage temperatures between 1-6°C for up to a maximum of 4 hours. (ER, OR, ICU) • **Safe-T-Vue® 10 -** for red blood cells and thawed plasma requiring safe transport temperatures between 1-10°C. (Infusion/Dialysis)	Placing a cold pack under the unit will help maintain temperature of blood during dispensing process. Multiple polar gel 16 oz cold packs are located in the bottom left of the blood product refrigerator. *Take great care to handle Safe-T-Vue® indicators by the colored label end only.*
3	Remove the adhesive cover and place sticky end of Safe-T-Vue on the bag or temperature-sensitive product being monitored BEFORE peeling off the printed white paper/foil like to expose the white and red rounds.	

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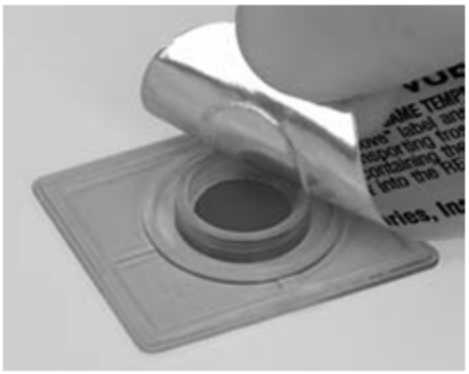
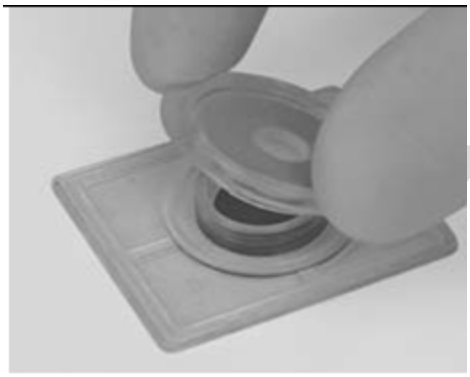
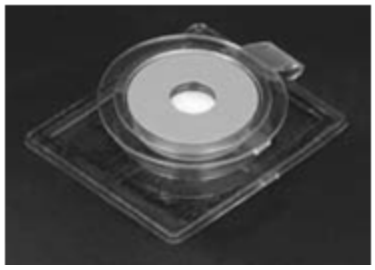
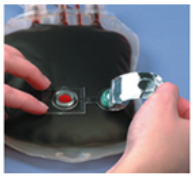
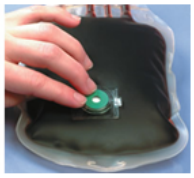
Step	Action	Comment
4	• Be certain that the Safe-T-Vue® Temperature indicator is completely in contact with the blood bag – no air pockets should be under the indicator due to a fold in the bag or other obstruction. • Place on area of the bag where there is the greatest volume of blood during placement and shipment or storage. • Peel off the printed white paper/foil lid to expose the white and red rounds.	
5	To Activate, firmly press the white round color-coded label end into the red round until they fully close together. Be careful to press ONLY on the white round color-coded label to activate properly. ***Safe-T-Vue indicators may remain on units as long as the red color has not been observed.***	 
6	 	

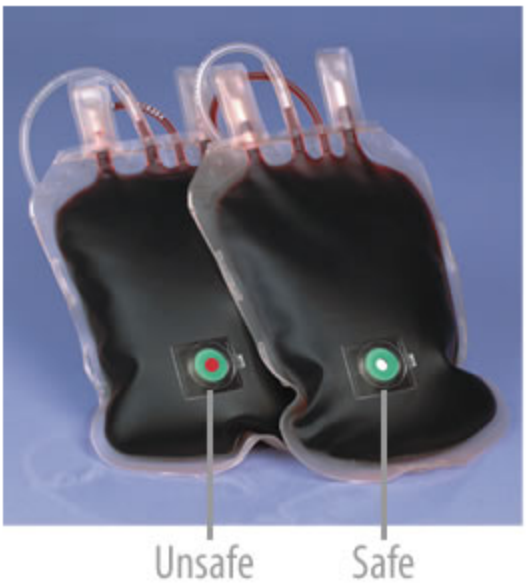
QUALITY CONTROL:

1. Safe-T-Vue® 6 and Safe-T-Vue® 10 lot specific quality assurance documents.
2. Safe-T-Vue® 6 and Safe-T-Vue® 10 Quality Control (SOP BB 8.9)

RESULTS:

Color change Interpretation

1. The color change may start taking place at approximately 1°C below the maximum allowed temperature of the Safe-T-Vue® indicators.
2. The maximum temperature has been reached ONLY when the entire white area is colored rose to red.
    a. Sometimes a pinkish hue or cast can be observed in the white disk at the start. THIS IS NOT A TEMPERATURE CHANGE. Depending upon the light source, it is a muted refraction of the bottom red disc. It is clearly distinguishable from the color change of rose to red. Use of a positive control is recommended to ensure correct interpretation.
3. The start of the color change is typically in spots of light rose to red anywhere in the white area but is not completed until the white area has entirely turned to red.



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LIMITATIONS:

When you observe a red color indication but are certain the blood or temperature-sensitive product being monitored is below the color-indicating temperature of the Safe-T-Vue® product you are using, please review the following list of actions and/or environmental factors to determine what may be provoking the red indication:

1. **Handling of Safe-T-Vue® at the Wrong end -** Indicator should be handled ONLY by the round, color-coded label end. Safe-T-Vue is extremely sensitive to its environment, and touching or grasping the red end of the indicator will usually provoke the temperature-sensitive materials contained in Safe-T-Vue®.

2. **Improper Activation -** when activating, be sure to press ONLY on the white, color-coded round label end into the red end. Pressing directly on the red end may provoke a color change.
3. **Premature Removal of Paper/Foil Lid -** peel the paper/foil lid only AFTER attaching the Safe-T-Vue® Temperature Indicator to the blood bag. Peeling before attachment may provoke a color change.
4. **Excessive Time Taken to Activate -** for Safe-T-Vue ® 10, activation should occur within 15 seconds from the time Safe-T-Vue® is removed from the refrigerator.
5. Since a cold start of less than 4.5°C is required, it is preferable to activate Safe-T-Vue® 6 in the blood refrigerator. Alternately, Safe-T-Vue® 6 can be activated IMMEDIATELY after removing the bag (with applied Safe-T-Vue®) from the blood refrigerator.
6. **Busy Refrigerator -** a high door-count blood refrigerator may warm Safe-T-Vue® if it is located in an area of the refrigerator where it is swept by warm room air. Safe-T-Vue® should be located in a sheltered area to maintain proper start temperature.
7. **Blood Not Cold Enough -** blood received from a supplier is sometimes very close to 10°C on arrival. Be certain blood is cooled in the refrigerator a minimum of 90 minutes before release from the blood bank when a return is likely, such as when sending to the OR.

REFERENCES:

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1. William Laboratories, Inc. Product Sheet SAL/0100-2, Rev 01, 11/16/07.
2. Package insert "*Handling/Use Instructions/Frequently Asked Questions (FAQs) and Color change Interpretation Information.*"
3. Use of Cold Packs during Dispensing of Blood; Feb. 27, 2008; Rev 0 ©Copyright, William Laboratories, Inc. 2008.
4. American Association of Blood Banks ,*Standards for Blood Banks and Transfusion Services*, Reissue of Blood and Components, 25th edition, 2008.


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Paper copy reviewed on 12/12/2023 by Janette O'Neill.
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All Revision Dates

2/9/2026, 2/27/2024, 12/1/2016

Approval Signatures

Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator, VCMC & SPH	2/9/2026

Laboratory Services Department	Erlinda Roxas: Director, Laboratory Services	2/8/2026
Laboratory Services Department	Kathrina Barcena: Supervisor-Blood Bank, Laboratory Services	2/5/2026
Laboratory Services Department	Linda Lee: Medical Director, VCMC Blood Bank	1/26/2026

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Status **Active** PolicyStat ID **19747328**

Origination	12/1/2002
Last Approved	2/9/2026
Effective	2/9/2026
Last Revised	2/9/2026
Next Review	2/9/2028
Owner	Kathrina Barcena: Supervisor-Blood Bank, Laboratory Services
Policy Area	Laboratory Services - Blood Bank

L.BB.10 Refrigerator and Freezer Alarm Testing

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PRINCIPLE:

Blood storage refrigerators and freezers must be equipped with a system for continuous temperature monitoring and an audible alarm. If a storage unit goes into alarm, it is essential that Blood Bank staff know the appropriate actions to take. The alarm on each blood-storage refrigerator and freezer must be checked periodically to be sure that it is functioning properly. The refrigerator will be tested for high and low temperatures of activation and the freezer for high temperature of activation. This testing will be performed quarterly. If a new refrigerator or freezer is purchased, the testing will be done monthly until consistent behavior has been demonstrated.

SPECIMEN COLLECTION:

N/A

REAGENTS- Special Supplies and Equipment:

1. Calibrated thermometer (s) – must read -15°C and -18°C
2. Crushed ice.
3. Water.
4. Pan large enough to hold the thermocouple container.
5. Table salt.

PROCEDURE:

Refrigerator:

1. Verify that the alarm circuits are operating, the alarm is switched on, and the starting temperature is 1°C to 6°C. Immerse an easy to read calibrated thermometer in the container with the alarm and chart recorder thermocouple.

Low phase testing

2. Place the container with the thermocouple and thermometer in a pan containing an ice and water slush at a temperature of -4° C or colder. To achieve this temperature, add several spoonfuls of table salt to the slush.
3. Close the refrigerator door to avoid changing the temperature of the storage compartment. Keep the container in the pan of cold slush, and gently agitate it periodically until the alarm sounds.
4. Record this temperature as the low-activation temperature.
5. Remove the container from the slush and allow unit to return to normal temperature.

High phase testing

6. Place the container with thermocouple and thermometer in a pan containing cool water (e.g., 12°C to 15 °C).
7. Close the refrigerator door. Allow the fluid in the container to warm slowly, with occasional agitation.
8. Record the temperature at which the alarm sounds as the high-activation temperature.
9. Record the date of testing, the refrigerator identification, the thermometer identification, and the identity of the person performing the test.
10. If temperatures of activation are too low or too high, take appropriate corrective actions such as those suggested by the manufacturer, record the nature of the corrections, and repeat the alarm check to document that the corrections were effective.

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Freezer:

1. Remove the thermo coupler from the bottle.
2. Leave at room temperature until the alarm sounds.
3. Record this as the temperature of activation.

Remote alarms may be inactivated during testing but must be reactivated as soon as temperature is in the acceptable range after completion of testing.

CALIBRATION:

N/A

CALCULATIONS:

N/A

QUALITY CONTROL:

Alarm activation temperatures are checked quarterly by Fisher Service Division for all blood bank refrigerator(s) and freezer(s).

RESULTS:

1. Refrigerator
    a. Low activation – should not be lower than 1°C.
    b. High activation – should not be higher than 6°C.
2. Freezer – should not be higher than -18° C.
3. If alarms do not sound when expected, notify the supervisor.

LIMITATIONS:

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1. When the temperature of alarm activation is checked, the temperature change should occur slowly enough so that the measurements and recording are accurate. Too rapid a change in temperature may give the false impression that the alarm does not sound until an inappropriate temperature is registered.
2. Alarms should sound simultaneously at the site of the refrigerator/freezer and at the location of remote alarms (when used). If remote alarms are used, the alarm check should include a verification that the alarm sounded at the remote location.
3. The low temperature of activation should be greater than 1°C (e.g., 1.5 °C); the high temperature of activation should be less than 6° C (e.g., 5.5 °C).
4. The high temperature of activation for the freezer should be less than -18°C (e.g., -19.5C).
5. Refrigerator/Freezer temperatures may increase above acceptable limits for several reasons, including:
    a. Improperly closed door.
    b. Insufficient refrigerant.
    c. Compressor failure.
    d. Dirty or blocked heat exchanger.
    e. Loss of electrical power.

REFERENCES:

1. *Standards for Blood Banks and Transfusion Services*. Bethesda, MD: Association for the Advancement of Blood and Biotherapies (AABB), current edition.

2. Cohn, Claudia S., MD, PhD. *Technical Manual*. Bethesda, MD: Association for the Advancement of Blood and Biotherapies (AABB), current edition.

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Paper copy reviewed on 12/12/2023 by Janette O'Neill.
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All Revision Dates

2/9/2026, 2/27/2024, 12/1/2016, 11/1/2015, 7/1/2010

Approval Signatures

Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator, VCMC & SPH	2/9/2026
Laboratory Services Department	Erlinda Roxas: Director, Laboratory Services	2/7/2026
Laboratory Services Department	Kathrina Barcena: Supervisor-Blood Bank, Laboratory Services	2/5/2026
Laboratory Services Department	Linda Lee: Medical Director, VCMC Blood Bank	1/29/2026

Status **Active** PolicyStat ID **19061016**

Origination	12/28/2011	Owner	Kathrina Barcena: Supervisor-Blood Bank, Laboratory Services
Last Approved	1/26/2026		
Effective	1/26/2026	Policy Area	Laboratory Services - Blood Bank
Last Revised	1/26/2026		
Next Review	1/26/2028		

L.BB.100 Critical Supplies and Services

COPY

PRINCIPLE:

Critical equipment, supplies, and services are defined as equipment, supplies and services that have the potential to impact the quality, safety, efficacy, or purity of products or services. Critical equipment must be approved, validated, calibrated, maintained and monitored per manufacturer's instructions and in accordance with Food and Drug Administration (FDA) and Association for the Advancement of Blood & Biotherapies (AABB) standards. Blood suppliers, reference laboratories and primary reagent suppliers must be approved (qualified) prior to use. Incoming reagents and critical supplies must be received, inspected and tested as necessary before acceptance or use. All materials shall be stored and used in accordance with the manufacturer's written instructions and shall meet specified requirements.

This procedure provides:

- A list of critical supplies, services and vendors for the Blood Bank/Transfusion Services department, approved by Ventura County Medical Center/Santa Paula Hospital management and it's purchasing group.
- Requirements and expectations set by the Blood Bank/Transfusion Services supervisor to help determine the ongoing ability of suppliers of products or services to meet the Blood Bank needs.

This procedure provides instruction for:

- Documentation of inspection of incoming critical materials.
- Corrective actions that prevent use of unacceptable supplies or services.
- Proper storage of incoming supplies.

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POLICY:

The blood bank/transfusion service evaluates the ability of suppliers of critical materials, equipment, and services to consistently meet agreed upon requirements.

1. **Supplier Qualification**:

   The Blood Bank/Transfusion Services department will use test methods, equipment, reagents, and materials that provide accurate, reliable test results, test records and reports.

   The Blood Bank/Transfusion Services department will provide blood components and derivatives for transfusion or injection that are collected, labeled, stored, processed and transported per standards defined by AABB, FDA, and State agencies.

   The Blood Bank/Transfusion Services evaluates and participates in the selection of suppliers.

   a. Tests and services are performed in laboratories that are:
      - Accredited by the AABB or equivalent accrediting body, and
      - Certified by the Centers for Medicare and Medicaid Services (CMS), and
      - Registered by the Food and Drug Administration (FDA).

2. **Agreements**:
   a. Contracts and agreements between Ventura County Medical Center/Santa Paula Hospital and its suppliers will define each party's expectations and be reviewed and signed periodically as determined by the parties involved.

3. **Failure to Meet Requirements**:
   a. The Blood Bank/Transfusion Services department has defined criteria for acceptability of critical supplies and services. Failure of products, or vendors, to meet these requirements will be documented (***see Attachment A, Suppliers Problem Evaluation Form***) and corrective action taken immediately. Recurrent problems with products or services will be reported by the Blood Bank/Transfusion Services supervisor to the Laboratory Manager.

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PROCEDURE:

I. **NEW PRODUCT EVALUATION**

   A. Administrative policy 107.038, ***New Product Evaluation*** should be followed for the submission of new products to the Product Evaluation Committee for evaluation and approval prior to purchase.

II. **CRITICAL SERVICES AND VENDORS**

   A. **VCMC/SPH BIOMEDICAL ENGINEERING DEPARTMENT**

      1. **Services Provided:**
         - Helps evaluate, inspect, and install new equipment.

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- Assigns unique identifiers to Blood Bank equipment.
- Performs inspections, calibrations, and required maintenance on equipment per manufacturer's instructions, AABB and FDA standards.
- Repairs equipment.

2. **Blood Bank Department's Criteria for Acceptable Service.**
    - Timely scheduled maintenance or repairs to ensure proper performance of equipment and to prevent delays in testing.
    - Complete documentation of all inspections and maintenance performed.
    - Mechanism to identify and track all critical equipment, including a list of critical equipment and a schedule for performing maintenance.

3. **Evaluation of Services/ Corrective Action.**
    - Equipment problems that require repair by Biomedical Engineering will be documented on the ***Preventative Maintenance and Corrective Action Log (see Attachment B)*** by the Blood Bank technologist identifying the problem. This should include the date Biomedical Engineering is notified. A Biomedical Engineering ***Broken Equipment Form (VCMC-540-002)*** will be completed and left with the instrument. Timeliness of repair will be evaluated.
    - Quarterly/Semi-Annual/Annual inspections and maintenance will be documented and any contracted service. Completed forms will be submitted to the Laboratory Manager and reviewed by the Blood Bank/Transfusion Services supervisor.
    - The Blood Bank/Transfusion Services supervisor will review the ***Equipment Preventative Maintenance Book*** and the ***Preventative Maintenance and Corrective Action Log (Attachment B)***. Any delays or problems with repairs or maintenance will be investigated. Recurrent problems will be addressed by the Blood Bank/Transfusion Services Supervisor and the head of the Biomedical Engineering Department. The Laboratory Manager will be notified of recurrent problems.

B. **VCMC/SPH MAINTENANCE DEPARTMENT**

1. **Services/Products Provided (Refrigerators and Freezers)**
    - Helps evaluate, inspect, and install new refrigerators and freezers.
    - Assigns unique identifiers to Blood Bank refrigerators and freezers.
    - Performs inspections, repairs and required maintenance on all

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refrigerators and freezers as required by the manufacturer's instructions, AABB and FDA standards.

- Retains and has available all documentation of preventative maintenance and repairs.

2. **Blood Bank's Criteria for Acceptable Service.**
    - Timely scheduled maintenance or repairs to ensure proper performance of equipment and to prevent delays in testing.
    - Complete documentation of all inspections and maintenance performed.
    - Mechanism to track all critical equipment, including a list of critical equipment and a schedule for performing maintenance.
3. **Evaluation of Service / Corrective Action.**
    - Refrigerator and/or freezer equipment problems that require repair by Maintenance will be documented on the ***Preventative Maintenance and Corrective Action Log (Attachment B)*** by the Blood Bank Technologist identifying the problem. This should include the date and time the Maintenance Department is notified. Timeliness of the response will be evaluated. Maintenance should respond immediately to any page from the blood bank regarding refrigerator and/or freezer equipment problems.
    - Preventative maintenance will be performed and documented and the records readily available.
    - Any delays or problems with repairs or maintenance will be investigated. Recurrent problems will be communicated by the Blood Bank supervisor to the Laboratory Manager.

C. **VITALANT**

1. **Services/Products Provided.**
    - Blood and components, including:
        - Red Blood Cells
        - Whole Blood
        - Frozen Plasma
        - Liquid Plasma
        - Platelets
        - Cryoprecipitate
    - Product testing and preparation, including:
        - ABO/Rh and unexpected antibody identification
        - Infectious disease testing

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        - CMV testing.
        - Hgb S testing.
        - Antigen screening.
        - HLA-matching.
        - Irradiation.
        - Leuko-reduction.
        - Sterile docking.
    - Reference laboratory for Immunohematology investigation and consultation.
    - Blood component delivery service.
    - Education Seminars.

2. **Blood Bank's Criteria for Acceptable Service.**
    - FDA/CBER-licensed / meet FDA requirements
    - AABB-accredited / meet AABB requirements
    - Have a quality system in place
    - Meet state requirements
    - Provide adequate stocking levels based on annual usage. Provide adequate restocking based on daily transfusions/ traumas/critical levels.
    - Timely notification of Vitalant Services stocking levels, including shortages, and critical levels.
    - Blood products are properly packaged to maintain appropriate temperatures during transportation to Ventura County Medical Center/Santa Paula Hospital from Vitalant Services.
    - Delivery services from Vitalant that are cost-effective, reliable, and frequent enough.
    - Competitive pricing that is comparable to alternate blood suppliers. Accurate and timely billing and credit.
    - Timely notification of changes affecting the safety of blood components are discovered, including look-back and recall.
    - Reference Laboratory providing Stat service. Timely verbal, faxed, and final reports. Competent staff who are willing to advise Ventura County Medical Center/Santa Paula Hospital Blood Bankers.

3. **Evaluation of Service / Corrective Action.**
    - Quality of the product
        - Units properly labeled

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- Acceptable visual inspection
- Sufficient number of segments
- Number of units recalled/questions of disposition

- Availability of products
  - Full range of products available
  - Adequate supply different ABO/Rh types available for all products

- Quality of service
  - Correct / Incorrect order
  - Shipment arrives on time
  - Product arrives in satisfactory condition
  - Consultation service responsiveness
  - Timely resolution of problem
  - Supplies required antigen-negative blood, timely manner
  - Billing problems/discrepancies

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III. CRITICAL SUPPLIES AND VENDORS

A. List of critical supplies:

1. Supplies and vendors critical to the daily operations of the Blood Bank department have been identified. Refer to SOP L.BB.99, ***Reagent/Supply Ordering, Receipt, Rejection, and Storage*** for all materials, forms, labels, reagents and vendors.
2. Blood components have been addressed in SOP L.BB.76, entitled ***Ordering, Storage, and Return of Blood Components*.**

B. SUPPLIERS OF REAGENTS AND DERIVATIVES

1. **Services / Products Provided**
   - Reagents for testing
   - Filters for the administration of blood components
2. **Blood Bank's Criteria for Acceptable Service**
   - Provide materials that meet applicable FDA requirements
   - Be able to supply products at a level that meets our needs.
   - Products are shipped appropriately
   - Supply training and support as needed
   - Suppliers of reagents and derivatives must provide written instructions for use of products.
   - Suppliers of reagents and derivatives must provide directions for

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handling and storage of products

- Provide Safety Data Sheets (SDS) where applicable
- Supplier should be facility-approved with a contract when feasible

3. **Evaluation of Service / Corrective Action**
    - Quality of product
        - Consistent satisfactory reagent quality control
        - Number of recalls
        - Red cell reagents not hemolyzed
    - Availability of reagents
        - Frequency of back-orders
        - Frequency of partial shipments
    - Frequency of problems with orders/ordering
    - Shipping problems
        - Reagents arrive on time and in good condition
    - Response to questions and problems
    - Knowledge of the sales representative
    - Courtesy and availability of the sales representative
    - Competitive pricing

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IV. INVENTORY MANAGEMENT OF CRITICAL SUPPLIES

A. Ordering supplies:

1. Standing Orders.
    - Will be created by written contract between the supplier and Ventura County Medical Center/Santa Paula Hospital purchasing department.
    - Quantities will be determined by the Blood Bank/Transfusion Services supervisor based on monthly usage but may be increased or decreased based on changes in workload.
    - Delivery dates and frequency of delivery will be determined by the supplier based on manufacturing dates and expiration dates of the products ordered.

B. Supplies ordered as needed.

1. The Blood Bank/Transfusion Services supervisor will determine stocking levels based on workload.
2. The Blood Bank/Transfusion Services supervisor will manage the inventory supplies by review of:

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- Quantities of supplies in stock
- Expiration dates of supplies in stock.

3. All blood bank technologists are responsible for alerting the Blood Bank/ Transfusion Services supervisor (or laboratory manager when the Blood Bank/Transfusion Services supervisor is not available) if any supply requires ordering due to spills or breakage, becomes contaminated during storage or use, is recalled by the manufacturer, or is adversely affected by equipment malfunction.

C. **Receipt, Inspection, and evaluating acceptability for use of Incoming Supplies**

1. Supplies will be delivered to the laboratory with packing slips. After reconciliation, the packing slip will be given to the Laboratory Manager for approval. Blood Bank technologists accepting delivery of supplies shall:
    - Verify all blood bank supplies received with the packing slips.
    - Alert the Blood Bank/Transfusion Services Supervisor, or the Laboratory Manager, to any unacceptable deliveries.
    - Follow SOP L.BB.99, ***Reagent/Supply Ordering, Receipt, Rejection, and Storage*** for receiving, inspecting, rejecting, and storing of all incoming supplies.
    - Date all supplies upon receipt.
    - Blood Bank labels, forms and red identification bands must be verified as the most current version in use. Follow the ***Label Control*** procedure in the **Label Control Manual** for receipt and acceptance of all blood bank labels.

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V. MANUFACTURER'S PRODUCT RECALL

In the event that the Blood Bank/Transfusion Services Department receives a Product Recall from a manufacturer:

- Remove from inventory and quarantine any of the reagents, supplies or blood components listed in the recall letter sent by the manufacturer or supplier.
- Bring any recall notification letter to the attention of the Blood Bank/Transfusion Services supervisor or the Laboratory Manager when the Blood Bank supervisor is unavailable.
- Document all required information about the disposition of the recalled products on the ***Disposition of Rejected Reagent/Supply Log (see SOP L.BB.99, Attachment B).***
- Refer to the Lookback procedure when a blood component is recalled by Vitalant. Any blood component that has been transfused requires additional investigation by the Blood Bank Department and notification of the patient's physician.
- Bring all Lookback / product recall notifications to the attention of the Laboratory Medical Director.
- Complete any documentation required by the manufacturer.

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REFERENCES:

1. Standards for Blood Banks and Transfusion Services. Bethesda, MD: American Association of Blood Banks, Current Edition.
2. Roback, John D. Technical Manual. Bethesda, MD: American Association of Blood Banks, Current Edition.

All Revision Dates

1/26/2026, 12/12/2023, 6/5/2020, 12/1/2016, 11/1/2015

Attachments

- A: Suppliers Problem Evaluation Form
- B: Preventative Maintenance and Corrective Action Log
- C: Broken Equipment Form
- D: Current Reagent / Blood Supplier Assessment / Re-Qualification
- E: Disposition of Rejected Reagent/Supply Log
- F: New Reagent / Blood Supplier Assessment / Qualification

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Approval Signatures

Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator, VCMC & SPH	1/26/2026
Laboratory Services Department	Erlinda Roxas: Director, Laboratory Services	1/24/2026
Laboratory Services Department	Kathrina Barcena: Supervisor-Blood Bank, Laboratory Services	11/4/2025
Laboratory Services Department	Linda Lee: Medical Director, VCMC Blood Bank	10/7/2025

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Last Revised	2/6/2026
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Owner	Kathrina Barcena: Supervisor-Blood Bank, Laboratory Services
Policy Area	Laboratory Services - Blood Bank

L.BB.17 Blood Bank Specimen Identification, Labeling and Rejection

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PRINCIPLE:

Proper patient identification is crucial at the time of specimen collection. The phlebotomist must ensure that the blood specimen is being drawn from the individual designated on the request form or Laboratory-generated specimen labels. The phlebotomist must not rely on a bed tag, charts, or records placed on the bed or nearby tables or equipment. The following information must be verified at the time of specimen collection:

1. Verify that the patient's hospital wristband and Blood Recipient ID wristband are in agreement with the request form or Laboratory-generated specimen labels.
2. The patient should be asked (if possible) to verify his/her name, and the phlebotomist should verify that the responses match the hospital wristband, the blood bank wristband, and the request form or Laboratory-generated specimen labels (see *Patient Interactions* policy for identification protocols.)
3. Verify the patient's date of birth matches the hospital wristband.

Additionally, the following practice should be adhered to when labeling specimens after proper patient identification has been performed:

1. Tubes should be labeled AFTER the specimen has been collected.
2. Do not label an empty tube before drawing the patient.
3. Complete the labeling of all tubes at the patient's bed/chair-side.
4. Do not re-label specimens.

SPECIMEN COLLECTION

1. EDTA K2 pink top blood bank tube (7mL).
2. CORD BLOOD – 1 lavender EDTA top tube (7mL) **and** 1 red top tube (7mL).

PROCEDURE

SPECIMEN LABELING

I. All specimens:

All blood bank specimens must be labeled with a handwritten Blood recipient ID Wristband or a computer generated label. The following must be present on all blood bank specimen labels:

a. Patient's Name.
b. Patient's Medical Record Number.
c. LIS ID of the person collecting the specimen.
d. Date and time of collection

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Truncated Patient Names

Truncation of a patient name occurs when the length of the name exceeds the capacity of the system to print all characters on the hospital identification band and/or the laboratory order.

When a patient's name has been truncated and is not complete on the hospital identification band the following will apply:

- **Date of Birth** - All blood bank labeling must include the "Date of Birth" in addition to the above required elements (name, medical record number, collector's identification, date and time of collection).

II. Blood Bank/ Crossmatch:

With a few exceptions, patients that must be banded with a Blood Recipient ID Wristband should be drawn at VCMC or Santa Paula Hospital.

Patients receiving red cells, thawed plasma, cryoprecipitate, and/or platelets must have a type and screen ordered and be banded with a Blood Recipient ID Wristband. All orders for additional products must be added to the original type and screen order so that when the product is issued, the Blood Bank identification band number appears on the Unit Issue Form and the product bag.

A. **Preparation of a Blood Bank Blood Recipient ID Wristband Label:**

   Using a ***ball-point pen,*** write on the Blood Recipient ID Wristband hard enough so that the

information will be transferred through to the part of the band which will be placed on the patient. The completed band **must** include the following:

1. **Patient's name** - last, first (include middle initial or full middle name as appears on the hospital wristband and the Laboratory requisition. All blood bank identification band labels must be identical with the hospital wristband and the Laboratory requisition.)
2. Medical Record Number
3. Collection date and time
4. Legible LIS ID of the phlebotomist or nurse that drew the blood. If a nurse drawing the specimen is accompanied by a phlebotomist, the LIS ID of both individuals should be on the label.

Truncated Patient Names

Truncation of a patient name occurs when the length of the name exceeds the capability of the system to print all characters on the hospital identification band and/ or the laboratory order.

When a patient's name has been truncated and is not complete on the hospital identification band the following will apply:

- **Date of Birth** - All blood bank labeling must include the "Date of Birth" in addition to the above required elements (name, medical record number, collector's identification, date and time of collection).

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B. **Application of the Blood Bank Blood Recipient ID Wristband labels to the tubes:**

Labeling Procedure for Nursing and Phlebotomy:

1. Lift up white flap on blood bank band, and using a ball point pen, fill in the patient name, Medical Record Number, phlebotomist LIS ID, and the date and time on the draw tube label. Make sure that if the computer order has an initial to include it on the label.
2. Remove draw tube label with the patient information from the wristband (Right to Left) so the carbon copy of the written information remains on the wristband.
3. Peel away white liner from the clear cover flap. Press clear cover flap down firmly from left to right, on a flat surface several times.
4. Apply patient information label to the K2 EDTA BD vacutainer draw tube. Align the V-Notch for visibility and proper patient identification.
5. Separate draw tube tail from Bar Code Blood Band at the perforation. Then remove the liner on the back of the tail of labels and attach to the draw tube.
6. Apply Bar Code Blood Band to patient allowing one finger space between wrist and wristband closure. Close plastic snap, and cut off any excess band.
7. For increased length, attach white extension band to the Blood Bank Band. Size

band, close snap, and cut off any excess band.

8. The procedure for outpatients is the same because of the self-laminating shield.

Alternative Labeling Procedure for phlebotomists only:

1. Lift up self- laminating shield away from the patient information area on blood bank band. Place the Laboratory bar code label on the area that would be printed on. Place the other Laboratory bar code label on the K2 EDTA BD vacutainer draw tube.
2. Remove a red striped barcoded label from the tail of the blood bank band and place it on the K2 EDTA BD vacutainer draw tube.
3. The LIS ID for the phlebotomist, the date, and time should be written legibly on the label and the blood bank band and on the blood bank tube.
4. Peel away white liner from the clear cover flap. Press clear cover flap down firmly from left to right, on a flat surface several times to seal flap.
5. Apply Bar Code Blood Band to patient allowing one finger space between wrist and wrist band closure. Size band, close snap, and cut off any excess band.
6. Using the Laboratory bar code enables the Pro-Vue to automatically order the test required.

C. **Cord Blood Specimens**

1. "Extra Cord Blood" orders will be entered into the Health-e-Connect system under the mother's encounter number prior to delivery. These specimens are "Nurse Collects." Nursing will enter the collection date, time, and LIS ID of the person collecting the specimen in the Health-e-Connect system and then deliver to the Laboratory.
2. Tubes are labeled with the mother's registration label and must have "*Cord Blood*" written on each tube. The date, time, and LIS ID of the person collecting the specimen must be on the tubes.
3. When the specimens are received in the Laboratory, labels will be printed and the specimens received in into central processing and delivered to the Blood Bank.

NAME CHANGES

1. If a patient's name is changed, after a sample is drawn, he/she must be re-drawn and re-banded using the new name. A patient **cannot** be transfused using the new name, their hospital number and the original Blood Bank Band identification number. If a critical situation occurs in which the patient must be transfused before work is completed on the new sample, uncrossmatched Emergency Release Blood will be used.
2. When a fictitious name is assigned to a patient using the STAT Registration Policy (see Administrative Policy 100.*063, STAT Patient Registration)*, his/her sample will be used for testing, crossmatching, issuing and transfusing until he/she is stable. At that time, a new sample will be obtained and tested using the proper name.
3. If an un-banded patient sample is in the Laboratory and the patient's physician decides that a

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type and screen is necessary, or that the patient needs to receive any product for which a type and screen is necessary, the **patient must be redrawn.** This would include red blood cells, thawed plasma, cryoprecipitate, and/or platelets.

MISLABELED SPECIMENS:

1. All labeling information (Blood Bank/ Crossmatch-A above) must be exact.
2. If a discrepancy is found, the patient will need to be redrawn and re-banded. ***Mislabeled specimens cannot be re-labeled by Medical, Nursing, or Laboratory staff once they have left the bedside of the patient***. If a critical situation occurs, in which the patient must be transfused before a new specimen can be recollected or before work is completed on the new sample, emergency release uncrossmatched O-negative blood will be used.

REJECTION OF SPECIMENS:

1. Specimen Labels – Specimens that are mislabeled cannot be re-labeled. The requisition will be canceled, noting the reason. A new order will be placed, and the patient will be re-drawn and re-banded for the new requisition.
    a. All mislabeled specimens are unacceptable.
    b. Blood Recipient ID wristband is missing from the patient or the tubes.
    c. The date of birth will be on all specimens when the name of the patient has been truncated on the hospital identification band due to the length of the name. If the truncated name is misspelled and/or either the medical record number or the date of birth is incorrect, the sample must be rejected as it does not have two correct identifiers.
2. Specimen Condition
    a. Hemolyzed specimen
    b. Time since collection is more than six hours without centrifugation and refrigeration.
    c. Insufficient quantity of specimen for the required testing.
    d. Incorrect collection tube or container.
    e. Contaminated specimen.

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PROCEDURAL NOTES:

1. Blood Recipient ID Wristband labels ***must not be labeled using a gel pen***.
2. When using the Laboratory label on the Blood Recipient ID Wristband (Alternative Labeling Procedure for Laboratory Phlebotomists only), all information must be on the Laboratory label. This should include the complete patient name and medical record number.

REFERENCES:

1. Administrative policy 100.063, *STAT Patient Registration 7/2010.*
2. Laboratory Specimen Collection Manual 4.1 *Patient Interactions.*

3. Standards for Blood Banks and Transfusion Services. Bethesda, MD: American Association of Blood Banks, Current Edition.
4. Fung, Mark K MD, PhD. Technical Manual. Bethesda, MD: American Association of Blood Banks, Current Edition.

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Approval Signatures

Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator, VCMC & SPH	2/6/2026
Laboratory Services Department	Kathrina Barcena: Supervisor-Blood Bank, Laboratory Services	2/5/2026
Laboratory Services Department	Erlinda Roxas: Director, Laboratory Services	1/24/2026
Laboratory Services Department	Linda Lee: Medical Director, VCMC Blood Bank	1/23/2026

Status **Active** PolicyStat ID **19747337**

VENTURA COUNTY HEALTH CARE AGENCY

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Owner	Kathrina Barcena: Supervisor-Blood Bank, Laboratory Services
Policy Area	Laboratory Services - Blood Bank

L.BB.23 Polyethylene Glycol Additive-Gamma PeG™

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PRINCIPLE:

The use of Gamma PeG as an additive for tests to detect blood group antibodies enhances the sensitivity of the antibody detection procedure and creates a low-ionic-strength test environment that increases the rate of antibody uptake during incubation.

SPECIMEN COLLECTION:

1. K2 EDTA pink top blood bank tube or serum.
2. No special preparation of the patient is required.
3. Testing should be performed as soon as possible. If delay in testing should occur, specimen should be stored at 1° to 10°C.

REAGENTS:

1. Gamma PeG
    a. Polyethylene glycol in a low-ionic-strength solution containing glycine at an iso-osmotic concentration.
    b. Do not use beyond expiration date.
    c. Do not freeze.
    d. Do not dilute.
    e. Do not use if turbid.
2. Reagent Red Cells
3. Anti-IgG

4. Coombs Control Cells
5. Saline
6. 12x75 mm Tubes
7. Centrifuge
8. Disposable pipettes

PROCEDURE:

1. Label an appropriate number of test tubes for each red blood cell suspension to be tested.
2. Place 2 drops of the serum or plasma (Eluate) to be tested into each of the tubes.
3. Add one drop of the appropriate red blood cell suspension, previously washed and re-suspended in saline to approximately 3-4%, to each appropriate tube. Reagent Red Blood Cells may be used directly from the vial. *NOTE: If desired, tubes may be incubated at room temperature for 5-30 minutes.*
4. Mix well and centrifuge for the calibrated time.
5. Examine for hemolysis and record if present.
6. Re-suspend the red blood cells by gentle shaking and examine for agglutination.
7. Record results.
8. Add 2 drops of Gamma PeG and mix well.
9. Incubate the tubes at 37° ± 1°C for 10-15 minutes. The incubation time may be extended up to 30 minutes. Incubating for the upper end of the time range may enhance reactivity.
10. The tubes may be examined for gross hemolysis. *NOTE: The test mixture cannot be centrifuged and examined reliably for direct agglutination after the incubation phase.*
11. Wash the red blood cells 4 times with saline.
12. Add 2 drops of Anti-IgG to the dry cell button.
13. Mix well and centrifuge for the calibrated time.
14. Re-suspend the red blood cells by gentle shaking and examine for agglutination. Negative reactions may be examined using an optical aid.
15. Record results.
16. *All negative antiglobulin tests should be confirmed by adding IgG-sensitized red blood cells.* Add 1 drop of Coombs Control Cells to each negative test.
17. Centrifuge for the calibrated time.
18. Read and record results.

CALIBRATION:

N/A

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CALCULATIONS:

N/A

QUALITY CONTROL:

1. See policy L.BB.24, ***Quality Control of 3% Surgiscreen Using PeG.***
2. Include an auto control with each patient.
3. RQC D (Weak) Cell Control – to insure that the product enhances reactivity.

RESULTS:

1. Agglutination and/or hemolysis of the red blood cells in the immediate-spin phase of testing, or agglutination occurring at the antiglobulin phase, constitutes a positive test result and indicates that the specimen being tested contains antibodies directed at an antigen or antigens present on the red blood cells.
2. No agglutination or hemolysis at any phase of testing constitutes a negative test result and indicates that the specimen being tested does not contain antibodies directed at antigens present on the red blood cells (as determined by this test method).
3. A positive autologous control test indicates the presence of an autoantibody. Further studies will be required to assure that alloantibodies are not also present in the serum/plasma. A Direct Antiglobulin Test should be run.

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LIMITATIONS:

1. Contaminated materials, improper incubation time, temperature, centrifugation, examination for agglutination, and deviation from the recommended test procedures may give rise to false results.
2. IgM antibodies may not be detected by the polyethylene glycol test procedure.
3. When using the polyethylene glycol procedure for crossmatching, ***an immediate-spin phase must be performed before adding the reagent*** to avoid missing some IgM examples of anti-A and anti-B.
4. The use of aged serum or plasma may result in failure to detect complement-dependent antibodies. The use of Anti-IgG Anti-Human Globulin may result in failure to detect complement-dependent antibodies.
5. Precipitation of fibrinogen may be observed when testing plasma samples. In such cases it may be necessary to wash the red blood cells more than three times to remove all unbound human protein.

PROCEDURE NOTES:

1. Most often, antibodies capable of producing hemolysis have specificity in the ABO, P, Lewis, Kidd or Vel blood groups.
2. Gamma PeG is designed to be used as an additive.

REFERENCES:

1. Standards for Blood Banks and Transfusion Services. Bethesda, MD: Association for the Advancement of Blood and Biotherapies (AABB), current edition.
2. Cohn, Claudia S., MD, PhD. Technical Manual. Bethesda, MD: Association for the Advancement of Blood and Biotherapies (AABB), current edition.
3. Immucor, Inc. 3130 Gateway Drive, Norcross, GA 30071 USA. Gamma PeG™ *Polyethylene Glycol Additive for Antibody Detection Tests.* Current Product Insert.


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Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator, VCMC & SPH	2/9/2026
Laboratory Services Department	Erlinda Roxas: Director, Laboratory Services	2/8/2026
Laboratory Services Department	Kathrina Barcena: Supervisor-Blood Bank, Laboratory Services	2/5/2026
Laboratory Services Department	Linda Lee: Medical Director, VCMC Blood Bank	1/29/2026

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Owner	Kathrina Barcena: Supervisor-Blood Bank, Laboratory Services
Policy Area	Laboratory Services - Blood Bank

L.BB.24 Quality Control of 3% Surgiscreen Cells Using PEG

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POLICY:

The purpose of daily quality assurance in the blood bank is to confirm the reliability of the test system. The test system includes reagents, test procedures, and equipment. Testing known samples is an accepted method of quality control. If expected test results are observed, procedures are being performed accurately and reagents and equipment are performing properly. The Laboratory must perform this quality control on each day of use. The Ventura County Medical Center daily quality control program utilizes the ORTHO Diagnostics Confidence System.

PRINCIPLE:

The procedures used with these reagents are based on the principle of agglutination. The antibody and cell samples provided in the ORTHO Confidence System will confirm the reactivity of the reagents used for the anti-IgG component of AHG, as well as reagent red blood cells used in antibody detection tests.

REAGENTS/MATERIALS

1. Ortho Confidence System, containing:
    - Confidence Antibody- Anti-A, Anti-B, Anti-D and Anti-c that react when tested by the indirect anti-globulin technique. Store at 2-8°C. Allow to come to room temperature before using.
2. 3% Surgiscreen Cells
3. Anti-IgG
4. Coombs Control Cells
5. 6% Bovine Serum Albumin (BSA)

6. Buffered Saline
7. Clean, empty 10 mL reagent bottle.
8. Blank White laboratory label.
9. Pipette and bulb
10. 12 x 75 mm tubes

PROCEDURE

A. Preparing 10 mL of 6% BSA

1. Pipette 7.3 mL of diluent (0.85% Buffered Saline) into a clean, empty 10 mL reagent bottle.
2. Pipette 2.7 mL of the dilute (22% BSA) into the same reagent bottle.
3. Mix thoroughly.
4. Use a blank white laboratory label to make a reagent label for the bottle. The label should contain the lot number of 22% BSA, date made, contents and initials of the preparer. The expiration date should be 6 months from date of preparation.

B. Testing Procedure

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1. Label four 12 x 75 tubes: 1, 2, 3, and 4.
2. Add two drops of ORTHO Confidence Antibody to tubes 1, 2, and 3.
3. Add two drops of 6% BSA to tube 4.
4. Add one drop of 3% screening cell 1 to tube 1and 4.
5. Add one drop of 3% screening cell 2 to tube 2.
6. Add one drop of 3% screening cell 3 to tube 3.
7. Add two drops of gamma PEG.
8. Mix well and centrifuge for a time appropriate to the calibration of the centrifuge.
9. Examine for hemolysis and record if present.
10. Re-suspend the red blood cells by gentle shaking and examine for agglutination. Record results.
11. Incubate the tubes at 37° ± 1°C for 10-15 minutes. The incubation time may be extended up to 30 minutes.
12. The tubes may be examined for gross hemolysis. *NOTE: The test mixture cannot be centrifuged and examined for reliability for direct agglutination after the incubation phase.*
13. Wash the red blood cells in the tube at least 3 times with saline.
14. Add 2 drops of Anti-IgG to each dry button of red blood cells.
15. Mix well and centrifuge for a time appropriate to the calibration of the centrifuge.
16. Re-suspend the red blood cells by gentle shaking and examine for agglutination. Negative reactions may be examined with an optical aid. Record results.

17. Add 1 drop of Coombs Control cells to all negative reactions.
18. Mix well and centrifuge for a time appropriate to the calibration of the centrifuge.
19. Re-suspend the red blood cells by gentle shaking and examine for agglutination. Record results.

EXPECTED RESULTS:

Reagent	Control	Phase	Expected Result
SC1	Confidence Antibody	IS	0, 1+ (minimum)
SC1	Confidence Antibody	AHG	1+, 2+, 3+, 4+
SC1	Confidence Antibody	CC	NT
SC2	Confidence Antibody	IS	0, 1+ (minimum)
SC2	Confidence Antibody	AHG	1+, 2+, 3+, 4+
SC2	Confidence Antibody	CC	NT
SC3	Confidence Antibody	IS	0, 1+ (minimum)
SC3	Confidence Antibody	AHG	1+, 2+, 3+, 4+
SC3	Confidence Antibody	CC	NT
SC1 Neg Control	6% BSA	IS	0
SC1 Neg Control	6% BSA	AHG	0
SC1 Neg Control	6% BSA	CC	1+, 2+, 3+, 4+

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PROCEDURE NOTES:

1. Quality Control results are entered concurrently with performance in the Health-e-Connect system.
2. Manual bench quality control reagent racks are chosen in the Blood Bank Subsection indicated as VCMC Blood Bank/SPH Blood Bank in the Health-e-Connect system.
3. Antibody screening cell 1will be performed each day of use with 6% BSA.
4. Daily Quality Control Form BB 8.2 is used during computer down times.

REFERENCES:

1. Standards for Blood Banks and Transfusion Services. Bethesda, MD: Association for the Advancement of Blood and Biotherapies (AABB), current edition.
2. Cohn, Claudia S., MD, PhD. Technical Manual. Bethesda, MD: Association for the Advancement of Blood and Biotherapies (AABB), current edition.
3. Current manufacturer's package inserts.

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Hospital Administration	Jason Arimura: Associate Hospital Administrator, VCMC & SPH	2/9/2026
Laboratory Services Department	Erlinda Roxas: Director, Laboratory Services	2/8/2026
Laboratory Services Department	Kathrina Barcena: Supervisor-Blood Bank, Laboratory Services	2/5/2026
Laboratory Services Department	Linda Lee: Medical Director, VCMC Blood Bank	1/29/2026

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Owner	Kathrina Barcena: Supervisor-Blood Bank, Laboratory Services
Policy Area	Laboratory Services - Blood Bank

L.BB.26 Repeat Testing of Donor Blood

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PRINCIPLE:

Before transfusion, all red cell products will have their ABO group verified. The Rh (D) type will be verified on all D-negative units (immediate spin only). Typing for antigens other than ABO/Rh will also be verified.

SPECIMEN COLLECTION:

1. Donor blood from an attached unit segment.

REAGENTS:

1. Anti-A.
2. Anti-B.
3. Anti-A,B.
4. Anti-D.
5. 12x75 mm glass tubes.
6. Disposable pipettes.

PROCEDURE:

1. Tube Testing
    a. Cut a segment from the unit to be tested and place it into a tube labeled with the unit number.
    b. Prepare a 3-4% cell suspension in normal saline.

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c. Test the cells with the appropriate antisera following the ABO Testing Procedure:

	Anti-A	Anti-B	Anti-A,B
Donor Group O			X
Donor Group A	X	X	
Donor Group B	X	X	
Donor Group AB	X	X	

d. Test the cells of D-Negative donors with anti-D following the Rh (D) Typing Procedure. If the immediate spin typing is negative, the unit is considered negative and no further testing is required.

e. If the ABO and/ or D type match the product label, attach the appropriate, completed yellow label to the unit. This label states that the unit type was retested, the date of the retesting and the initials of the technologist who did the retesting.

f. To repeat typing of other antigens follow Procedure L.BB.92, ***Red Cell Antigen Typing***.

2. Computer Entry

a. Open Result Entry application.

b. In "New Worksheet" window, check Product Number and Daily QC group.

c. Click <OK>.

d. Scan the unit Donor Identification Number.

e. The Unit ABO/Rh test should load for the scanned unit.

f. Perform ABO/Rh confirmation testing and record testing results in the appropriate fields.

g. Choose the appropriate blood type interpretation from the drop down list. The system will verify the interpretation.

h. Verify the results by clicking <Verify> located at the bottom right.

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CALIBRATION:

N/A

CALCULATIONS:

N/A

QUALITY CONTROL:

See Daily Quality Control.

RESULTS:

Refer to Procedure L.BB.19 ***ABO Grouping*** and L.BB.59 ***Rh$_0$ (D) Typing*** for interpretation of results.

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PROCEDURE NOTES:

1. If the retype does not agree with the product label, quarantine the unit for return to the blood supplier.
2. Reverse grouping is not necessary.
3. Plasma products do not require retyping.

REFERENCES:

1. Standards for Blood Banks and Transfusion Services. Bethesda, MD: Association for the Advancement of Blood and Biotherapies (AABB), Current Edition.
2. Cohn, Claudia S. Technical Manual. Bethesda, MD: Association for the Advancement of Blood and Biotherapies (AABB), Current Edition.
3. Transfusion Medicine Ortho Anti-D (Monoclonal-Polyclonal Blend) Bioclone for Rapid Tube, Slide, and Microplate Tests, 10 mL, 15s. Current Package Insert.
4. Transfusion Medicine Blood Grouping Reagents Anti-A, B, AB (Murine Monoclonal Blend) Bioclone for Slide, Tube, and Microplate tests Blood Grouping Reagents, Anti-A, -B, -A,B Bioclone, Current Package Insert.

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All Revision Dates

1/26/2026, 6/5/2020, 12/1/2016, 12/1/2011, 1/1/2008, 4/1/2002, 10/1/1993

Approval Signatures

Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator, VCMC & SPH	1/26/2026
Laboratory Services Department	Erlinda Roxas: Director, Laboratory Services	1/24/2026
Laboratory Services Department	Kathrina Barcena: Supervisor-Blood Bank, Laboratory Services	11/4/2025
Laboratory Services Department	Linda Lee: Medical Director, VCMC Blood Bank	10/29/2025

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Status **Active** PolicyStat ID **19747340**

Origination	5/1/1986	Owner	Kathrina Barcena: Supervisor-Blood Bank, Laboratory Services
Last Approved	2/9/2026		
Effective	2/9/2026	Policy Area	Laboratory Services - Blood Bank
Last Revised	2/9/2026		
Next Review	2/9/2028		

L.BB.29 Cold Antibody Identification

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PRINCIPLE:

Cold antibodies react optimally at room temperature and below, while reactions after 37°C incubation and with Anti-IgG are negative or weakly reactive. Some cold agglutinating antibodies, notably anti-I, -IH, and -H, bind complement following the antigen-antibody interaction at low temperatures. Subsequent incubation at 37°C may cause the antibody to elute from the cell, but the attached complement remains and produces a positive reaction when antiglobulin serum is added. The use of Anti-IgG usually prevents this, but occasionally, there will be carry-over that is detected with the Anti-IgG.

The specificity of cold auto-antibodies can be demonstrated by testing against an abbreviated panel of cells incubated at room temperature and below. If an IgM antibody other than anti-I,-IH or -H is suspected, a 10 cell panel may be run.

SPECIMEN:

Blood containing a cold reacting antibody.

REAGENTS - SPECIAL SUPPLIES AND EQUIPMENT:

1. Reagent Cells – 3% Screening Cells, A1, A2, and B Cells
2. 3-5% Suspension of Washed Group O Cord Blood Cells
3. Physiologic Saline
4. 12x75 mm Test Tubes
5. Centrifuge
6. Ice Water

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QUALITY CONTROL:

See Daily Reagent Quality Control

PROCEDURE:

1. Label tubes for an auto control, O cord cells, screening cells {I, II & III}, and A_1, A_2, and/or B cells (dependent on patient type - see below).

Patient Type	Cells to Use	A_1	A_2	B
O		-	-	-
A		Y	Y	-
B		-	-	Y
AB		Y	Y	Y

2. Add 2 drops of serum/plasma to each tube.
3. Add 1 drop of each 3-5% cell suspension to the appropriate tube.
4. Mix well and incubate at room temperature for 30 min.
5. Centrifuge for the calibrated time, read macroscopically and record results.
6. Incubate at 16-18°C for 30 min.
7. Centrifuge, read macroscopically and record results.
8. Incubate at 4°C (place small amount of water in a container in the refrigerator) for 30 min.
9. Centrifuge, replace in cold water for 5 min., read and record results.

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RESULTS:

Cell	A_1	A_2	B	O Adult	O Cord
Anti-I	2-4+	2-4+	2-4+	2-4+	0-2+
Anti-IH	0-2+	2-4+	0-2+	2-4+	0-2+
Anti-H	0-2+	2-4+	0-2+	2-4+	2-3+
Anti-Pr	4+	4+	4+	4+	4+

Anti-Pr does not react with enzyme treated cells.

Anti- IH and -H are seen predominantly in A_1 and A_1B persons.

PROCEDURE NOTES:

1. If the antibody does not appear to be anti-I,-IH, or -H, a 10 cell panel may be run. If an auto control has not been run, include it with this panel.
2. Cold reacting antibodies are not considered to be clinically significant however they may mask the presence of allo-antibodies. Pre-warming or auto-adsorbing may be useful in antibody

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detection in patients with cold auto-antibodies.

3. High titered cold agglutinins may require titration to determine the specificity.

REFERENCES:

1. Standards for Blood Banks and Transfusion Services. Bethesda, MD: Association for the Advancement of Blood and Biotherapies (AABB), current edition.
2. Cohn, Claudia S., MD, PhD. Technical Manual. Bethesda, MD: Association for the Advancement of Blood and Biotherapies (AABB), current edition.
3. Transfusion Medicine Red Blood Cells (Pooled Cells) Affirmagen®. Current package insert.
4. Transfusion Medicine Reagent Red Blood Cells ORTHO pooled screening cells. Current package insert.
5. Transfusion Medicine Reagent Red Blood Cells (Pooled Cells) ORTHO A2 cells. Current package insert.


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Paper copy reviewed on 12/12/2023 by Janette O'Neill.
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All Revision Dates

2/9/2026, 2/27/2024, 12/1/2016, 12/1/2012, 11/1/1997

Approval Signatures

Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator, VCMC & SPH	2/9/2026
Laboratory Services Department	Erlinda Roxas: Director, Laboratory Services	2/8/2026
Laboratory Services Department	Kathrina Barcena: Supervisor-Blood Bank, Laboratory Services	2/5/2026
Laboratory Services Department	Linda Lee: Medical Director, VCMC Blood Bank	1/28/2026

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Status **Active** PolicyStat ID **19747344**

Origination	5/1/2002
Last Approved	2/6/2026
Effective	2/6/2026
Last Revised	2/6/2026
Next Review	2/6/2028
Owner	Kathrina Barcena: Supervisor-Blood Bank, Laboratory Services
Policy Area	Laboratory Services - Blood Bank

L.BB.30 Post Rh Immune Globulin Panel

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PRINCIPLE:

The antepartum administration of Rh Immune Globulin (RhIG) at 28 weeks of pregnancy can result in a positive antibody screen for up to 6 months post-injection.

In order to eliminate the necessity of running a full panel, a selected cell panel is a sub-part of our Ortho 0.8% Resolve Panel A. Panel cells which have an @ next to them on the Antigram Antigen Profile can be used to check for antibodies in serum/plasma known to contain anti-D. If these cells are negative, no clinically significant antibodies are present in the patient's serum, in addition to the anti-D from Rh Immune Globulin.

SPECIMEN:

1. EDTA whole blood and serum or plasma.
2. No special preparation of the patient is required prior to specimen collection.
3. Store 2 to 8°C.
    a. All blood bank specimens are retained for 14 days after collection.

REAGENTS:

1. @ sub panel of Ortho 0.8% Resolve Panel A.
2. MTS™ Anti-IgG Card (Do not use beyond expiration date. Store at 2-25°C. Use at room temperature).
3. Pipettes: 25 µL, 50 µL
4. Pipette Tips

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5. MTS™ Centrifuge
6. MTS™ Incubator

QUALITY CONTROL:

1. A control consisting of the serum/plasma and autologous red blood cells prepared according to the ID-Micro Typing System package insert should be tested in parallel with 0.8% Resolve Panel A. A positive reaction indicates patient abnormality which must be resolved before the test results can be interpreted.
2. The 0.8% Resolve Panel A should be tested periodically with weak antibodies.

PROCEDURE:

1. Bring samples and reagents to room temperature (18-25°C).
2. Visually inspect gel cards before use. Each microtube should have a clear liquid layer on top of opaque gel.
3. Label the MTS™ Anti-IgG Card with the appropriate patient identification. The specimen laboratory label may be used.
4. Label 3 or 4 microtubes of the MTS gel card with the panel cell numbers which have been designated with the @ symbol. Include a patient auto control.
5. Remove the foil seal from the MTS™ Anti-IgG Card or from the individual microtubes to be used for testing.
6. Add 50 µL of red blood cells to each microtube. ***The pipette tip should not touch the gel card. Erroneous results due to carryover may occur.***
7. Add 25 µL of serum or plasma to each microtube of the MTS™ Anti-IgG Card. The mixture may or may not touch the gel suspension. ***The pipette tip should not touch the gel card. Erroneous results due to carryover may occur.***
8. Incubate the MTS™ Anti-IgG Card for 15 minutes at 37 ± 2°C. ***Incubation times may be extended, if desired, to a maximum of 40 minutes.***
9. After incubation, centrifuge the prepared cards in the MTS™ Centrifuge at the preset conditions (10 minutes) installed by the manufacturer.
10. After centrifugation, remove the MTS™ Anti-IgG Cards from the centrifuge.
11. Observe, read macroscopically the front and back of each microtube for agglutination and/or hemolysis.
12. Record reactions on the antibiogram panel sheet.
13. Call the patient's caregiver to find out when Mom received Rh Immune Globulin. Document this communication in the computer as a result comment of "RHIG."

RESULTS:

1. If no reactions are seen then the only antibody present is the anti-D from Rh Immune Globulin.
2. Result the antibody Identification as Anti-D (RhIG) and add the following result comment:

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a. Canned comment "RHIG" which says, "The Anti-D detected in this patient's plasma is probably passively acquired, due to administration of Rh Immune Globulin on _."
b. Enter the administration date of the Rh Immune Globulin in the (_).

3. If positive reactions are seen then proceed to do complete antibody identification.

REFERENCES:

1. Standards for Blood Banks and Transfusion Services. Bethesda, MD: American Association of Blood Banks, 2015. 30th Edition
2. Fung, Mark K MD, PhD. Technical Manual. Bethesda, MD: American Association of Blood Banks, 2014. 18th Edition.


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Paper copy reviewed on 12/12/2023 by Janette O'Neill.
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All Revision Dates

2/6/2026, 2/27/2024, 12/1/2016

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Approval Signatures

Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator, VCMC & SPH	2/6/2026
Laboratory Services Department	Kathrina Barcena: Supervisor-Blood Bank, Laboratory Services	2/5/2026
Laboratory Services Department	Erlinda Roxas: Director, Laboratory Services	1/24/2026
Laboratory Services Department	Linda Lee: Medical Director, VCMC Blood Bank	1/23/2026

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Status **Active** PolicyStat ID **19191806**

Origination	12/1/2015	Owner	Kathrina Barcena: Supervisor-Blood Bank, Laboratory Services
Last Approved	1/23/2026		
Effective	12/16/2025		
Last Revised	1/23/2026	Policy Area	Laboratory Services - Blood Bank
Next Review	1/23/2028		

L.BB.36 Check Type - ABO/Rh Confirmation

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PRINCIPLE:

Current FDA guidelines and The Joint Commission and College of American Pathologists (CAP) accreditation standards require a second ABO/Rh type for confirmation to be performed on blood from a separate blood draw before the patient can be issued ABO type specific red blood cells and before the Blood Bank can employ a rapid computer-supported blood crossmatch that speeds the delivery of safe blood. This policy is designed to reduce the incidence of mistransfusion of ABO-incompatible red blood cells due to the wrong patient's blood being drawn for type and crossmatch, an event that happens with 1/2000-blood specimens.

POLICY:

Upon completion of an initial ABO/Rh typing on a current specimen submitted for pre-transfusion testing, the Blood Bank staff will compare the current specimen's ABO/Rh typing result with existing VCMC/SPH historical Blood Bank records to ensure that they are identical. If there are no historical ABO/Rh typing records on file, or if the current sample does not agree with historical records, the Blood Bank will initiate a Check Type by ordering the reflex test, "***ABO/Rh retype***," for the collection of a second sample to verify the ABO/Rh of the patient.

A second sample can be obtained from the Hematology Department if the sample is from a different draw and if the sample is labeled appropriately. If a second sample, drawn at a different time, is unavailable in the laboratory or the patient is unable to have a second sample collected, group O Rh Negative red blood cells will be crossmatched for transfusion.

The Blood Bank will help to minimize delays in blood availability by notifying the appropriate location and requesting a 2nd blood specimen to be drawn for ABO/Rh confirmation on all patients for whom a Check

Type is required.

SPECIMEN COLLECTION:

1. Lavender top EDTA (3 mL) or a pink top EDTA
2. No special preparation of the patient is necessary.
3. Specimens for confirmation of blood type are labeled with the Laboratory label generated by the "ABO/Rh retype" request.
4. Blood Bank recipient wristbands are not required for confirmatory specimens.

PROCEDURE:

1. Perform the ABO/Rh test for Type and Screen or Type and Crossmatch orders received.
2. Perform a computer search for previous historical records in the Laboratory Information System and the Legacy System.
3. If the patient has a prior ABO/Rh type on file, and the current specimen confirms the historical blood type, no Check Type is required and the Type and Screen or Type and Cross match testing can be completed with type specific/type compatible red blood cells being cross matched and issued for transfusion.
4. A patient requires a second ABO/Rh type to confirm their blood type prior to issuing type specific red blood cells if any the following apply:
    a. There is no blood type (ABO/Rh) in the patient's historical record in the laboratory information system,
    b. There is a discrepancy between the historical blood type and the current typing,
    c. Patient is greater than 4 months of age (less than 4 months of age follow a different policy).
    d. Patient does not have autologous blood at VCMC/SPH at this time.
5. The Blood Bank staff will perform the Type and Screen and/or Type and Crossmatch testing and determine if a confirmatory sample will be required prior to compatibility testing and dispensing of type specific red blood cells.
    a. ABO/Rh retype confirmation is **not** required:
        - ABO/Rh history on file and current typing confirms historical typing.
        - Patient has autologous red blood cells.
    b. ABO/Rh retype confirmation **is** required:
        - Reflex order a STAT "ABO/Rh retype."
        - Print the laboratory label.
        - Search the Laboratory Information System for a recent CBC order from a different phlebotomy. If a second sample from a different phlebotomy is available, add-on a STAT "ABO/Rh retype" order to the sample and perform testing. If a second sample from a different phlebotomy is unavailable,

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reflex order a STAT "ABO/Rh retype" and send a phlebotomist to collect the specimen.

- Perform testing and confirm the ABO/Rh type of the second sample matches the current ABO/Rh type.
- Cross match type specific or type compatible red blood cells.

6. **PRE-OP PATIENTS**:

   Patients presenting to the laboratory with pre-op orders for Blood Bank.

   a. **TYPE AND SCREEN ORDERS:**

      - A second ABO/Rh will not be collected at this time. The policy will be implemented if a physician places an order to convert a type and screen to a type and cross match.

   b. **TYPE AND CROSSMATCH ORDERS – *Check Type required***

      The phlebotomist, drawing a patient with Type and Crossmatch orders, will let the patient know that a second sample may need to be drawn for Blood Bank if the Blood Bank does not have a blood type history on file. The phlebotomist will ask the patient to wait while they go check with the Blood Bank.

      a. ***2nd Sample is not required***: Blood Bank has an ABO/Rh history on file. The phlebotomist will return to the drawing room and inform the patient a second sample is not required and they may leave.

      b. ***2nd Sample is required*:** Blood Bank does not have an ABO/Rh history on file.

         i. The Blood Bank will order an ***ABO/Rh retype***, print a laboratory label, and give this label and a lavender EDTA 3mL tube to the phlebotomist.

         ii. The phlebotomist will return to the drawing room and perform a second phlebotomy to obtain a second specimen drawn at a different collection time.

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PROCEDURAL NOTES

1. Exception is made for trauma patients for whom the Blood Bank recipient blood banding system is used as a means to prevent identification errors.
2. All patients receiving blood products must have a Blood Bank recipient blood band on as an additional means to prevent identification errors.
3. Patients receiving Autologous Units – Confirm the current sample testing with the labeled ABO/Rh typing on the unit.
4. Patients receiving Directed Donor Units are subject to the Check Type policy.

REFERENCES:

1. Standards for Blood Banks and Transfusion Services. Bethesda, MD: American Association of Blood Banks, 2024. 34th Edition.
2. Fung, Mark K MD, PhD. Technical Manual. Bethesda, MD: American Association of Blood Banks, 2014. 19th Edition.
3. College of American Pathologist (CAP) current 12/26/2024 checklist, TRM.30575.

All Revision Dates

1/23/2026, 1/11/2024, 12/1/2016

Approval Signatures

Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator, VCMC & SPH	1/23/2026
Laboratory Services Department	Erlinda Roxas: Director, Laboratory Services	1/23/2026
Laboratory Services Department	Linda Lee: Medical Director, VCMC Blood Bank	12/16/2025
Laboratory Services Department	Kathrina Barcena: Supervisor-Blood Bank, Laboratory Services	12/16/2025

Status **Active** PolicyStat ID **19747201**

VENTURA COUNTY HEALTH CARE AGENCY

Origination	5/10/1991
Last Approved	2/6/2026
Effective	2/6/2026
Last Revised	2/6/2026
Next Review	2/6/2028
Owner	Kathrina Barcena: Supervisor-Blood Bank, Laboratory Services
Policy Area	Laboratory Services - Blood Bank

L.BB.38 Blood Bank Critical Values/Deviation from Standard Operating Procedures

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PRINCIPLE:

Delays or failures in the communication of life threatening test results to the physician or responsible licensed caregiver may lead to delays in treatment and potentially adverse patient outcomes. It is the policy of Ventura County Medical Center/Santa Paula Hospital to safeguard patient safety by identifying and establishing the responsibilities of staff who report and receive critical test results; define critical tests and critical results for particular departments; to establish the acceptable time frames for reporting results; and to define the process of reporting critical tests/results.

DEFINITIONS:

1. **Critical Tests**: tests ordered for a patient with potentially life threatening symptoms that require rapid communication of results even if the results are normal.
2. **Critical Results**: results, even from routine tests, that represent a life threatening state that require rapid communication to the physician or responsible caregiver.
3. **Licensed Responsible Caregiver**: staff within the scope of their practice and in accordance with organizational policy that may receive and act on a critical result: a Nurse Practitioner, Physician Assistant, Registered Nurse, or Licensed Vocational Nurse.

POLICY:

1. Blood Bank Critical Values – The patient's physician or caregiver will be notified when any of the following occur:

a. Their patient is receiving blood that was issued on emergency release, and that patient is

found to have a positive antibody screen, a positive direct antiglobulin test, or a positive crossmatch. ***NOTIFY THE PHYSICIAN IMMEDIATELY.***

b. A positive antibody screen or a positive direct antiglobulin test on a pre-surgery patient. The physician will be told that the antibody could cause a delay in the availability of compatible blood.

c. The Blood Bank will verify that a physician is aware of any suspected transfusion reaction.

d. Positive Direct Coombs for infants being screened for hemolytic disease of the newborn.

2. Deviation From Standard Operating Procedures – Any deviation from the Standard Operating Procedures must be approved by the Medical Director or the Pathologist on call. Complete the "***Deviation from Standard Operating Procedure Form***" (Attachment A) and consult with the Pathologist. The Pathologist must sign the form if approval for the deviation from Standard Operating Procedure is granted. Initial verbal approval can be documented on the form if the pathologist is not on site at the time of consultation and approval. Submit the form to the blood bank supervisor who will obtain the required signature of the Pathologist.

SPECIMEN COLLECTION:

N/A

REAGENTS:

N/A

PROCEDURE:

1. The Blood Bank Technologist will document in the computer notification of the critical test results, including time, date, and recipient of the critical test/result. Documentation of the licensed caregiver receiving the notification should include their first and last name.
2. **Read Back Procedure**:
    a. A licensed caregiver receiving the verbal or telephone critical test result must read back the critical test/result to the blood bank Technologist who will document the read back process was performed.

CALIBRATION:

N/A

CALCULATIONS:

N/A

QUALITY CONTROL:

N/A

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RESULTS:

N/A

LIMITATIONS:

N/A

REFERENCES:

1. VCMC/SPH Administrative policy 100.030, *Critical Tests/Critical Results (Reported Verbally)*
2. Standards for Blood Banks and Transfusion Services. Bethesda, MD: American Association of Blood Banks, 2015. 30th Edition.
3. Fung, Mark K MD, PhD. Technical Manual. Bethesda, MD: American Association of Blood Banks, 2014. 18th Edition.

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All Revision Dates

2/6/2026, 12/1/2016, 9/1/2015, 12/1/2011, 3/1/1998

Attachments

A: Deviation From Standard Operating Procedure Form

Approval Signatures

Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator, VCMC & SPH	2/6/2026
Laboratory Services Department	Kathrina Barcena: Supervisor-Blood Bank, Laboratory Services	2/5/2026
Laboratory Services Department	Erlinda Roxas: Director, Laboratory Services	1/23/2026
Laboratory Services Department	Linda Lee: Medical Director, VCMC Blood Bank	1/23/2026

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VENTURA COUNTY HEALTH CARE AGENCY

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Last Revised	2/6/2026
Next Review	2/6/2028
Owner	Kathrina Barcena: Supervisor-Blood Bank, Laboratory Services
Policy Area	Laboratory Services - Blood Bank

L.BB.40 Positive Direct Antiglobulin Test Investigation

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POLICY:

The Blood Bank will investigate all positive direct antiglobulin tests (DAT) to determine if they are clinically significant and/or if hemolysis is occurring.

PROCEDURE:

1. Obtain the diagnosis, drug therapy and transfusion history.
2. Look for evidence of hemolysis – reticulocytosis, hemoglobinemia, elevated unconjugated bilirubin, decreased serum haptoglobin, elevated LDH, etc.
3. Perform Direct Antiglobulin Test (DAT) procedure using anti-IgG and Anti-C3b,C3d.
4. Perform antibody screen (whether ordered or not).
5. **An eluate must be done when anti-IgG positive and any of the following is true:**
    a. The patient has been transfused in the past 3 months.
    b. Antibodies are present in the serum/plasma.
    c. The Direct Antiglobulin Test (DAT) has increased in strength from a previous one.
    d. There is evidence of hemolysis.
    EXCEPTION: Newborns.

    When an eluate is not indicated, STOP. No further serologic testing is necessary.

    If an eluate is required, proceed to step 6.
6. Prepare an eluate according to BB 5.13 "Acid Elution" procedure.

7. Perform a red cell panel on the eluate. Test the eluate with A1 and B cells if the patient received blood components of ABO group other than his own.

When no unexpected antibodies are present in the serum, when the patient has not been recently transfused, and when autoantibody is the only activity in the eluate, STOP. No further serologic testing is necessary.

When further testing is indicated, consult the Blood Bank Supervisor and/or the Pathologist.

CLASSIFICATION OF IMMUNE HEMOLYTIC ANEMIA:

Autoimmune Hemolytic Anemia

1. Warm-reactive autoantibodies (WAIHA)
    a. Primary (idiopathic)
    b. Secondary (lymphoma, SLE, carcinoma, etc.)
2. Cold-reactive autoantibodies
    a. Cold agglutinin disease (CAD)
        1. Primary (idiopathic)
        2. Secondary (lymphoma, mycoplasma pneumonia, infectious mono)
    b. Paroxysmal Cold hemoglobinuria (PCH)
        1. Primary (idiopathic)
        2. Secondary (syphilis, viral infections)

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Drug-Induced Hemolytic Anemia

1. Drug adsorption – penicillin, cephalosporins
2. Immune complex – phenacetin, quinidine
3. Membrane modification – cephalosporins
4. Induction of autoimmunity – methyldopa

Alloimmune Hemolytic Anemia

1. Hemolytic disease of the newborn
2. Hemolytic transfusion reactions

Table 17-1:	Drugs Associated with a Positive DAT and/or Immune Hemolytic Anemia
Table 17-4:	Serological Finding in Auto Immune Hemolytic Anemia
Table III:	Clinical and Laboratory Findings in Drug-Induced Immunohematologic Abnormalities.
Table IV:	Interpreting a Positive DAT (Non-Neonatal)

REFERENCES:

1. Standards for Blood Banks and Transfusion Services. Bethesda, MD: American Association of Blood Banks, 2015. 30th Edition.
2. Fung, Mark K MD, PhD. Technical Manual. Bethesda, MD: American Association of Blood Banks, 2014. 18th Edition.

All Revision Dates

2/6/2026, 12/1/2016, 12/1/2013

Approval Signatures

Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator, VCMC & SPH	2/6/2026
Laboratory Services Department	Kathrina Barcena: Supervisor-Blood Bank, Laboratory Services	2/5/2026
Laboratory Services Department	Erlinda Roxas: Director, Laboratory Services	1/24/2026
Laboratory Services Department	Linda Lee: Medical Director, VCMC Blood Bank	1/23/2026

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Last Revised	2/9/2026
Next Review	2/9/2028
Owner	Kathrina Barcena: Supervisor-Blood Bank, Laboratory Services
Policy Area	Laboratory Services - Blood Bank

L.BB.49 Biological Product Deviation Reports

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POLICY:

The FDA requires that a system be in place for the reporting of any deviation or unexpected event that may affect the safety, purity, or potency of distributed blood or blood components, to the Center for Biologics Evaluation and Research (CBER).

The report must be filed by the facility where the deviation occurred within 45 days of the event.

If a mislabeled blood product is received from the blood supplier and returned without being issued, the Biological Product Deviation Report (BPDR) will be filed by the blood supplier. If a deviation is discovered at the transfusion facility but the product has not been issued, a Biological Product Deviation Report (BPDR) is not filed. (Note: an Occurrence Report is still required so that the event can be investigated and analyzed.)

DEFINITIONS:

1. **Control** means having responsibility for maintaining the continued safety, purity, and potency of the product and for compliance with applicable product and establishment standards, and for compliance with current good manufacturing practices.
2. **Safety** means the relative freedom from harmful effect to persons affected, directly or indirectly, by a product when prudently administered, taking into consideration the character of the product in relation to the condition of the recipient at the time.
3. **Purity** means relative freedom from extraneous matter in the finished product, whether harmful to the recipient or deleterious to the product. Purity includes but is not limited to relative freedom from residual moisture or other volatile substances and pyrogenic substances.

4. **Potency** is interpreted to mean the specific ability or capacity of the product, as indicated by appropriate laboratory tests or by adequately controlled clinical data obtained through the administration of the product in the manner intended, to effect a given result.
5. **Manufacture** means all steps in propagation or manufacture and preparation of products and includes but is not limited to filling, testing, labeling, packaging, and storage by the manufacturer.

PROCEDURE:

A. Who must report:

The manufacturer that had **control** over the product when the deviation from current good manufacturing practice, applicable regulations, applicable standards, or established specifications or an unexpected or unforeseeable event that may affect the safety, purity, or potency occurred must submit a report. This reporting requirement applies to:

- Licensed manufacturers of blood and blood components;
- Unlicensed registered blood establishments; and
- Transfusion services.

B. What is reportable:

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A facility must report any event, and information relevant to the event, associated with the manufacturing or with the holding or distribution, of both licensed and unlicensed blood and blood components, if that event meets all the following criteria:

1. Either:
    a. Represents a deviation from current good manufacturing practice, applicable regulations, applicable standards, or established specifications that may affect the safety, purity, or potency of that product; or
    b. Represents an unexpected or unforeseeable event that may affect the safety, purity, or potency of that product; and
    c. Involves distributed blood or blood components.
    d. Occurs while the facility had control of or was responsible for the product.

A reportable event is any deviation in the manufacturing process: collection, testing, processing, packing, labeling, storing, holding, or distributing or compatibility testing including manipulation, sampling, testing or control procedures, storage, labeling and record keeping.

1. Examples of reportable Biological Product Deviations (BPD)
    a. Testing:
        1. Testing not performed in accordance with instructions
            - Incorrect incubation time or temperature
            - Incorrect reagent used
            - Incorrect addition of reagents

- Expired reagents used unless approved by FDA

2. Unsuitable sample used for testing
    - sample improperly stored
    - sample diluted
    - sample not identified appropriately to relate back to patient or autologous donor

b. Quality Control and Distribution:

1. Unsuitable unit distributed
    - Clotted unit or segment
    - Hemolyzed unit or segment
    - Outdated unit
    - Unit shipped or stored at incorrect temperature
2. Failure to quarantine unit due to:
    - Incorrect, incomplete, or positive testing
    - Testing not performed or not documented
3. Transfusion service received an order requiring special processing or testing and fails to meet that requirement and issued for transfusion
    - CMV negative
    - Leukoreduced
    - Irradiated
    - Hemoglobin S negative
4. Wrong unit or product issued for patient transfusion.
5. Improper ABO or Rh blood product selected for patient and issued for transfusion.
6. Antibody screening results not recorded for AHG phase and issued for transfusion.
7. SOP requires use of check cells following reading of AHG phase. Check cells results were not recorded and discovered after unit is issued for transfusion.
8. Samples collected from the wrong patient for a crossmatch and unit was issued for transfusion.
9. Blood Bank staff failed to check whether the patient had been identified with a previous atypical antibody. Crossmatch was performed and no atypical antibody was identified. Unit was transfused and patient had delay transfusion reaction. Investigation revealed that the patient had a previous atypical

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antibody identified in the blood bank file.

c. Labeling:

1. Product labeled with incorrect ABO, Rh, product code, or unit number.
2. Information missing: ABO, Rh, product code, expiration date, unit number.
3. Unit labeled with extended expiration date or time.

2. Examples of Non-Reportable Biological Product Deviations (BPD)

a. Testing:

1. Testing was performed and units issued prior to daily QC testing of reagents.

b. Quality control and distribution

1. Frozen product breaks during thawing, and the product is discarded.
2. Product breaks or is damaged during shipment, and the product is discarded.
3. Allogeneic unit issued when Autologous or Directed Donor units are available.
4. Unit returned to Blood Bank is determined to be unsuitable and discarded (e.g. out of temperature range).
5. The correct unit was issued for transfusion, but the nurse gave the unit to the wrong recipient.
6. Discovered by the issuing Blood Bank staff that the blood unit identification (BUI) number on the Unit Issue Form or the crossmatch tag was different than the BUI number on the unit.

c. Labeling

1. Unit labeled with incorrect facility identification; unit acceptable.
2. Unit labeled with shortened expiration date or time.
3. Directed unit, suitable for allogeneic use, labeled with incorrect name, SSN, or date of birth.

C. Report form Instructions:

1. Events which qualify as a Biological Product Deviation (BPD) must be reported to the FDA using FDA Form 3486: Biological Product Deviation Report form. Biological Product Report submission is performed electronically at http://www.fda.gov/cber/biodev/biodevsub.htm. Current reporting codes and instructions are available online.
2. A copy of the final report shall be made and retained in the "Biological Product Deviation Report" binder.

a. Prior to mailing, the Blood Bank Medical Director and Laboratory

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Administrative Manager shall review the report. This review shall be documented on the Blood Bank copy.

b. All reportable events shall be tracked and presented to the Transfusion Committee for review.

3. The final Biological Product Deviation Report shall be submitted to CBER within 45 days of when it is first determined that a reportable event has occurred.

D. Record Retention:

1. All information, data, forms, and reports associated with a Biological Product Deviation Report shall be retained in the Blood Bank indefinitely.

REFERENCES:

1. Guidance for Industry: Biological Product Deviation Reporting for Blood and Plasma Establishments, October 2006
2. Code of federal regulations, 21 CFR 600.14
3. Code of federal regulations, 21 CFR 606.171

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All Revision Dates

2/9/2026, 12/1/2016

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Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator, VCMC & SPH	2/9/2026
Laboratory Services Department	Erlinda Roxas: Director, Laboratory Services	2/8/2026
Laboratory Services Department	Kathrina Barcena: Supervisor-Blood Bank, Laboratory Services	2/5/2026
Laboratory Services Department	Linda Lee: Medical Director, VCMC Blood Bank	1/29/2026

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Owner	Kathrina Barcena: Supervisor-Blood Bank, Laboratory Services
Policy Area	Laboratory Services - Blood Bank

L.BB.56 Selected Cell Panel

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PRINCIPLE

In order to confirm or rule out a serum antibody or multiple antibodies, panel cells may be chosen for testing based on the cell antigen phenotype.

SPECIMEN:

Refer to Antibody Identification Procedure SOP BB 5.1

REAGENTS – SPECIAL SUPPLIES AND EQUIPMENT

1. Reagent
    a. ***Panel Cells to confirm presence of an antibody*** – choose cells that are positive for the corresponding antigen. If more than one antibody is present, chose cells that are antigen positive for only the antigen/antibody in question.
    b. ***Panel Cells to rule out an antibody*** – choose cells that are positive for the corresponding antigen. If there is possibly more than one antibody present, choose cells that are differentially positive for the antigen/antibody in question.

EXAMPLE: Patient has anti-D and anti-Fy^a is to be ruled out. Choose cells that are Fy^a positive and D negative.

QUALITY CONTROL:

See Daily Reagent Quality Control and Antigen Typing Procedures

PROCEDURE:

1. Label one tube or MTS gel card for each cell to be tested with the patient's laboratory label and the panel cell number.
2. Refer to Antibody Identification Procedure.

RESULTS:

1. If the antibody is present, a positive reaction will be observed.
2. If the antibody can be ruled out, a negative reaction will be observed.

REFERENCES:

1. Standards for Blood Banks and Transfusion Services. Bethesda, MD: Association for the Advancement of Blood and Biotherapies (AABB), current edition.
2. Cohn, Claudia S., MD, PhD. Technical Manual. Bethesda, MD: Association for the Advancement of Blood and Biotherapies (AABB), current edition.

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Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator, VCMC & SPH	2/9/2026
Laboratory Services Department	Erlinda Roxas: Director, Laboratory Services	2/7/2026
Laboratory Services Department	Kathrina Barcena: Supervisor-Blood Bank, Laboratory Services	2/5/2026
Laboratory Services Department	Linda Lee: Medical Director, VCMC Blood Bank	1/29/2026

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Owner	Kathrina Barcena: Supervisor-Blood Bank, Laboratory Services
Policy Area	Laboratory Services - Blood Bank

L.BB.58 Lo-Ion Enhancement Medium

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PRINCIPLE:

Incubation of serum/plasma and red blood cells in a reduced ionic environment increases the rate at which blood group antibodies in the serum/plasma bind to the antigen sites on the red cells. This enhances reactivity either by direct agglutination or the indirect anti-globulin test.

SPECIMEN COLLECTION:

1. Serum or Plasma.
2. No special preparation of the patient is required prior to specimen collection.
3. If specimens are stored before testing, they should be stored at 2-8°C.

REAGENTS – SPECIAL SUPPLIES AND EQUIPMENT:

1. Ortho Enhancement Reagent
    a. An aqueous, phosphate-buffered low ionic strength solution (LISS) containing glycine and thimerosal.
    b. Store at 2-8°C – do not freeze.
    c. Do not use if turbid.
    d. Do not use reagent beyond the expiration date.
2. Reagent Red Cells for antibody detection or antibody identification.
3. Anti-human globulin.

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4. Coombs Control Cells.
5. Reagent Quality Control D(Weak) Cell.
6. Saline.
7. 12X75 MM Test Tubes.
8. Centrifuge.
9. Pipettes.
10. Water bath or incubator, 37°C.
11. Optical aid.

PROCEDURE:

1. With a clean pipette, place two drops of serum/plasma to be tested into each appropriately labeled test tube.
2. With a clean pipette, add one drop of the prepared 3-5% cell suspension.
    a. For antibody screening or identification, reagent red blood cells may be used directly from the vial.
    b. For compatibility testing, prepare a 3% to 5% suspension of donor red blood cells in isotonic saline.
3. Add two drops of Ortho Antibody Enhancement Solution.
4. Mix contents well.
5. Incubate at 37°C for 10 minutes. (Incubation may be extended up to 30 minutes, if desired.)
6. Centrifuge.
7. Check for hemolysis.
8. Re-suspend the cells by gentle agitation and examine ***macroscopically*** for agglutination.
9. Wash the cell/serum mixture four times with isotonic saline.
10. Add two (2) drops of anti-human globulin to the dry cell button.
11. Mix contents well and centrifuge for the calibrated time.
12. Re-suspend the cells by gentle agitation. Antibody detection and identification results should be examined ***macroscopically.*** An optical aid may be used for the final reading of test results but microscopic examination is discouraged when LISS procedures are used.
13. Read for agglutination and record results.
14. To all negative anti-globulin tests, add one drop of Coombs Control Cells.
15. Re-suspend the cells by gentle agitation.
16. Read for agglutination and record results.

CALIBRATION:

N/A

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CALCULATIONS:

N/A

QUALITY CONTROL:

1. See Daily Reagent Quality Control – SOP 8.3
2. Perform an auto control with each patient.

RESULTS:

1. Agglutination and/or hemolysis of the red cells is a positive test and indicates that the serum/plasma being tested has antibodies directed at an antigen or antigens on the red cell.
2. No hemolysis or agglutination is a negative test result and indicates the absence of an antibody/antigen reaction. Negative tests are verified by the addition of Coombs control cells.
    a. No agglutination after the addition of Coombs control cells to a negative test indicates that the anti-human globulin was inactivated, neutralized or omitted. In such a case, the negative test result should be considered invalid, and the entire antibody detection or identification test should be repeated.
    b. Agglutination after the addition of Coombs control cells to a negative test indicates that the anti-human globulin added was capable of reacting, and the negative test result may be considered valid.
3. A positive auto control indicates the presence of an auto-antibody. Further studies will be required to assure that allo-antibodies are not also present. A ***Direct Anti-globulin Test*** should be run.

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LIMITATIONS:

1. Most often, antibodies capable of producing hemolysis have specificity in the ABO, P, Lewis, Kidd, or Vel blood groups.
2. The ionic strength of the test system is dependent on the amount of serum used. The use of excess serum should be avoided as it will increase the ionic strength of the mixture.
3. Red blood cells that have a positive direct anti-globulin test must not be used for the indirect anti-globulin test.
4. Improper technique may invalidate the results obtained with this reagent.
5. Weaker reactions may be obtained if the tests are incubated less than 10 minutes or more than 30 minutes.
6. Complement-dependent antibodies may not be detected if a plasma specimen is used.

REFERENCES:

1. Transfusion Medicine ORTHO Antibody Enhancement Solution, 10 mL, 15s IFU No. e631206778 - V May 2005

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2. Standards for Blood Banks and Transfusion Services. Bethesda, MD: American Association of Blood Banks, 2015. 30th Edition
3. Fung, Mark K MD, PhD. Technical Manual. Bethesda, MD: American Association of Blood Banks, 2014. 18th Edition.

All Revision Dates

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Approval Signatures

Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator, VCMC & SPH	2/9/2026
Laboratory Services Department	Erlinda Roxas: Director, Laboratory Services	2/8/2026
Laboratory Services Department	Kathrina Barcena: Supervisor-Blood Bank, Laboratory Services	2/5/2026
Laboratory Services Department	Linda Lee: Medical Director, VCMC Blood Bank	1/28/2026

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Owner	Kathrina Barcena: Supervisor-Blood Bank, Laboratory Services
Policy Area	Laboratory Services - Blood Bank

L.BB.60 Storage and Transportation of Blood Products

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POLICY:

The storage guidelines listed below are the requirements of the Association for the Advancement of Blood and Biotherapies (AABB) as found in the Standards for Blood Banks and Transfusion Services. All blood products are to be stored in monitored refrigerators and freezers. Blood Bank reagents may be stored in refrigerators that are not monitored.

SPECIMEN COLLECTION:

N/A

REAGENTS/MATERIALS:

N/A

PROCEDURE:

Storage:

1. The Blood Bank blood storage refrigerator and freezer should contain only blood products and Rh Immune Globulin products.
2. The internal storage temperatures of refrigerators, freezers, and platelet incubators shall be monitored. Refrigerators, freezers, and platelet incubators are available with continuous temperature monitoring devices that will detect a temperature deviation before blood components might be affected. If blood components are stored in an open storage area or an automated temperature recording device is not used or temporarily in-operable, temperatures of the blood component storage environment must be measured manually and recorded every

4 hours. (Blood Bank Quality Control/BB 8.1Form 5 v1)

3. Temperature charts from the seven-day mechanical recorder must be changed weekly, and dated inclusively. Any temperature variation from normal should be explained in writing on the chart next to the tracing, as well as dated and initialed by the person noting the deviation.
4. The temperature of the Blood Bank blood storage refrigerator must be maintained at 1-6°C in all areas of the refrigerator.
5. The temperature of the Blood Bank component storage freezer must be maintained at -18°C or colder.
6. The temperature of the Blood Bank platelet storage incubator must be maintained at 20-24°C.
7. The visible and audible alarm shall be activated under conditions that will allow proper action to be taken before blood, blood components, or derivatives reach unacceptable conditions. The electrical source for the alarm system should be separate from that of the refrigerator and freezer. Activation of the alarm shall initiate a process for immediate investigation and appropriate corrective action. (See ***Steps to take if a Blood Bank Alarm Sounds***)
8. Blood Products:
    a. Whole Blood, Red Blood Cells, and Washed Red Cells – Store ONLY in a monitored blood bank refrigerator between 1-6°C.
    b. Fresh Frozen Plasma, Plasma Frozen within 24 Hours, Jumbo Plasma, pediatric plasma and Cryoprecipitate – Store in a monitored Blood Bank freezer at -18° or colder.
    c. Platelets – Store between 20-24°C with continuous gentle agitation.
    d. Rh Immune Globulin – Store between1-6°C.
    e. Thawed Plasma – Store between1-6°C.
    f. Thawed Cryoprecipitate – Store between 20-24°C.

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Transportation:

1. When issued for transfusion, blood should not be allowed to stand unnecessarily at room temperature. Blood stored at 1-6°C will exceed 10°C in approximately 30 minutes at room temperature.
2. Unused blood will only be released to the blood supplier personnel, in person, with the required documentation.
    a. Remove all Ventura County Medical Center/Santa Paula Hospital labels and unit tags.
    b. The courier from the blood supplier must sign consignment papers for units released and the blood bank will retain a copy signed by the Technologist.
3. Blood is transported with the patient only when it is to be given in transit. The blood is issued, and the Blood Unit Issue Forms will be sent with the blood. Blood is not to be transported with the patient outside the county unless used in transit.
4. During transport to all areas within the facility, blood must be kept at 1-10°C. Follow ***Supplying Blood in Blood Transport Coolers***.

CALIBRATION:

N/A

CALCULATIONS:

N/A

QUALITY CONTROL:

Blood Bank Quality Control (SOP 8.1)

RESULTS:

N/A

REFERENCES:

1. Standards for Blood Banks and Transfusion Services. Bethesda, MD: Association for the Advancement of Blood and Biotherapies (AABB), Current Edition.
2. Cohn, Claudia S. Technical Manual. Bethesda, MD: AABB, Current Edition.

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Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator, VCMC & SPH	1/26/2026
Laboratory Services Department	Erlinda Roxas: Director, Laboratory Services	1/24/2026
Laboratory Services Department	Kathrina Barcena: Supervisor-Blood Bank, Laboratory Services	11/4/2025
Laboratory Services Department	Linda Lee: Medical Director, VCMC Blood Bank	10/29/2025

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Owner	Kathrina Barcena: Supervisor-Blood Bank, Laboratory Services
Policy Area	Laboratory Services - Blood Bank

L.BB.62 Cryoprecipitated Antihemophilic Factor (AHF)

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PRINCIPLE:

Cryoprecipitated Antihemophilic Factor (AHF) is a concentrated source of certain plasma proteins. It is prepared by thawing 1 unit of Fresh Frozen Plasma (FFP) at 1 to 6 C. After it is thawed, the supernatant plasma is removed, which leaves the cold-precipitated protein plus 10 to 15 mL of plasma in the bag. This material is then refrozen at -18 C or colder within 1 hour and has a shelf life of 1 year from the original collection date.

Cryoprecipitated AHF contains concentrated Factor VIII:C (the procoagulant activity), Factor VIII:vWF (von Willebrand factor), fibrinogen, and Factor XIII. Each bag of Cryoprecipitated AHF contains at least 80 units of factor VIII, at least 150 mg of fibrinogen, and about 20% to 30% of the Factor XIII present in the initial unit. Approximately 40% to 70% of the vWF present in the initial unit of FFP is recovered in the cryoprecipitate. The main source of concentrated fibrinogen is Cryoprecipitated AHF.

Cryoprecipitated AHF may be indicated for the treatment of congenital or acquired fibrinogen deficiency or Factor XIII deficiency. When fibrinogen consumption (eg, DIC) or loss (eg, massive hemorrhage), or both, are occurring, exogenous replacement may be necessary to maintain plasma's coagulation potential. Dysfibrinogenemias are rare congenital abnormalities that result in dysfunctional fibrinogen molecules and can lead to increased tendencies to thrombosis or bleeding or both or to no clinical manifestations. Patients may require administration of cryoprecipitate to correct the deficiency.

Cryoprecipitated Antihemophilic Factor (AHF) is routinely prepared by the blood supplier and contains a volume of 5 to 15 mL per unit. Contracted blood supplier also provides pooled units of Cryoprecipitated AHF. Each pooled unit contains the equivalent of 5 individual units of Cryoprecipitated AHF.

SPECIMEN COLLECTION:

- 1 pink top (7 mL) EDTA tube
- Patient must be banded with a current blood bank wristband.
- Type and screen testing performed for current admission.

SUPPLIES AND EQUIPMENT:

1. Water bath – 30-37 C.
2. Waterproof plastic Helmer bags.
3. ISBT printer

PROCEDURE:

1. Select units of cryoprecipitate. ABO compatible is preferred but not required, and Rh need not be considered.
2. Modify the expiration date, prior to thawing the unit, in the computer:
    a. ***Health-e-Connect: Thawing and assigning***
        i. Open Modify Products application.
        ii. In modification field select "Thaw Product" from the drop down list.
        iii. Scan the unit Donor Identification number under Product Number in Original Products.
        iv. The new product will appear in the New Product table below.
        v. Edit the volume of the component by entering the volume shown on the component label located on the lower left of the unit label.
        vi. Use ISBT label generated from the modification or handwrite the new expiration date and time on the unit (downtime procedure). Verify ISBT label for completeness.
            1. Thawed single units, if not entered, must be administered within 6 hours of thawing.
            2. Pre-storage pooled Cryoprecipitated AHF has an expiration time of 4 hours once thawed. (This time is in contrast to 6 hours for thawed single units.)
        vii. The product expiration date and time has been updated by the system and this date and time should be visible on the newly generated ISBT label or can be written on the unit label (downtime procedure).
        viii. In the New Product table, highlight the new product and click the "assign to person" icon at the top.
        ix. Click <Save>.
3. Thaw units rapidly at 30-37 C in plastic bags (do not exceed 15 minutes of thawing).

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4. Thawed Cryoprecipitated AHF prepared for transfusion must be stored at room temperature.
5. Label Verify the thawed product and affix the corresponding ISBT label if available over the initial product label. Do not relabel the unit number.
6. Place a patient requisition label and a blood bank wristband identification number on the thawed unit.

REFERENCES:

1. Roback, John D. *Technical Manual*. Bethesda, MD: American Association of Blood Banks, Current Edition
2. *Standards for Blood Banks and Transfusion Services*. Bethesda, MD: American Association of Blood Banks, Current Edition.
3. King, Karen E. *Blood Transfusion Therapy, A Physician's Handbook*, 9th Edition, 2008.

All Revision Dates

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Approval Signatures

Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator, VCMC & SPH	1/26/2026
Laboratory Services Department	Erlinda Roxas: Director, Laboratory Services	1/24/2026
Laboratory Services Department	Kathrina Barcena: Supervisor-Blood Bank, Laboratory Services	12/7/2025
Laboratory Services Department	Linda Lee: Medical Director, VCMC Blood Bank	10/7/2025

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Owner	Kathrina Barcena: Supervisor-Blood Bank, Laboratory Services
Policy Area	Laboratory Services - Blood Bank

L.BB.69 Thawed Plasma – 5 Day

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PRINCIPLE:

Thawed Plasma is derived from Fresh Frozen Plasma (FFP) and Plasma Frozen Within 24 hours of phlebotomy (PF24) that has been thawed at 30° to 37°C in a closed system and stored at 1° to 6°C for 1 to 5 days. The expiration date is 5 days after thawing of the original component. Thawed Plasma contains somewhat reduced amounts of labile coagulation Factors V and VIII.

SPECIMEN COLLECTION:

1. Pink EDTA blood bank tube.
2. Type and Screen performed.
3. Blood bank band on the blood bank tube and the patient banded with the corresponding Blood Bank wristband.

REAGENTS-SPECIAL SUPPLIES AND EQUIPMENT:

1. Waterbath- 30° to 37° Centigrade.
2. Waterproof plastic Helmer bags.
3. Product code labels.
4. ISBT printer with ISBT label

PROCEDURE:

Selection of Units

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1. ABO group specific is preferred. If not available use only the options listed below. The Rh(D) type is not a consideration.

PATIENT TYPE	DONOR TYPE
O	**O, A, B, AB**
A	**A, AB**
B	**B, AB**
AB	**AB**

2. If the patient does not have a current blood bank specimen, provide AB plasma until a blood bank specimen can be drawn and testing completed. Use the "Dispense and Assign Products - emergency dispense mode" to issue the blood product. The attending physician will be asked to sign an emergency waiver for the units(s).
3. **Trauma Protocol**
    a. Thaw 2 - 6 units of AB plasma.
    b. Place thawed units on the trauma/emergency release shelf in the blood bank refrigerator.
    c. May utilize liquid plasma in place of AB plasma in most trauma settings.
4. Perform a modification of the product in the computer prior to putting the plasma in the bath to be thawed.
    a. ***Health-e-Connect: Thaw Product***
        i. Open Modify Products application.
        ii. In modification field select "Thaw Product" from the drop down list.
        iii. Scan the unit Donor Identification number under Product Number in Original Products.
        iv. The new product will appear in the New Product table below.
        v. Edit the volume of the component by entering the volume shown on the component label located on the lower left.
        vi. The product expiration date and time has been updated by the system, and this date and time should be written on the unit label.
        vii. In the New Product table, highlight the new product and click the "assign to person" icon at the top.
        viii. Click <Save>.
    b. ***Health-e-Connect: Extend Product***
        i. Open Modify Products application.
        ii. In modification field select "Extend Product" from the drop down list.
        iii. Scan the unit Donor Identification Number of original product into Product Number field.
        iv. The new product will appear in the New Product table below.

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v. Modify the expiration date to a 5-day expiration date from the date of the original thaw. The time of expiration should be the same as the original expiration time.

vi. Edit the volume of the component by entering the volume shown on the component label located on the lower left.

vii. The ISBT label should print when you save your modification. Review the label for completeness (volume and product code not cut off). Affix the ISBT label to the product. **Do not relabel the product with the ISBT unit number label.**

viii. For downtime procedure, re-label the unit by placing the appropriate "Thawed Plasma" product label code label over the current product code label. Line the label up in the lower left of the large label. (see appendix A for correct product code label). Enter the unit volume on the new label. Cross out the component expiration date and manually write the new expiration date and time. Draw a line through the license information on the upper left of the label that identifies the facility name.

ix. Click <Save>.

x. Perform a label verification using the computer label verify application. The printed report, which prints after successful label verification, should be saved.

xi. If the unit is for the trauma protocol, do not assign it to a patient until it is dispensed.

c. **Health-e-connect: 5 Day Plasma:** Plasma can be thawed and directly extend to 5-day expiration. Click 5 Day Plasma option in Modification Products when ISBT printer is in use. Label Verify the thawed product as in previous section.

d. All Thawed Plasma - 5 day is stored at 1 - 6C for up to 5 days.

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PROCEDURE NOTES:

- Thawing will take approximately 30 minutes.
- Place appropriate number of units of FFP/Plasma into plastic waterproof bags.
- Place the bag into the 37° Centigrade waterbath.
- Check the plasma at periodic intervals until it is completely defrosted.
- Avoid getting the ports wet.
- Usually only 1 or 2 plasma(s) should be defrosted for a patient at a time.

REFERENCES:

1. Standards for Blood Banks and Transfusion Services. Bethesda, MD. Association for the Advancement of Blood and Biotherapies (AABB), Current Edition.
2. Consensus Standards for the Uniform Labeling of Blood and Blood Uniform Labeling Guideline (FDA).

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APPENDIX A:

For downtime procedure, the following table is used to look up the appropriate product code label for 5 day thawed plasma products. The left column are frozen and 24 hour thawed product codes and the right column is the corresponding label for all extended 5 day thawed plasma products.

1. Look at the plasma product that requires extending the expiration to 5 days.
2. The frozen or 24 hour thawed product code is in the lower left quadrant of the unit label.
3. Find that product code in the left column of the table below.
4. Follow that line to the left column and that will be the product code to re-label you product with.

FROZEN PRODUCT CODE	5 DAY THAWED PRODUCT CODE
E2555V00	E2684V00
E2619V00	E2720V00
E7646V00	E5548V00
E7648V00	E5549V00
E7650V00	E5550V00
E7607V00	E6396V00

COPY

All Revision Dates

2/9/2026, 3/19/2024, 2/5/2024, 6/5/2020, 12/1/2016, 5/1/2016

Approval Signatures

Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator, VCMC & SPH	2/9/2026
Laboratory Services Department	Erlinda Roxas: Director, Laboratory Services	2/8/2026
Laboratory Services Department	Kathrina Barcena: Supervisor-Blood Bank, Laboratory Services	2/5/2026
Laboratory Services Department	Linda Lee: Medical Director, VCMC Blood Bank	1/28/2026

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Owner	Kathrina Barcena: Supervisor-Blood Bank, Laboratory Services
Policy Area	Laboratory Services - Blood Bank

L.BB.71 Blood Bank Type and Screen/Crossmatch

COPY

PRINCIPLE:

Pre-transfusion testing is performed in order to prevent the transfusion of incompatible donor red cells that might result in an immune-mediated hemolytic transfusion reaction. Requests for blood and blood components must contain sufficient information for accurate recipient identification. Two independent patient identifiers are required. Transfusion recipients are identified by the patient's first and last name and any middle name or middle initial used and the medical record number.

POLICY

It is the policy of Ventura County Medical Center and Santa Paula Hospital to use a Blood Recipient ID Wristband to verify positive identification of the blood recipient, blood sample, and blood bank products. All blood bank specimens for possible transfusion must use the Blood Recipient ID Wristband.

Specimen Policies

1. Patient specimens for transfusion testing may be used for 3 days. Day 0 is the day of draw.
2. Specimens for preop patients ***who have not been transfused or pregnant in the last three months*** are current up to 7 days. Day 0 is the day of draw. All preop patients presenting to the Laboratory for preop labs will be asked for their transfusion and pregnancy history of the last 3 months (see attachment A). If the patient has not been transfused or pregnant in the last 3 months, the specimen expiration may be extended to 7 days (See "***Flexible Specimen Expiration***" procedure located in Health-e-Connect in Patient Product Inquiry application).
3. If a patient has been transfused in the preceding 3 months with blood or a blood component containing allogeneic red cells, has been pregnant within the preceding 3 months, or if the history is uncertain or unavailable, a sample shall be obtained from the patient within 3 days of the scheduled transfusion. Day 0 is the day of draw.

4. Specimens for the transfusion of plasma components (plasma, platelets, and cryoprecipitate) are current up to 7 days of planned transfusion.
5. All requests for possible transfusions of blood and blood components must include an ABO grouping, Rh typing, and an antibody screen.
6. When the antibody screen is positive, additional testing shall be performed for identification of clinically significant antibodies.
7. All patients with historical or current clinically significant antibodies will have two units of antigen negative RBCs ordered and an immediate spin and antiglobulin crossmatch performed. This policy includes patients with Anti-D from residual Rh Immune Globulin injection.

SPECIMEN COLLECTION:

1. EDTA K2 pink top blood bank tube (7ml)

MATERIALS:

1. Blood Recipient ID Wristbands.
2. Safeguard Super Insert (for Pre-Op outpatient use)

COPY

PROCEDURE:

1. Verify that the name and medical record number written on the blood bank tube matches the name and medical record number on the laboratory request.
2. All patient specimens must be properly labeled as outlined in the procedure for Blood Bank Specimens L.BB.17 "***Identification, Labeling, and Rejection***", and the request must be properly completed. The request should include the following:
    a. Component and quantity
    b. Special requests such as Irradiation, CMV-negative, and Hemoglobin S-negative for Sickle Cell Disease patients.
    c. Transfusion indications
    d. Expected date of use
3. The Blood Recipient ID Wristband strip of numbers should be submitted with the request form.
4. Check the Laboratory Information System and the antibody file for previous records.
5. Document the historical record for ABO/RhD type and antibody screen in result entry in the computer. If there is no prior history, record "No Type on File." If there is history, record "Type on File."
6. Perform an ABO group, RhD type, antibody screen, and crossmatch (if requested). Record testing results in Result Entry application in the computer. All documentation in Result Entry must be done concurrently with testing. Review results and interpretations.
7. Re-type the donor unit if necessary and attach a yellow "***ABO Group Confirmed"*** sticker to the

unit.

8. Apply the laboratory patient label and a red Blood Recipient ID Wristband number on the crossmatch compatible unit assigned to the patient.
9. If a type and screen was initially performed for a patient with no crossmatch available/needed, the ABO/RhD type will be repeated by the technologist performing a crossmatch at a later time. (Accession add-on ABO/Rh Retype test to the current sample in Department Order Entry)
10. Crossmatched blood will be held for the designated patient for three days.

CALIBRATION:

N/A

CALCULATIONS:

N/A

QUALITY CONTROL:

See Daily Quality Control

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RESULTS:

N/A

PROCEDURAL NOTES:

1. NEONATAL TRANSFUSION – See L.BB.41, *Neonatal Transfusions*.
2. AUTOLOGOUS/RECIPIENT SPECIFIC DONATION – Follow the above steps.

REFERENCES:

1. Blood Bank SOP L.BB.17, *Blood Bank Specimens – Identification, Labeling, and Rejection.*
2. Standards for Blood Banks and Transfusion Services. Bethesda, MD: American Association of Blood Banks, 2015. 30th Edition.
3. Fung, Mark K MD, PhD. Technical Manual. Bethesda, MD: American Association of Blood Banks, 2014. 18th Edition.

All Revision Dates

2/6/2026, 12/1/2016, 7/1/2015

Attachments

A: Flexible Specimen Expiration Transfusion History Form

Approval Signatures

Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator, VCMC & SPH	2/6/2026
Laboratory Services Department	Kathrina Barcena: Supervisor-Blood Bank, Laboratory Services	2/5/2026
Laboratory Services Department	Erlinda Roxas: Director, Laboratory Services	1/23/2026
Laboratory Services Department	Linda Lee: Medical Director, VCMC Blood Bank	1/23/2026

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Owner	Kathrina Barcena: Supervisor-Blood Bank, Laboratory Services
Policy Area	Laboratory Services - Blood Bank

L.BB.76 Ordering, Storage, and Return of Blood Components

COPY

PRINCIPLE:

All blood and blood products, including apheresis platelets, frozen plasma, cryoprecipitate, and Rh Immune Globulin, should be ordered through the hospital laboratory Blood Bank. Early and exact ordering of blood and/or blood products will enable the laboratory blood bank to meet most efficiently and most economically the needs of the patient and the physician.

Blood Components will be ordered from Vitalant of Ventura (blood supplier) to maintain a minimum routine inventory of uncrossmatched red blood cells, frozen components, and apheresis platelets that is adequate to meet the transfusion requirements of the patient population at Ventura County Medical Center and Santa Paula Hospital. This inventory level is established by agreement with the blood center and is reviewed annually. Additional special components may be ordered as needed to satisfy special patient requirements. Upon receipt, the laboratory blood bank will scan blood products into the Laboratory Information System and store the components in compliance with regulatory requirements.

SPECIMEN COLLECTION:

N/A

MATERIALS / EQUIPMENT:

A. Blood center Invoices.
B. ***Daily Inventory and Order Request Form***.
C. Laboratory Information System.

D. Digitrax Scanner.

E. Blood supplier customer portal

F. Vitalant Customer Portal User Guide

PROCEDURE:

Vitalant's blood center in Ventura maintains service twenty-four (24) hours a day, seven (7) days a week. Hospital Services can be contacted at 805-654-1603. The center has an answering service for after-hours ordering.

A. Inventory and Ordering of Blood Products.

1. On the first shift of the day, an evaluation of the inventory will be done and the **Daily Inventory and Order Request Form (see attachment)** completed and posted. The evening and night shifts should evaluate the inventory for additional products needed to replenish stock.
2. Orders for blood products will be placed through Vitalant's customer portal. Use the following terminology in placing orders:
    a. **Routine:** Routine stock orders are for replenishment of inventory to established levels.
    b. **ASAP:** Delivery will not be more than 4 hours from the time an order is received by the blood center to the time it is shipped from the blood center. Please confirm portal orders have been received by the blood center by following up with a phone call. This is especially important on the evening and night shifts when couriers may be out of the center.
    c. **STAT:** Delivery will not be more than 1 hour from the time an order is received by the blood center to the time it is shipped from the blood center. Please confirm portal orders have been received by the blood center by following up with a phone call. This is especially important on the evening and night shifts when couriers may be out of the center.

B. Receiving Blood Products.

1. Upon receipt of all ordered products, make a thorough visual inspection of each unit. Sign all invoices presented by the couriers, and retain the original copy for VCMC/ SPH records.
2. Scan all units into the Laboratory Information System using the "Receive Products" application.
3. Once all units received have been scanned into inventory, close the "Receive Products "application. A Cerner “Products Received Report” listing of all products just received will print.
4. Reconcile the invoice from the blood center with the "Products Received Report" printed from the Laboratory Information System. Review each scanned component on the inventory list for accuracy of the donor identification number, blood type, product code, and expiration date.

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5. Staple the "Products Received Report" to the back of the blood center invoice and file.
6. Reconciliation of received products in Vitalant's customer portal.
    a. On the menu, choose reconciliation-product reception.
    b. Scan the invoice bar code in the “shipment/donation #” field.
    c. Enter the total number of products on the invoice.
    d. A list of each of the product numbers will appear with a box next to it.
    e. Verify and place a check for each product received and deemed acceptable.
    f. Click "confirm" to accept.

C. Return of Blood Components to Vitalant
    1. A request to return products to the blood supplier can be done through the portal. (see procedural notes for blood center return policies).
    2. Components to be returned to the blood supplier must be transferred in the Laboratory Information System.
        a. Open Final Disposition application.
        b. Select your location
        c. Open the task menu at the top and select "dispose."
        d. Select a dispose reason. This will depend on the reason for the return.
        e. Select a destruction method of "Return to Supplier."
        f. Scan each unit's Donor Identification Number in the Product list under the product number.
        g. Once all the units have been scanned, click <Save> and exit the application.
        h. A list of all transferred units will print out when the application is closed.
        i. File report.

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CALCULATIONS:

N/A

PROCEDURAL NOTES:

A. The blood supplier should be notified of any discrepancies between the delivered products and the invoices.

B. Any labeling problem with any blood component should be communicated to the blood supplier. The component involved should be quarantined pending instructions from the blood supplier. Quarantine unit in LIS system using the "Quarantine Products Application" until final disposition can be determined. Place all quarantined units on the quarantined shelf in the blood component refrigerator with a note.

C. Any component that does not pass visual inspection at the time of delivery should be rejected and sent back with the courier to the blood center.

D. In general, STAT and ASAP orders, platelets, and frozen, specialty, altered or modified blood products are not returnable. Examples include, but are not limited to, frozen plasma, cryoprecipitate, irradiated blood products, blood products with special testing or other modification, such as CMV-negative, antigen negative, sterile docking, divided units or HLA/HPA-matched units.

E. The blood supplier may provide credit to the hospital for **expired** blood products received, not transfused and discarded by the hospital under the following circumstances:

1. Red Blood Cells are provided to hospital less than seven (7) days prior to expiration.
2. Platelets are provided to hospital less than twenty-four (24) hours prior to expiration; or
3. AB Red Blood Cell products.

F. The blood supplier may permit the hospital to return **unexpired** Red Blood Cells for credit, subject to a fifty percent (50%) restocking fee, provided hospital complies with all the following conditions:

1. Hospital shall verify that proper temperature requirements have been satisfied and monitored during the storage period, in compliance with the regulatory requirements, including Title 21 of the Code of Federal Regulations and Standards of the AABB.
2. Hospital shall verify that the integrity of the unit container has been maintained and neither the unit container nor the affixed label is damaged, broken, disturbed, defaced, tampered with, or otherwise manipulated.
3. Hospital shall ensure that the original label is intact, unmarked and uncovered. Any labels or tags affixed by the hospital to the unit must be removed prior to return.
4. At least two (2) crossmatch segments must remain available for use, unless the blood supplier has approved use of the last crossmatch segment.
5. All requests to receive credit for unused blood products must be received by the blood supplier no more than seven (7) days from the expiration date of any such blood products.
6. All returned blood products must have a minimum of fifteen (15) days remaining prior to expiration at the time they are received by the blood supplier.
7. All requests to receive credit for returned blood products must comply with the blood supplier's ordering and return instructions, billing protocols and where applicable, the on-line product management system.

G. Hospital is responsible for appropriate disposal of any expired products.

H. Received red blood cell inventory will be retested for ABO grouping and all Rh-negative units confirmed before becoming available for compatibility testing. Regroup testing must be entered in the computer before the computer will allow any compatibility testing.

COPY

REFERENCES:

1. Standards for Blood Banks and Transfusion Services. Bethesda, MD: American Association of Blood Banks, Current Edition.
2. Roback, John D. Technical Manual. Bethesda, MD: American Association of Blood Banks, Current Edition.
3. Vitalant Customer Portal User Guide Rev 4, 2019.

All Revision Dates

2/6/2026, 12/23/2021, 6/5/2020, 12/1/2016, 12/1/2013

Attachments

VCMC Daily Inventory and Order Request Form.xls

COPY

Approval Signatures

Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator, VCMC & SPH	2/6/2026
Laboratory Services Department	Kathrina Barcena: Supervisor-Blood Bank, Laboratory Services	2/5/2026
Laboratory Services Department	Erlinda Roxas: Director, Laboratory Services	1/23/2026
Laboratory Services Department	Linda Lee: Medical Director, VCMC Blood Bank	1/23/2026

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Last Approved	1/23/2026		
Effective	1/23/2026	Policy Area	Laboratory Services - Blood Bank
Last Revised	1/23/2026		
Next Review	1/23/2028		

L.BB.78 Blood Bank Correlation of Methods

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PRINCIPLE:

There are many standard approaches to antibody detection. The protocols that laboratories choose will affect what they subsequently detect and, thus, what they need to investigate. Currently there are three main ways to investigate antibodies: test tube, gel, and solid-phase testing.

Ventura County Medical Center (VCMC) and Santa Paula Hospital (SPH) Blood Bank routinely perform antibody detection or identification using the Ortho MTS IgG gel card methodology. No single method is optimal for detecting all antibodies. The blood bank may employ tube testing using Ortho Antibody Enhancement Solution technique as an alternative approach for use in special circumstances or as a backup for troubleshooting. PeG and Albumin enhancements are used for investigation and don't require method correlation.

Correlation will be performed for all primary methods. Santa Paula Hospital primary methods, include tube ABO/Rh, manual gel, and tube antibody screen using Ortho Antibody Enhancement Solution. Ventura County Medical Center primary methods include, Ortho Vision, manual gel, tube ABO/Rh, and tube antibody screen using Ortho Antibody Enhancement Reagent.

SPECIMEN COLLECTION:

1. Patient samples collected in EDTA (K2) pink top tubes.
2. Patient specimens do not require blood bank wristbands.
3. Patient specimens (2) – Antibody screen positive by Ortho Vision or manual gel.
4. Patient specimens (2) – Antibody screen negative by Ortho Vision or manual gel.
5. Patient specimens (8) - One for each ABO/Rh blood type.

6. Red blood cell Unit segments (8) – One for each ABO/Rh blood type.
7. Patient specimen (1) – Antibody identified by MTS IgG gel card method.

REAGENTS/SUPPLIES AND MATERIALS

1. MTS IgG Gel Cards
2. Ortho Antibody Enhancement Solution.
3. 3% Surgiscreen Cells.
4. 0.8% Surgiscreen Cells.
5. MTS ABD & Reverse Gel Cards.
6. MTS A/B/D grouping Gel Cards
7. Anti-A reagent
8. Anti-B reagent
9. Anti-D reagent
10. Anti-Rh reagent
11. A1 Cells, 2-5% cell suspension.
12. B Cells, 2-5% cell suspension.
13. A1 Cells, 0.8% cell suspension.
14. B Cells, 0.8% cell suspension.
15. Test Tubes 12x75 mm.
16. Physiological saline.
17. Pipets: 50 uL, 25 uL.
18. Disposable Blood Bank pipets.
19. Panel A- 3%.
20. Panel A – 0.8%
21. Panel B – 0.8%
22. Methods Correlation Worksheet.

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PROCEDURE:

SANTA PAULA HOSPITAL CORRELATIONS – ANTIBODY SCREENS

1. Obtain four patient samples that have had antibody screens performed using manual MTS IgG gel card method. Include at least two positive screens and two negative screens.
2. Perform antibody screens on the four samples using the following tube method:
    a. Ortho Antibody Enhancement Solution.
3. Record all testing results and interpretations on the Correlation of Methods worksheet.

VENTURA COUNTY MEDICAL CENTER CORRELATIONS

ANTIBODY SCREENS:

1. Obtain four patient samples that have had antibody screens performed on the Ortho Vision automated instrument. Include at least two positive screens and two negative screens.
2. Perform antibody screens on the four samples using the manual MTS IgG gel card method.
3. Perform antibody screens on the four samples using the following tube method:
    a. Ortho Antibody Enhancement Solution.
4. Record all testing results and interpretations on the Correlation of Methods worksheet.

ABO/RH TYPING:

1. Obtain eight (8) patient specimens that have had ABO/Rh typing performed on the Ortho Vision. Choose one to represent each of the following blood groups:
    a. O Negative
    b. O Positive
    c. A Positive
    d. A Negative
    e. B Positive
    f. B Negative
    g. AB Positive
    h. AB Negative
2. Perform ABO/Rh typing by tube method on the eight specimens.
3. Record all testing results and interpretations on the Correlation of Methods worksheet.

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ABO/RH UNIT CONFIRMATION:

1. Obtain eight (8) red blood cell unit segments from the stock inventory. Choose one to represent each of the following blood groups:
    a. O Negative
    b. O Positive
    c. A Positive
    d. A Negative
    e. B Positive
    f. B Negative

g. AB Positive

h. AB Negative

2. Perform an ABO/Rh type for each segment on the Ortho Vision using the MTS A/B/D Grouping Card.
3. Perform an ABO/Rh type for each segment using the tube method.
4. Record all testing results and interpretations on the Correlation of Methods worksheet.

ANTIBODY IDENTIFICATION

5. Obtain one patient that had an antibody identification performed using the MTS IgG gel card methodology.
6. Perform an antibody identification using 3% Panel A using a tube method with Ortho Antibody Enhancement Solution.
7. Record all testing results and interpretations on the Correlation of Methods worksheet.

CALIBRATION:

N/A

CALCULATIONS:

N/A

COPY

QUALITY CONTROL:

See policy *L.BB.96 Quality Control of Blood Bank Reagents*.

RESULTS:

Compare the final interpretations of the antibody screens and observe the differences in grading strengths between the enhancement reagent method and the Ortho MTS IgG gel methods. It is not unexpected to have variation in strengths of reactions because all antibodies will react differently in different enhancement mediums. The gel methodology is generally the most sensitive and may produce the strongest reactions.
Compare the final interpretation of antibody identifications for the different methods performed. The various phases of antibody reactions can be seen with tube methods whereas the gel method only allows for one phase of reaction.

Compare the final interpretations for the patient ABO/Rh types and the ABO/Rh unit confirmation testing performed by gel and by tube. All interpretations should correlate. Tube testing reactions may not be as sensitive as the gel method but should closely correlate in reaction strength.

LIMITATIONS:

1. No single method is optimal for detecting all antibodies.

2. The laboratory that performs antibody detection or identification should have routine methods, as well as access to some alternative approaches. The use of enhancement techniques may be helpful.
3. Each enhancement reagent has specific characteristics that may be beneficial in the identification of some antibodies while being less than helpful in the identification of others. As such they are used to provide additional information in the solution to complex problems.
4. The general stock inventory does not routinely include B Negative, AB Positive, and AB Negative red blood cells. If these blood types are not available for correlation indicate this on the Correlation of Methods worksheet.

REFERENCES:

1. Standards for Blood Banks and Transfusion Services. Bethesda, MD: Association for the Advancement of Blood and Biotherapies (AABB). Current Edition.
2. Cohn, Claudia S. Technical Manual. Bethesda, MD: Association for the Advancement of Blood and Biotherapies (AABB). Current Edition.

COPY

All Revision Dates

1/23/2026, 1/11/2024, 12/1/2016, 11/1/2015

Attachments

- Correlation of Methods for Antibody Screens in the Blood Bank
- ProVue A/B/D Monoclonal Grouping Card™ and Tube Testing with Ortho Reagents

Approval Signatures

Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator, VCMC & SPH	1/23/2026
Laboratory Services Department	Erlinda Roxas: Director, Laboratory Services	1/23/2026
Laboratory Services Department	Linda Lee: Medical Director, VCMC Blood Bank	11/4/2025

Laboratory Services Department	Kathrina Barcena: Supervisor-Blood Bank, Laboratory Services	11/4/2025

COPY

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Effective	2/9/2026
Last Revised	2/9/2026
Next Review	2/9/2028
Owner	Kathrina Barcena: Supervisor-Blood Bank, Laboratory Services
Policy Area	Laboratory Services - Blood Bank

L.BB.91 MTS™ Diluent Quality Control

COPY

POLICY:

Quality control of MTS™ Diluent 2 is performed each day of use.

PRINCIPLE:

An IgG antiglobulin crossmatch must be performed on any patient that has a clinically significant unexpected antibody in the plasma or a previously identified clinically significant antibody. The IgG antiglobulin crossmatch can be performed using the MTS™ anti-IgG gel card system. MTS™ Diluent 2 is used to prepare a 0.8% red cell suspension of antigen negative donor washed red blood cells. Proper controls are essential in the performance of all laboratory procedures. Daily quality control should consist of known positive and negative red blood cells diluted with each lot of MTS™ Diluent 2 and tested with the ID-Micro Typing System™ test being used.

SPECIMEN COLLECTION:

1. Donor blood collected in CPDA-1 or CPD may be used in the preparation of red blood cell suspensions up to the expiration date of the unit.
2. Fresh red blood cells are preferred for testing and may be collected as clotted samples or in anticoagulants such as CPDA-1, CPD, ACD or EDTA.
3. EDTA K2 pink top blood bank tube. Can be used up to 5 days after collection.

REAGENTS/Materials:

1. MTS™ Diluent 2
2. A segment from a donor unit of blood which is negative for the antigen(s) corresponding to the

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patient's antibody(s).

3. Ortho Confidence Antibody Reagent.
4. MTS™ Anti-IgG gel cards.
5. MTS™ Diluent Quality Control Form

PROCEDURE:

1. **Preparation of cell suspensions**
    a. Screen donor units to find ones negative for the relevant antigen(s). [Blood Bank Procedure 2.5].
    b. Obtain new segments from two donor units, which are negative for the relevant antigen(s).
    c. Using a Hemotype Segment Device, express the cells from the unit segment into a test tube labeled with the last three digits of the unit identification number.
    d. Fill the tubes with saline, mix well, and centrifuge.
    e. Remove all the saline from each tube with a pipette.
    f. Label test tubes with the last three digits of each unit's identification number and the letters MTS.
    g. Place 1.0 mL of MTS™ Diluent 2 into each of the tubes labeled in (F).
    h. Add 10 µL of the cells prepared in (E) to the corresponding tubes prepared in (G) and mix well. These are the cell suspensions, which will be used for the crossmatches and the MTS™ Diluent 2 quality control.
2. **Crossmatch and Quality Control**
    a. Label the MTS™ anti-IgG gel card microtubes with the last three digits of each unit's identification number.
    b. Label an additional microtubule with the last three digits of **one** of the unit identification numbers and the letters PC (Positive Control).
    c. Add 50 µL of the cell suspension prepared in (h) to the appropriate microtubule.
    d. Add 25 µL of patient plasma to the microtubes labeled with the last three digits of the unit identification numbers.
    e. Add 25 µL of Ortho Confidence Antibody to the microtubes labeled with the last three digits of a unit identification number and the letters P.C.
    f. Incubate the MTS™ gel card for fifteen (15) minutes at 37°C ± 2°C.
    g. Centrifuge the MTS™ anti-IgG gel card.
    h. Read and record results.

CALIBRATION:

NA

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CALCULATIONS:

NA

QUALITY CONTROL:

1. Negative Control - Red Blood Cell units negative for the antigen corresponding to the patient's antibody.
2. Positive Control - Test the same donor unit, as in #1 above, with Ortho Confidence Antibody.

RESULTS

1. The crossmatches should be compatible.
2. The microtubule labeled with the last three digits of the unit identification number and the letter P.C. should be positive.
3. If the expected results do not occur, consult a supervisor.
4. **Recording results on the Daily Q.C. sheet**
    a. Date- line through if the MTS Q.C. is not done that day.
    b. Record the unit number of the unit used for the Positive Control.
    c. Record the antigen(s) which the units were negative for.
    d. Record the patient chart number whose serum was used for the MTS Diluent Negative Control testing.
    e. Positive Control - Record the results of the microtubule labels with the last three digits of the unit identification number and the letters P.C.
    f. Negative Control – Record the results of the microtubule of crossmatch done on the unit used for the Positive Control, done in (E) above.
    g. Visual Inspection – Perform a visual inspection of the MTS Diluent for discoloration, turbidity or any other signs of bacterial contamination. Record the acceptability of the MTS Diluent visual inspection by noting OK on the Quality Control sheet.

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LIMITATIONS:

1. For best results it is recommended that red blood cells be used on the day of dilution. When diluted red blood cells are not being used they should be stored at 2-8°C.
2. Variations in red blood cell concentration can markedly affect the sensitivity of test results. If red blood cell suspensions are too concentrated, they can give weaker results due to the increase in the antigen/antibody ratio. In addition, red blood cells may fail to completely migrate to the bottom of the microtube and could cause a false positive interpretation. When red blood cells are too low in concentration, they become difficult to visualize, and, in extreme cases, a weak positive can fail to be detected.
3. False positive or false negative test results can occur from bacterial or chemical contamination of test materials, inadequate incubation time or temperature, improper

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centrifugation, improper storage of materials, or omission of test samples.

4. Anomalous results may be caused by fibrin or particulate matter in serum or plasma, or red blood cells that stick to the sides of the microtube.
5. False-positive results may occur if a gel card that shows signs of drying is used in the ID-Micro Typing System™ test.

REFERENCES:

Transfusion Medicine MTS Diluent 2 - Red Blood Cell Diluent IFU No. J32936 - V 2.0.

All Revision Dates

2/9/2026, 12/1/2016, 12/1/2011

Attachments

MTS™ Diluent 2 Quality Control

COPY

Approval Signatures

Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator, VCMC & SPH	2/9/2026
Laboratory Services Department	Erlinda Roxas: Director, Laboratory Services	2/7/2026
Laboratory Services Department	Kathrina Barcena: Supervisor-Blood Bank, Laboratory Services	2/5/2026
Laboratory Services Department	Linda Lee: Medical Director, VCMC Blood Bank	1/29/2026

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Next Review	2/9/2028
Owner	Kathrina Barcena: Supervisor-Blood Bank, Laboratory Services
Policy Area	Laboratory Services - Blood Bank

L.BB.92 Red Cell Antigen Typing

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PRINCIPLE:

Whenever possible, red blood cell units selected for transfusion to a patient with potentially clinically significant antibodies should be tested and found negative for the corresponding antigen(s). Even if the antibody is no longer detectable, all subsequent red blood cell transfusions to that patient should lack the antigen in order to prevent a secondary immune response.

Antigens other than ABO and D are not routinely considered in the selection of units of blood for non-alloimmunized patients. However, in certain medical conditions, such as sickle-cell disease, phenotypically matched RBCs for transfusion may be selected to prevent alloimmunization in this frequently transfused population.

Patient red cell antigen typing is performed as part of an antibody identification workup or when ordered by a physician.

SPECIMEN COLLECTION:

1. EDTA K2 pink top blood bank tube (7 mL).
2. Donor red blood cells for transfusion: 3%-5% suspensions in saline.

REAGENTS, MATERIALS AND EQUIPMENT:

1. 3% Panel A red cells.
2. 12x75 mm glass tubes.
3. Physiological Saline.
4. Valid reagent antiserum of the same specificity as the patient's alloantibody.
5. Anti-IgG, as required in the "Instructions for Use" for the reagent antiserum.

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6. Coombs Control Cells as required.
7. Special Reagent Testing Form.

PROCEDURE:

1. Refer to the manufacturer's "***Instructions for Use***" for each antiserum. The manufacturer's procedures can vary.
2. Record the name of the reagent, manufacturer, lot number, expiration date, and technologist's initials on the blood bank ***Special Reagent Testing Log*** form located in the Daily Quality Control Binder.
3. Using the Antigram® Antigen Profile for the current lot of 3% Panel A cells, choose the appropriate positive and negative control cells to use. Record the lot number, expiration date, and cell number on the Blood Bank ***Special Reagent Testing Log***.
4. Prepare a 3-5% cell suspension of washed patient/donor red cells in buffered saline.
5. For each antisera, label the test tubes as follows:
    a. Label the tube for the positive control with the antigen and PC.
    b. Label the tube for the negative control with the antigen and NC.
    c. Label the patient tube with the last three letters of the patient's last name and the antigen.
    d. Label the donor tube with one of the donor number stickers from the back of the unit.
6. Follow each manufacturer's "***Instructions for Use"*** for the performance of testing.
7. Read and record all results concurrently with testing on the ***Special Reagent Testing Log***.
8. In Department Order Entry, order the test "Antigen Typing" to the current patient specimen using the accession number of the specimen. Enter antigen typing testing results and interpretations for the patient in the Laboratory Information System.
9. Enter all antigen typing interpretations for each donor red cell in the Laboratory Information System.

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CALIBRATION:

N/A

CALCULATIONS:

N/A

QUALITY CONTROL:

Choose control cells from the 3% Panel A red cells. Use the appropriate Antigram® Antigen Profile from the current lot to choose the control cells required.

1. A positive and negative control must be run for each antisera used (once per 24 hours).
2. **Positive Control -** Choose a ***heterozygous cell*** for the positive control.
3. **Negative Control –** Choose any antigen negative cell for the negative control.

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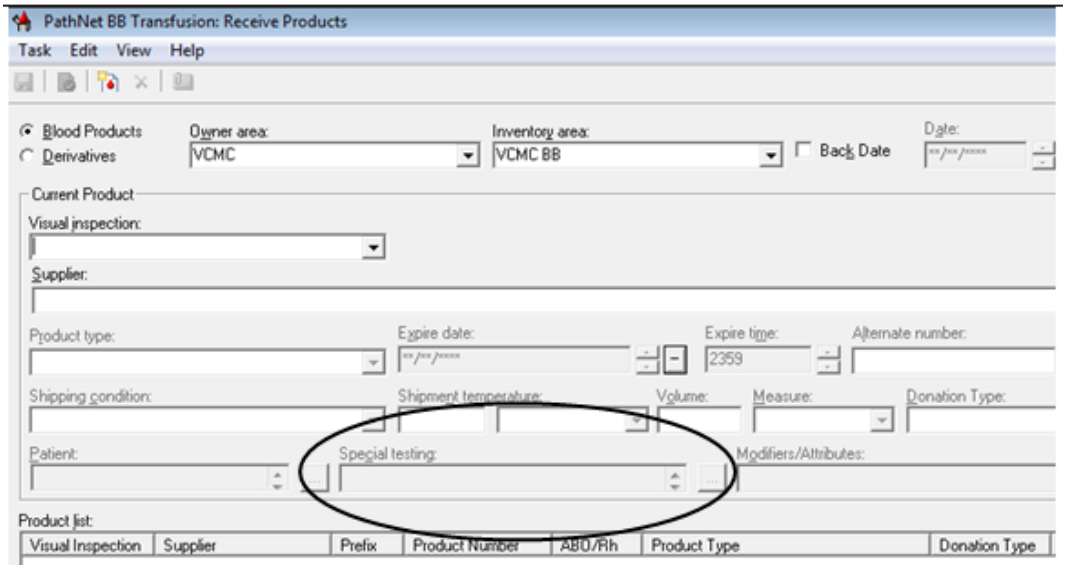
RESULTS:

1. Positive Control – The positive control should be positive.
2. Negative Control – The negative control should be negative.

PROCEDURE NOTES:

1. If there is an adequate quantity of the patient's serum/plasma, it may be used to screen for antigen-negative units. Then, the absence of the antigen in compatible units can be confirmed with commercial reagents.
2. If the patient has previously been typed for an antigen, retyping is not necessary.
3. The cells used to screen and crossmatch a unit of blood must be obtained from separate donor unit segments.
4. Red cells must be confirmed with an FDA-licensed reagent, when available.
5. Antigen negative units can be ordered for patients through the blood supplier. Complete the "Special Order" form and fax to the laboratory in San Luis Obispo.
    a. **Presumptive antigen negative units**: These units have not been confirmed to be negative for the antigen requested but are provided based on a computer search of donor historical records. Presumptive antigen negative units require in-house antigen testing for the appropriate antigen with in-dated reagent antisera.
    b. **Confirmed antigen negative units**: These units have been antigen tested and confirmed to be negative for the ordered antigen requested. The red blood cell units will be labeled by the blood supplier indicating the unit is negative for the requested antigen. In-house confirmation is not required when orders are placed for "confirmed" antigen negative units.
    c. Requested antigen negative units, that have been confirmed and tagged by the blood supplier, should be entered into the computer in the received products application. When in this application, enter the antigen testing in "special testing".



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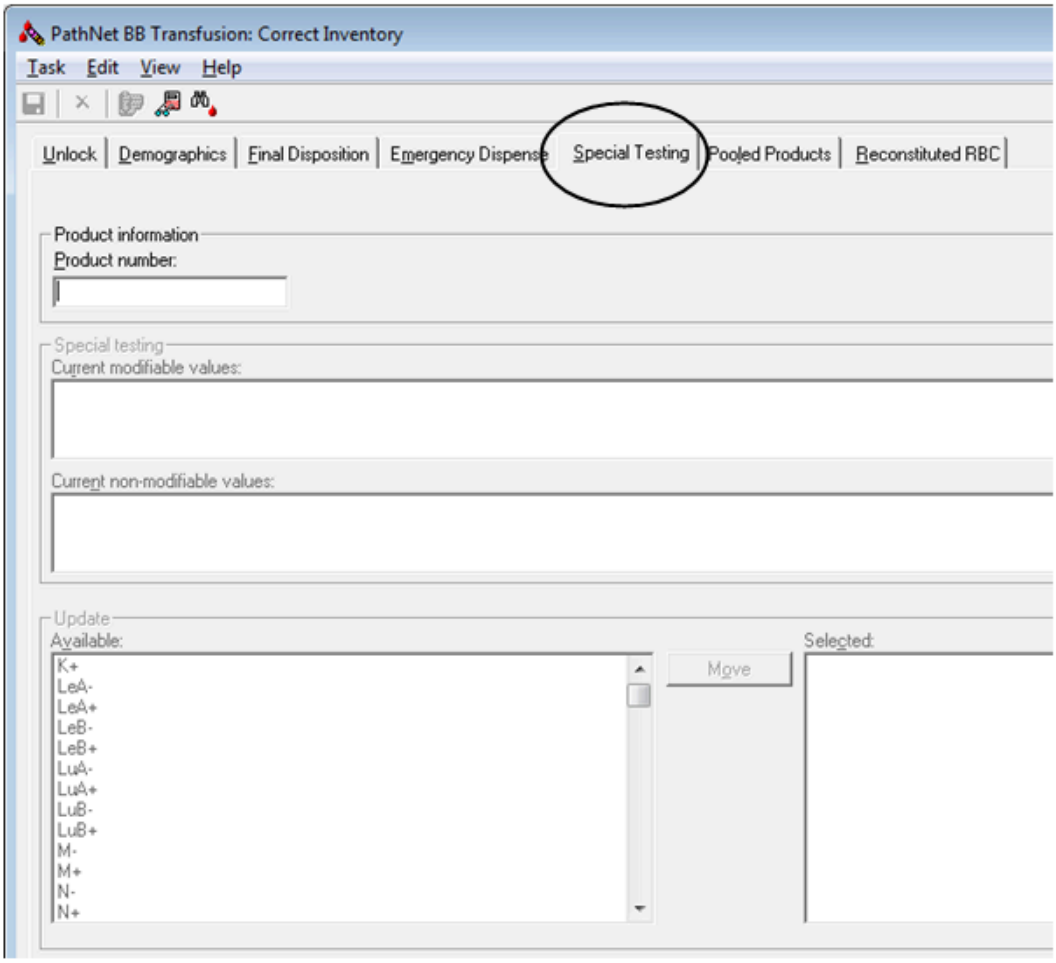
Special testing can also be entered through the correct inventory application.



6. Rare reagents may be used beyond their expiration date if appropriate positive and negative controls are run each day of use and react as expected. The FDA permits this exception. A rare reagent would be considered any FDA-licensed reagent antisera unavailable from a manufacturer. (NOTE: This does NOT apply to reagents that are readily available.)

REFERENCES:

1. *Standards for Blood Banks and Transfusion Services*. Bethesda, MD: Association for the Advancement of Blood and Biotherapies (AABB), current edition.
2. Cohn, Claudia S., MD, PhD. *Technical Manual*. Bethesda, MD: Association for the Advancement of Blood and Biotherapies (AABB), current edition.

All Revision Dates

2/9/2026, 4/13/2021, 12/1/2016, 10/1/2015, 6/1/2015, 12/1/2011

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Attachments

BLOOD BANK SPECIAL REAGENT TESTING LOG

BS_129S_R11.pdf

Approval Signatures

Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator, VCMC & SPH	2/9/2026
Laboratory Services Department	Erlinda Roxas: Director, Laboratory Services	2/7/2026
Laboratory Services Department	Kathrina Barcena: Supervisor-Blood Bank, Laboratory Services	2/5/2026
Laboratory Services Department	Linda Lee: Medical Director, VCMC Blood Bank	1/29/2026

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Status **Active** PolicyStat ID **19747206**

Origination	9/28/2016
Last Approved	2/6/2026
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Last Revised	2/6/2026
Next Review	2/6/2028
Owner	Kathrina Barcena: Supervisor-Blood Bank, Laboratory Services
Policy Area	Laboratory Services - Blood Bank

L.BB.94 In-Vivo Crossmatch

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PRINCIPLE:

Occasionally, transfusion of RBCs may be necessary when no serologically compatible units are available for a patient. This most often occurs in patients with autoantibodies that typically are reactive with red cells from all donors; however, as long as the presence of alloantibodies can be ruled out, the transfused cells should survive as long as autologous cells.

Other situations in which all units appear to be incompatible include the presence of alloantibodies to high-frequency antigens and/or multiple antibody specificities. If serologic testing fails to resolve the problem or the problem is identified but sufficient time is not available to acquire compatible units, consultation between the transfusion service physician and the patient's clinician is required to weigh the risks and benefits of transfusion and to consider which alternative therapies are suitable. If the need is sufficiently urgent, ABO-compatible but crossmatch-incompatible RBCs may need to be used.

Depending on the alloantibody specificity or possible specificities that have not been ruled out, incompatible RBC transfusion does not always result in immediate hemolysis, and the incompatible cells may remain in the circulation long enough to provide therapeutic benefit.

POLICY:

When a warm autoantibody has been identified and alloantibodies are identified or ruled out, incompatible units of blood may need to be transfused. Transfusion should take place in a carefully monitored situation, looking for hemolysis in a sample drawn after transfusing the initial 25-50 mL of blood to evaluate for apparent compatibility.

A "Deviation from Standard Operating Procedure" form must be completed and signed by the pathologist after consultation with the clinician.

SPECIMEN COLLECTION:

1. No special preparation of the patient is required prior to specimen collection.
2. EDTA whole blood
3. Store at 2 to 8°C.

MATERIALS AND SPECIAL EQUIPMENT:

1. Centrifuge
2. Form - "Deviation from Standard Operating Procedures"
3. Manila tags

PROCEDURE:

Obtain consent from the Pathologist and the patient's physician before proceeding with the transfusion. Document this in the Laboratory Information System when resulting the compatibility testing. When the unit of blood is issued, the crossmatch tag will generally read "Least Incompatible." Attach a manila tag to the unit indicating: IN-VIVO CROSSMATCH. Be sure the nursing staff providing care for the patient is aware of the need for an in-vivo crossmatch.

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"In-Vivo Crossmatched" Blood Transfusion

1. An "In-vivo crossmatch" procedure will be initiated by the Blood Bank.
2. The blood transfusion procedure for obtaining the unit and completing the verification process will be followed.
3. Administering "in-vivo crossmatched" blood:
    a. Cautiously transfuse 25-50 mL of red blood cells over 20-30 minutes.
    b. The nurse must remain with the patient monitoring for symptoms of transfusion reaction.
    c. Vital signs should be taken every 5 minutes for the duration of the initial (50 mL) transfusion.
    d. If a transfusion reaction occurs, stop the transfusion and follow the Blood Transfusion Reaction procedure.
    e. If no adverse symptoms, stop the blood after completion of the first 50 mL: infuse the Normal Saline and notify the Blood Bank of the completion time.
    f. The Blood Bank will draw a 30 minute post transfusion specimen (see procedure note #1). The sample will be spun and evaluated for hemolysis. If there is no adverse reaction or hemolysis, the Blood Bank will notify the nurse to transfuse the remainder of the unit.
    g. The remaining transfusion will be administered slowly and with careful clinical monitoring. Vital signs will be taken after 15 minutes of restart. The total unit of blood must be administered within four (4) hours of initial start time.

When the sample is received in the Blood Bank, it is spun and the plasma compared with the pre-transfusion sample. If hemolysis is noted, notify the Pathologist at once and proceed with a Transfusion Reaction workup. Notify the nurse taking care of the patient and discontinue the transfusion. If no hemolysis is noted, notify the nurse to continue the transfusion.

PROCEDURE NOTES:

1. An "***In-Vivo Crossmatch Hemolysis Check***" order will be placed in Department Order Entry by the Blood Bank, a label printed, and a phlebotomist dispatched STAT to collect the required sample.
2. Determination of the patient's phenotype before transfusion simplifies subsequent investigations of the presence of alloantibodies.
    a. Perform a computer search for any previously performed phenotype of the patient's red cells.
3. Prior to performing any phenotype of a patient's red blood cells, request a transfusion history from the provider as well as performing a computer search for VCMC/SPH history. If the patient has been transfused within the last three (3) months, a sample can be submitted to the reference laboratory for phenotype/genotype testing.

REFERENCE:

Fung, Mark K. Technical Manual. Bethesda, MD: American Association of Blood Banks, 2014. 18th Edition.

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All Revision Dates

2/6/2026, 9/28/2016

Attachments

A: “In-Vivo Crossmatched” Blood Transfusion

Approval Signatures

Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator, VCMC & SPH	2/6/2026

Laboratory Services Department	Kathrina Barcena: Supervisor-Blood Bank, Laboratory Services	2/5/2026
Laboratory Services Department	Erlinda Roxas: Director, Laboratory Services	1/23/2026
Laboratory Services Department	Linda Lee: Medical Director, VCMC Blood Bank	1/23/2026

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Status **Active** PolicyStat ID **19747210**

Origination	2/1/2013
Last Approved	2/6/2026
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Owner	Kathrina Barcena: Supervisor-Blood Bank, Laboratory Services
Policy Area	Laboratory Services - Blood Bank

L.BB.95 FMH Rapid Screen

COPY

PRINCIPLE:

(Rh)D immunization in pregnancy most commonly results from the fact that, at delivery, a variable amount of fetal blood enters the maternal circulation when the placenta separates from the uterine wall. D-negative mothers delivering D-positive infants can be protected from forming anti-D antibodies through the administration of Rh Immune Globulin (RhIG) within 72 hours of delivery. One dose of RhIG will suppress (Rh)D immunization provided that no more than 15 mL of fetal red blood cells (equivalent to 30 mL of whole blood) have entered the maternal circulation. Massive fetomaternal hemorrhage may be one cause for the failure of prophylaxis. Therefore, a test to detect hemorrhage of an amount greater than 15 mL is necessary and is a requirement of AABB standards.

A red blood cell suspension from the D-negative mother is first incubated for **5 minutes at room temperature** with a reagent containing anti-D and then washed to remove all unbound antibody. A weak suspension of D-positive red blood cells is added. The red blood cell mixture is centrifuged and examined microscopically for mixed-field agglutination. Since any minor population of D-positive red blood cells will have become coated with anti-D during the incubation phase, the D-positive indicator cells added after washing form rosettes around the individual cells of the minor population, leading to larger and readily detected agglutinates. In most cases, the fetomaternal hemorrhage is not sufficient to cause a positive test; but in the cases where a significant volume of fetal blood has entered the maternal circulation, the test provides an indication that a quantitative test is required to determine whether the bleed was sufficient to warrant a larger dose of RhIG to the mother.

This test should be performed on all post-partum RhIG candidates. This group consists of all D-negative mothers with no pre-existing active anti-D antibodies who have delivered an D-positive child.

This test will be reflex ordered by the computer whenever RhIG is requested. Rare cases will occur when this test is not needed (e.g. giving RhIG to women of child bearing age who receive an D-positive

apheresis platelets). The test will be resulted as N.D. (not done) in these cases and a comment will be made explaining why the test was not done.

SPECIMEN COLLECTION:

1. **POST PARTUM** blood drawn from the mother. It is best to wait about an hour after delivery but as soon as possible thereafter.
2. EDTA whole blood specimen.
3. Store at 1-10 degrees and test within 2 days of collection.

REAGENTS:

1. Immucor Gamma FMH Rapid Screen Kit:
    a. Anti-D Reagent: Contains monoclonal IgM anti-D antibodies.
    b. Indicator Cells – An approximate 0.5% suspension of group O red blood cells obtained from a donor of the DcEe (R_2r) phenotype.
    c. Positive Control – A 2-4% suspension of red blood cells comprising approximately 99.4% of group O D-negative cells and approximately 0.6% group O D-positive cells obtained from a donor having heterozygous expression of the D antigen.
    d. Negative Control – A 2-4% suspension of group O D-Negative red blood cells.

    Precautions:

    - Store at 1° to 10°C when not in use.
    - Do not freeze, dilute, or use beyond the expiration date.
    - Marked hemolysis and/or darkening of the cells are indication of product deterioration.
    - Gently re-suspend cell suspensions before using.
    - The Indicator Cells must be well mixed before use.
    - The Anti-D Reagent must not be used to type red blood cells for the D antigen.

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ADDITIONAL MATERIALS REQUIRED:

1. Test tubes – 12 x 75 mm.
2. Transfer pipettes.
3. 0.9% buffered saline.
4. 37degree incubator.
5. Centrifuge.
6. Microscope.

PROCEDURE:

1. Make a 2-4% suspension of the well-mixed maternal red blood cells to be tested in isotonic saline.
2. Label 12 x 75 mm test tubes:
    a. POS – positive control
    b. NEG – negative control
    c. Patient – Label a tube with the last two (2) letters of the patient's last name.
3. Add one drop of the Anti-D reagent to each tube.
4. Place one (1) drop of the prepared maternal red blood cell suspension in the appropriately labeled test tube. Add one (1) drop of the positive and negative control cells to the appropriately labeled test tubes.
5. Mix well and incubate for 5 minutes (± 1 minute) at room temperature (18C to 30°C).
6. Wash the red blood cells four times with the tubes filled with saline, being careful to decant the saline completely between washes, and to re-suspend the red blood cells thoroughly when adding saline for the next wash.
7. Decant the saline completely after the last wash.
8. Add one (1) drop of Indicator Cells to each tube and mix well by gently shaking the tube.
9. Centrifuge immediately for 15 seconds at 3400 rpm.
10. Re-suspend the red blood cell button completely and examine five (5) low-power fields microscopically for mixed-field agglutination using approximately 100 x magnifications.

    Note: Microscopic examination can be carried out either in the tube or on a microscope slide. If agglutinates are seen in the tube, the contents should be transferred to a microscope slide so that the number of agglutinates per low-power field can be evaluated.
11. Test and control results should be interpreted immediately upon completion of the test.

CALIBRATION:

N/A

CALCULATIONS:

N/A

QUALITY CONTROL:

1. Positive and Negative Control Cells, supplied with the FMH Rapid Screen Test Kit, will be run in parallel with each test or batch of tests.
2. The test must be repeated if the control cells do not react as expected

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RESULTS:

1. **Positive** – After examining five low-power fields, if five or more agglutinates of red blood cells are observed, the test is positive and indicates the presence of D-positive fetal red blood cells in possibly significant numbers in the maternal blood.
2. **Negative** – After examining five low-power fields, if four or fewer agglutinates of red blood cells are observed, the test is negative, indicating that a large fetomaternal hemorrhage did not occur.
3. **Invalid** – If the infant's red blood cells possess a weak D antigen or partial D antigen, enter "Invalid" in the result field and perform a Fetal Cell Stain for quantitation of fetal cells.
4. **Positive FMH rapid screen test** - the following tests should be reflexed and performed:
    a. Weak D testing will be performed on positive FMH rapid screens from postpartum specimens. Maternal weak D types that are reactive only in the indirect antiglobulin test phase can result in a false-positive rosette test.
    b. A Fetal Cell Stain must be run in order to quantitate the amount of fetal cells present and the number of doses of RhIG to provide protection from immunization against the (Rh)D antigen.

PROCEDURE NOTES:

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1. For correct interpretation of the test results, the test must be performed on the blood of a known D-negative mother of a recently delivered D-positive child. If the infant's red blood cells possess a weak D antigen or partial D antigen, the test may not detect a fetomaternal hemorrhage exceeding 30 mL of whole blood. When the D antigen on the infant's red blood cells requires a weak D test for detection, a test to detect fetomaternal hemorrhage based on fetal hemoglobin is recommended. If the mother is D-positive, including weak D, strong agglutination provides no information about the extent of fetomaternal hemorrhage. If the infant is D-negative, a negative test result can be expected to occur, regardless of the volume of fetomaternal hemorrhage.
2. In cases of ABO incompatibility between mother and child, the mother's natural ABO antibodies may destroy any fetal cells in the maternal blood specimen before testing is performed. This is true for any method of detecting fetal cells in the maternal blood.
3. Failure to carry out the washing stages of the test procedure properly may give rise to a false-positive test result due to agglutination of the indicator cells by free anti-D remaining in the test system.
4. A false-positive test result may occur if the maternal red blood cells have a positive direct antiglobulin test due to an autoantibody capable of reacting with the indicator cells.
5. A positive test result does not of itself provide evidence that an increased dose of RhIG is required to protect the mother from producing anti-D, but merely indicates that a larger-than-normal fetomaternal hemorrhage may have occurred. A quantitative procedure is required to determine the volume of fetomaternal hemorrhage.
6. The reactivity of red blood cells may tend to diminish over the dating period.
7. Do not use grossly hemolyzed specimens for testing.

REFERENCES:

1. Immucor, Inc., Norcross, GA 30071 USA. FMH RAPIDSCREEN- For the Detection of D-Positive Red Cells in D-Negative Mothers. Current Package Insert.
2. Standards for Blood Banks and Transfusion Services. Bethesda, MD: American Association of Blood Banks, 2015. 30th Edition
3. Fung, Mark K MD, PhD. Technical Manual. Bethesda, MD: American Association of Blood Banks, 2014. 18th Edition.

All Revision Dates

2/6/2026, 12/1/2016, 12/1/2015

Attachments

A: Additional Information for the FMH Rapid Screen

COPY

Approval Signatures

Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator, VCMC & SPH	2/6/2026
Laboratory Services Department	Kathrina Barcena: Supervisor-Blood Bank, Laboratory Services	2/5/2026
Laboratory Services Department	Erlinda Roxas: Director, Laboratory Services	1/23/2026
Laboratory Services Department	Linda Lee: Medical Director, VCMC Blood Bank	1/23/2026

Status **Active** PolicyStat ID **19191826**

Origination	11/1/1997
Last Approved	1/26/2026
Effective	1/26/2026
Last Revised	1/26/2026
Next Review	1/26/2028
Owner	Kathrina Barcena: Supervisor-Blood Bank, Laboratory Services
Policy Area	Laboratory Services - Blood Bank

L.BB.96 Quality Control of Blood Bank Reagents

COPY

POLICY:

The purpose of daily quality assurance in the Blood Bank is to confirm the reliability of the test system. The test system includes reagents, test procedures, and equipment. Testing known samples is an accepted method of quality control. If expected test results are observed, procedures are being performed accurately and reagents and equipment are performing properly. The Laboratory must perform this quality control on each day of use. The Ventura County Medical Center daily quality control program utilizes the ORTHO Diagnostics Confidence System.

PROCEDURE:

The procedures used with these reagents are based on the principle of agglutination. The antibody and cell samples provided in the ORTHO Confidence System will confirm the reactivity of the reagents used for ABO and Rh determinations, the MTS Anti-IgG Card, the anti-IgG component of AHG, as well as reverse grouping cells and reagent red blood cells used in antibody detection tests. For the ORTHO Vision Blood Bank analyzer quality control information, see the ORTHO Vision procedure manual.

REAGENTS:

1. Ortho Confidence System, containing:
    - Cell I – A1B rr (ce/ce) human red blood cells, pooled, 3%.
        - Provides the positive control for ABO Blood Grouping Reagents and a negative control for Anti-D.
    - Cell II – O R1r (Dce/ce) human red blood cells, pooled, 3%.
        - Provides the positive control for Anti-D
    - Confidence Antibody- Anti-A, Anti-B, Anti-D and Anit-c that react when tested by the

indirect anti-globulin technique.

- Store at 2-8°C. Allow to come to room temperature before using.

2. Anti-A, Anti-B, Anti-A,B, Anti-D, Rh Control, A1 Cells, and B Cells. Stored at 2-8°C and allowed to come to room temperature before using.
3. MTS Anti-IgG Card, Anti-IgG (rabbit) suspended in gel. Store at 18-25°C.
4. Antibody Screening cells comprised of three vials of human red blood cells as: 0.8%, ready for use in MTS Anti-IgG Gel testing; and 3% to perform tube method antibody screen tests, or to be modified to 0.8% in-house for use in MTS Anti-IgG testing. Store at 2-8°C. Allow reagents to come to room temperature before using.
5. Plasma from an O positive patient with a negative antibody screen using the MTS Gel card. Store at 2-8°C. Use for 7 days.
6. Ortho 7% BSA – an aqueous solution of bovine serum, inorganic salts, and preservatives. Storage and Stability

Reagent	Storage Condition	Stability
Unopened	Frozen ≤ 18 °C	Until expiration date
	Refrigerated 2-8 ° C	Until expiration date
Opened	Refrigerated 2-8 ° C	≤ 28 days if tightly stoppered

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EQUIPMENT AND MATERIALS

1. Laboratory Information System (LIS)
2. Daily Quality Control Form BB 8.2 (Computer Down Form)
3. 12x75mm glass tubes.
4. MTS Incubator/Centrifuge

PROCEDURE

Visual Inspection of reagents:

- Before mixing the reagent vials, inspect the red cells for hemolysis or contamination. If hemolysis is moderate, use a new set of cells and note the action taken in the comment section of Quality Control Result Entry (see Appendix A). If any other reagent appears cloudy, has particulate matter or is possibly contaminated, discard and note action taken.
- Document the performance and acceptance of reagent visual inspection by indicating "Satisfactory" in the visual inspection column in the Health-e-Connect System or placing a (√) under the appropriate day on the Daily Quality Control Form used when the computer is down.

Tube Quality Control (see Blood Bank QC Matrix)

1. Label 13 12x75 mm test tubes 1 through 13.
2. Add 1 drop of Anti-A to tubes 1 and 9.
3. Add 1 drop of Anti-B to tubes 2 and 10.
4. Add 1 drop of Anti-A,B to tubes 3 and 11.

5. Add 1 drop of Anti-D to tubes 4 and 5.
6. Add 2 drops of Ortho Confidence antibody reagent to tubes 6 and 7.
7. Add 1 drop of Rh Control to tube 8.
8. Add 2 drop of 7% BSA to tubes 12 and 13.
9. Add 1 drop of Confidence Cell 1 to tubes 1, 2, 3, and 4.
10. Add 1 drop of Confidence Cell 2 to tubes 5, 8, 9, 10, and 11.
11. Add 1 drop of A1 Cells to tube 6 and 12.
12. Add 1 drop of B Cells to tube 7 and 13.
13. Mix tubes gently and centrifuge for the calibrated time in the Blood Bank serofuge.
14. Examine for hemolysis and then gently re-suspend the cell button. Using the agglutination viewer, examine for macroscopic agglutination.
15. Grade the reactions and record the results.
16. Incubate tube 4 for 15 minutes at 37 degrees.
17. At the end of the incubation time, spin tube 4 for 15 seconds. Examine the tube for hemolysis and gently re-suspend while examining for agglutination. Record the results.
18. Wash tube 4 four times. Add two drops of IgG to the tube and spin for 15 seconds.
19. Examine tube for hemolysis and gently re-suspend while examining for agglutination. Record the results.
20. Add one drop of Coombs Control cells to tube 4 and spin for 15 seconds. Gently re-suspend while examining for agglutination. Record the results prior to disposing of the tubes.

Manual MTS IgG Gel Card QC (see Blood Bank QC Matrix)

21. Label the first 3 columns of an MTS Gel Card 1, 2, 3. Label columns 4-6 with 01, 02, and 03.
22. Add 50 µl of the appropriate 0.8% Screening Cell to the MTS Gel Card columns marked 1, 2, and 3.
23. Add 50 µl of the appropriate 0.8% Screening Cell to the MTS Gel Card column marked 01, 02, and 03.
24. Add 25 µl of the Confidence Antibody Reagent to the MTS Gel Card the columns marked 1, 2, and 3.
25. Add 25 µl of the negative patient control to the MTS Gel Card column position marked 01, 02, and 03.
26. Incubate MTS gel card for 15 minutes.
27. Centrifuge for 10 minutes.
28. Read and record results.

CALIBRATION:

See Laboratory Blood Bank policy L.BB.97, *Verification of Functional Calibration of Serologic Centrifuges,* for calibration of serological centrifuges.

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CALCULATIONS:

N/A

EXPECTED RESULTS:

Reagent	Control	Phase	Expected Result
Anti-A	Confidence Cell 1	IS	2+, 3+, 4+
Anti-B	Confidence Cell 1	IS	2+, 3+, 4+
Anti-A,B	Confidence Cell 1	IS	2+, 3+, 4+
Anti-D	Confidence Cell 1	IS	0
Anti-D	Confidence Cell 1	37	0
Anti-D	Confidence Cell 1	AHG	0
Anti-D	Confidence Cell 1	CC	1+, 2+, 3+, 4+
Anti-D	Confidence Cell 2	IS	1+, 2+, 3+, 4+
A1 Cells	Confidence Antibody	IS	2+, 3+, 4+
B Cells	Confidence Antibody	IS	2+, 3+, 4+
D Con (Rh Control)	Confidence Cell 2	IS	0
Anti-A Neg Ctr	Confidence Cell 2	IS	0
Anti-B Neg Ctr	Confidence Cell 2	IS	0
Anti-AB Neg Ctr	Confidence Cell 2	IS	0
SC1	Confidence Antibody	AHG – Gel	1+, 2+, 3+, 4+
SC2	Confidence Antibody	AHG – Gel	1+, 2+, 3+, 4+
SC3	Confidence Antibody	AHG – Gel	1+, 2+, 3+, 4+
SC1 Neg Control	Patient Control	AHG – Gel	0, NT
SC2 Neg Control	Patient Control	AHG – Gel	0, NT
SC3 Neg Control	Patient Control	AHG – Gel	0, NT
A1 Cell Neg Ctr	7% BSA	IS	0
B Cell Neg Ctr	7% BSA	IS	0

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PROCEDURE NOTES:

1. Quality Control results are entered concurrently with performance in the Health-e-Connect system. Follow procedure as outlined in Laboratory Blood Bank policy *Quality Control Scheduling and Result Entry*.
2. Manual bench quality control reagent racks are chosen in the Blood Bank Subsection indicated as VCMC Blood Bank/SPH Blood Bank.
3. ORTHO Vision automated quality control reagent racks are chosen in the Blood Bank Subsection indicated as VCMC Vision.

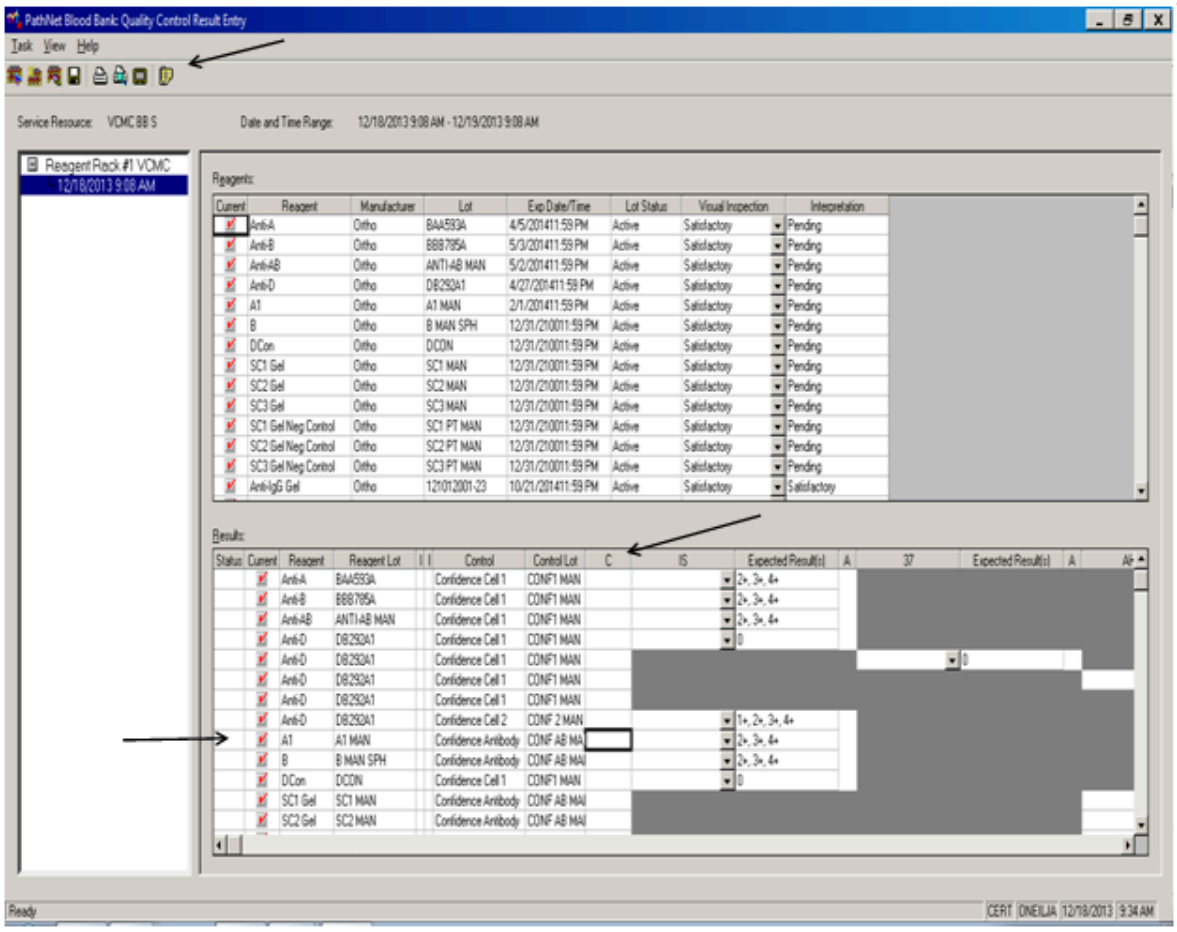
4. Appendix A gives directions on entering QC comments in the Health-e-Connect system.

REFERENCES:

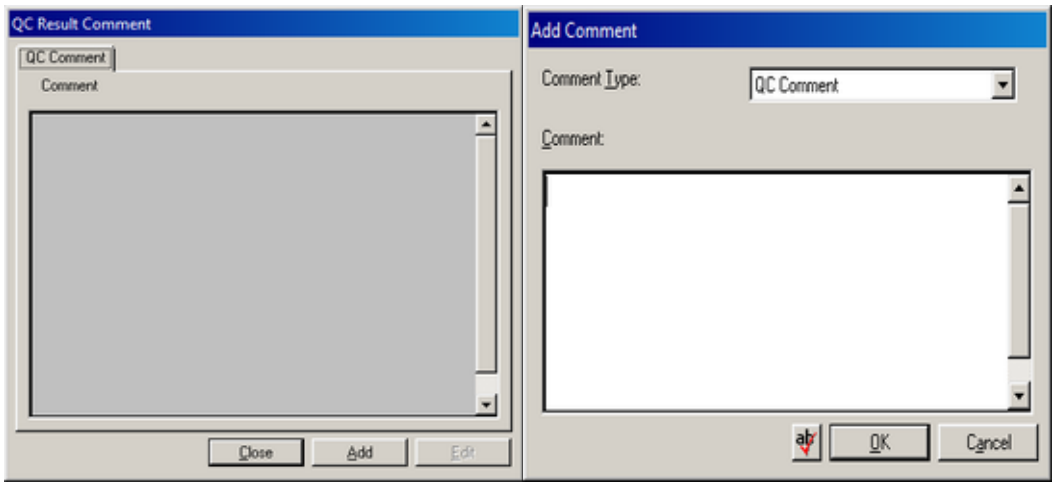
1. Standards for Blood Banks and Transfusion Services. Bethesda, MD: Association for the Advancement of Blood and Biotherapies (AABB), Current Edition.
2. Cohn, Claudia S. Technical Manual. Bethesda, MD: Association for the Advancement of Blood and Biotherapies (AABB), Current Edition.
3. Current Manufacturer's package inserts.

APPENDIX A: Entering a QC Comment

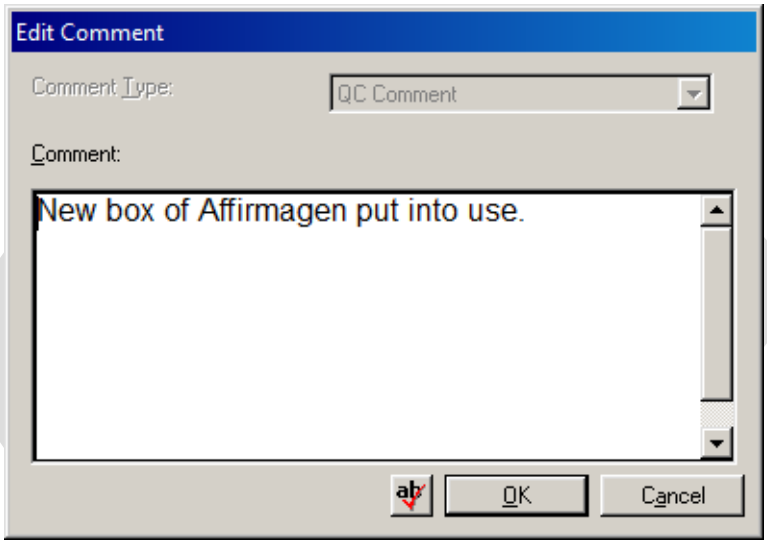
1. In the Results section, select the appropriate Reagent and then move through the row to the "C" column and place the cursor at this box.
2. Click on "Comment" icon.



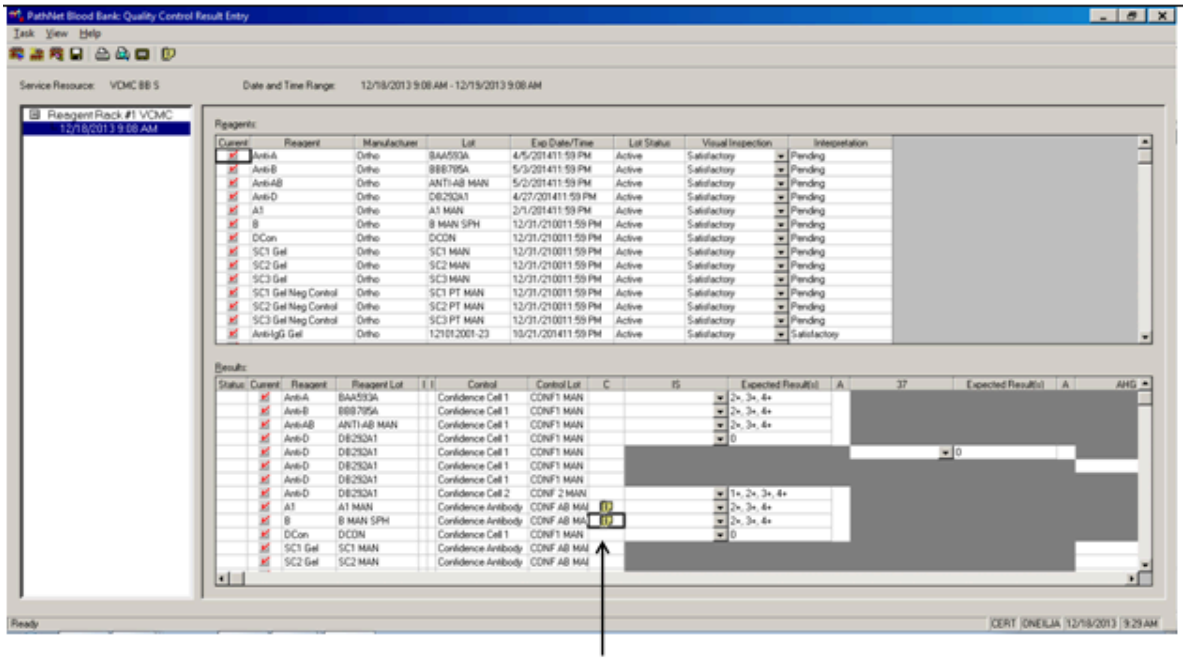
3. Click "Add" to enter a QC Comment.



4. Enter desired QC comment and click <OK>.



5. Comment icon will now appear in "C" column in Results section in the appropriate reagent row.



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All Revision Dates

1/26/2026, 1/18/2024, 2/19/2021, 3/1/2017, 12/1/2016, 11/1/2015, 7/1/2013

Attachments

Blood Bank QC Matrix

Approval Signatures

Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator, VCMC & SPH	1/26/2026
Laboratory Services Department	Erlinda Roxas: Director, Laboratory Services	1/24/2026
Laboratory Services Department	Kathrina Barcena: Supervisor-Blood Bank, Laboratory Services	11/4/2025
Laboratory Services Department	Linda Lee: Medical Director, VCMC Blood Bank	10/29/2025

Status **Active** PolicyStat ID **19747218**

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Last Revised	2/9/2026
Next Review	2/9/2028
Owner	Kathrina Barcena: Supervisor-Blood Bank, Laboratory Services
Policy Area	Laboratory Services - Blood Bank

L.BB.97 Verification of Functional Calibration on Serological Centrifuges

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PRINCIPLE:

The centrifuge is used to enhance the red blood cell agglutination of in vitro antigen-antibody reactions. Each centrifuge must be calibrated for each technique for which it is used in order to find the speed and/or time that will best provide a clear-cut agglutination without producing false positive results. Each centrifuge should be calibrated upon receipt, after adjustments or repairs, and annually in routine use. Optimum speed and time of centrifugation will be marked on the outside of each centrifuge, and all observations will be recorded permanently in the quality assurance records.

This procedure is for fixed speed centrifuges; only the time will be varied.

SPECIMEN COLLECTION:

N/A

REAGENTS/SUPPLIES, MATERIALS AND EQUIPMENT:

Materials

1. Test tubes, 12x75 mm.
2. Serologic centrifuge.
3. 0.85% Buffered Saline.
4. Bovine Albumin – 22%.

5. Coombs Control Cells.
6. Anti-A.
7. Anti-D.
8. Anti-Human Globulin (IgG).
9. 3-5% Group A red blood cells.
10. 3-5% Group B red blood cells.
11. 3-5% D+ red blood cells (R_1R_1).
12. 3-5% D- red blood cells.
13. Centrifuge Calibration Chart form for recording results.

PROCEDURE:

A. Preparation of reagents -

1. For ***saline-active antibodies***:
    - Perform a serial dilution of anti-A in saline. Use the titer which gives a 1+ macroscopic reaction as the dilution for the testing.
    - ***Positive control:*** Group A red cells in a 2% to 5% saline suspension.
    - ***Negative control:*** Group B red cells in a 2% to 5% saline suspension.
2. For ***albumin antibodies***:
    - Perform a serial dilution of anti-D in 22% albumin. Use the titer which gives a 1+ macroscopic reaction at the dilution for the testing.
    - ***Positive control:*** D+ red cells in a 2% to 5% saline suspension.
    - ***Negative control:*** D- red cells in a 2% to 5% saline suspension.
3. For ***Anti-human globulin:***
    - ***Positive control:*** a 2% to 5% saline suspension of D+ (R_1R_1) red cells incubated for 15 minutes at 37C with anti-D diluted to a give 1+ macroscopic agglutination after addition of AHG. Wash the cells four times in saline before using.
    - ***Negative control:*** a 2% to 5% suspension of D+ red cells incubated for 15 minutes at 37C with 6% albumin. [Note: D- red cells incubated with diluted anti-D may also be used as a negative control.]

B. Testing

1. For each phase of testing, label the appropriate number of tubes according to the centrifuge calibration chart, one set for the test and a duplicate set for a negative control. Add the serum to each tube but ***do not add the cells until just before centrifugation.*** Do not let them stand after adding the cells.
    - Saline antibodies – Add 2 drops diluted anti-A to each of the labeled tubes. For the test, add 1 drop of group A cells. For the negative control, add 1

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drop of group B cells.

- Albumin antibodies - Add 2 drops of the albumin diluted anti-D to each of the tubes. For the test, add 1 drop of the D+ cells. For the negative control add 1 drop of the D- cells.
- Anti-human globulin (IgG) – For the test, add 1 drop of sensitized red blood cells to each of the labeled tubes. For the negative control, add 1 drop of D- red blood cells to the labeled tubes. Wash cells four times with saline. Add Anti-human globulin (IgG) to the test and the negative control.

2. In pairs of one test and one negative control centrifuge immediately for the desired time interval (eg 10 seconds).
3. Repeat steps 1 and 2 for each time interval (eg, 15, 20, 30, and 45 seconds).
4. Observe each tube for agglutination and record observations.

CALCULATIONS:

N/A

QUALITY CONTROL:

N/A

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RESULTS:

1. Select the optimal time of centrifugation, which is the shortest time required to fulfill the following criteria:
    a. Agglutination in the positive tubes is 1+ and as strong as determined in preparing the reagents.
    b. There is no agglutination or ambiguity in the negative tubes.
    c. The red cell button is clearly delineated and the periphery is sharply defined, not fuzzy.
    d. The supernatant fluid is clear.
    e. The red cell button is easily re-suspended.
2. Record centrifuge identification, the times selected, the date, and the identity of the person performing the calibration

PROCEDURAL NOTES:

Periodic recalibration is performed to verify that the timing in use continues to be the optimal timing. This may be accomplished by using a shortened version of the procedures outlined above. For example, use the current timing, as well as times just above and just below, for a particular centrifuge and each medium.

REFERENCES:

1. *Standards for Blood Banks and Transfusion Services*. Bethesda, MD: Association for the Advancement of Blood and Biotherapies (AABB), current edition.
2. Cohn, Claudia S., MD, PhD. *Technical Manual*. Bethesda, MD: Association for the Advancement of Blood and Biotherapies (AABB), current edition.

All Revision Dates

2/9/2026, 2/1/2016, 11/1/2015

Attachments

A: Centrifuge Calibration Chart

Approval Signatures

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Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator, VCMC & SPH	2/9/2026
Laboratory Services Department	Erlinda Roxas: Director, Laboratory Services	2/7/2026
Laboratory Services Department	Kathrina Barcena: Supervisor-Blood Bank, Laboratory Services	2/5/2026
Laboratory Services Department	Linda Lee: Medical Director, VCMC Blood Bank	1/29/2026

Status **Active** PolicyStat ID **19472402**

Origination	3/1/2007	Owner	Gayle Haider: Supervisor-Quality Assurance, Laboratory Services
Last Approved	1/23/2026		
Effective	1/23/2026	Policy Area	Laboratory Services
Last Revised	1/23/2026		
Next Review	1/23/2028		

L.06 Terms of Accreditation by the College of American Pathologists

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POLICY:

A Laboratory that is accredited by the College of American Pathologists (CAP) must adhere to the Terms of Use for CAP Certification of Accreditation.

PROCEDURE:

The laboratories at Ventura County Medical Center and Santa Paula Hospital are accredited by the College of American Pathologists (CAP) and adhere to the following Terms of Accreditation:

- The Laboratory shall cooperate with any College of American Pathologists (CAP) investigation of inspection. The laboratory promptly notifies CAP, if the laboratory at Ventura County Medical Center or Santa Paula Hospital becomes the subject of:
  - An investigation by a government entity (including national, federal, state, or local,) or by another accreditation organization
  - A validation inspection
  - Adverse media attention related to laboratory performance
- The Laboratory promptly notifies CAP:
  - If the laboratory discovers laboratory personnel actions that appear to violate national, federal, state, or local laws that regulate laboratories
  - Of any changes in laboratory activity menu prior to beginning that testing or implementing scope of service/analytic method changes, or the laboratory permanently or temporarily discontinues some or all testing

    - Of any changes in directorship, location, ownership, name, insolvency, or bankruptcy within two days. Laboratories subject to the Clinical Laboratory Improvement Amendments (CLIA) regulations must also notify the Centers for Medicare Services & Medicaid Services (CMS) of pertinent changes.

- The Laboratory will provide an inspection team comparable in size and scope to that required for its own inspection if requested by the region and/or state commissioner at least once during the two- year accreditation period.
- The Laboratory is subject to the US CLIA regulations and will:
    - On a reasonable basis, have the Laboratory's annual PT results available upon request of any person
    - Allow the CMS or its agent to perform a validation or complaint inspection at any time during the Laboratory's hours of operations and permit the CMS to monitor the correction of any deficiencies found during such an inspection
- Adherence to the Certificate Mark Terms of Use/Agreement for the CAP Certification Mark and Design if the laboratory is/or will use the CAP Certification Mark for accreditation. The agreement can be downloaded and printed from www.cap.org.

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All Revision Dates

1/23/2026, 7/27/2024, 10/7/2022, 11/1/2016, 8/1/2012

Approval Signatures

Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator, VCMC & SPH	1/23/2026
Laboratory Services Department	Erlinda Roxas: Director, Laboratory Services	1/23/2026
Laboratory Services Department	M. Anwar Molani: Medical Director, Laboratory Services	12/11/2025
Laboratory Services Department	Gayle Haider: Supervisor-Quality Assurance, Laboratory Services	12/11/2025

Status **Active** PolicyStat ID **19658153**

Origination	8/12/2004	Owner	Gayle Haider: Supervisor-Quality Assurance, Laboratory Services
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Effective	1/23/2026	Policy Area	Laboratory Services
Last Revised	1/23/2026		
Next Review	1/23/2028		

L.16 Laboratory Employee Orientation

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POLICY:

All new Laboratory employees will receive orientation to the Ventura County Health Care Agency, the Laboratory Department and the specific area(s) within the Laboratory in which they will be working.

PROCEDURE:

1. At the time of hire, Human Resources will assign the new employee to the Health Care Agency orientation.
2. Each new employee will receive a Laboratory orientation including, but not limited to, procedures for payroll, sick time, vacation requests, break times, phone operation and courtesy, computer use, dress code, and Laboratory safety.
3. The Laboratory Director or Designee will order a computer account creation for the new hire before the new hire's start date. The computer account creation will include at minimum a Windows login, Cerner Access, and Microsoft Outlook.
4. Each department in the Laboratory has an orientation checklist. The department supervisor will direct orientation, ensure that the checklist is completed and that all of the new employee's questions have been answered.

All Revision Dates

1/23/2026, 11/1/2016

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Approval Signatures

Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator, VCMC & SPH	1/23/2026
Laboratory Services Department	Erlinda Roxas: Director, Laboratory Services	1/23/2026
Laboratory Services Department	M. Anwar Molani: Medical Director, Laboratory Services	1/12/2026
Laboratory Services Department	Gayle Haider: Supervisor-Quality Assurance, Laboratory Services	1/12/2026

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Status **Active** PolicyStat ID **16069669**

Origination	6/1/1988	Owner	Gayle Haider: Supervisor-Quality Assurance, Laboratory Services
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Effective	1/26/2026	Policy Area	Laboratory Services
Last Revised	1/26/2026		
Next Review	1/26/2028		

L.26 Laboratory Quality Control

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POLICY

The Laboratory Quality Control (QC) program provides for optimal patient specimen and result integrity throughout the pre-analytical (patient identification and preparation; specimen collection, identification, preservation, transportation), analytical (specimen processing) and post-analytical (result reporting) processes.

Testing Procedures and Policies

Standards, controls and linearity studies for individual tests will be performed according to instructions in the Department's Manual. The tolerance limits and corrective action protocol are described in each manual.

Method Correlations

Tests processed on multiple instruments or methodologies have comparability studies performed according to instructions in the Department's Manual. Patient test results are monitored with both delta checks for consistency and absolute value limits for possible dilution and/or critical values. Additionally, Department Supervisors or a designee reviews the daily Patient Exception Reports for appropriate actions and notifications.

PROCEDURE

Pre-Analytical

Instructions for patient preparation and specimen collection are provided in the Laboratory Directory, available at all nursing stations and clinics. These instructions are also available in the Phlebotomy

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Manual and in the appropriate department manuals.
The Office/Phlebotomy Supervisor and Department Supervisors are responsible for maintaining these procedures.

Analytical

All Laboratory results are subject to variations that may interfere with data evaluation and interpretation. Although some variation is within and some outside the control of testing personnel (Clinical Laboratory Scientist, Medical Laboratory Technician), the Laboratory must be able to evaluate and recognize the extent of any analytical variation and determine its clinical significance.

The Quality Control programs are designed to monitor the variance of the systems. The foundation for the program is the analysis of pre-assayed controls at specified intervals.

A. Controls for quantitative and qualitative tests are performed each day of testing or more frequently as specified in manufacturer's instructions, laboratory procedures, or accrediting agency, and when changes occur that may impact patient results.
B. Quality Control (QC) is performed:
    1. Prior to resuming patient testing when changes occur that may impact patient results
    2. After a change of analytically critical reagents
    3. After a major preventive maintenance
    4. After change of critical instrument component
    5. After software changes, as appropriate
C. Daily QC is performed as follows:
    1. Qualitative: a negative control and a positive control, when patient testing is performed.
    2. Quantitative: at least two levels of different concentrations at least daily
    3. Tests producing a graded or titered result: a negative control and a control material with graded or titered reactivity, as applicable, at least daily, or when patient testing is performed.

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Control Range Establishment or Verification

For each lot of control material, acceptable ranges are established or verified.

A. Assayed control materials: ranges supplied by the manufacturer are verified by repetitive analysis.
B. Unassayed control materials: acceptable ranges are established by repetitive analysis in runs that include previously tested control material.

Alternative Control Procedures

For tests procedures without commercially available control materials, the laboratory performs alternative procedures such as:

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- Split-sample analysis with another method or with another CLIA-laboratory,
- Testing of previously tested patient specimens in duplicate,
- Testing of patient specimens in duplicate

QC Material Handling

Quality control materials are tested in the same manner and by the same personnel as patient samples. Clinical laboratory scientists and medical laboratory technicians who routinely perform patient testing runs QC as scheduled.

Post-Analytical

Documentation and Evaluation

QC Data

The results of all Quality Control testing are recorded and initialed/verified by the testing personnel. Upon computer entry, the system automatically runs the preset Multi-Rules. Any results that fall outside of the range, as a result of clerical or analytical error, are immediately flagged. The procedures following an out-of-control result will also be documented and initialed. The records are reviewed and noted each day by the appropriate Department Supervisor or designee.

QC data is reviewed by the testing personnel in the laboratory information system or instrument printouts. QC data is retained for at three (3) years.

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QC Numeric Data

Imprecision statistics (eg, standard deviation and coefficient of variation) is calculated monthly to confirm that the test system is performing within acceptable limits.

If the controls satisfy the statistical analyses, the reagent and instrumentation are determined to be 'in-control." If, however, the control results fail the statistical analyses, the reagent and/or instrumentation is "out-of-control" and patient results are withheld (and repeated) until the problem is corrected.

QC Corrective Actiion

When QC results exceed defined acceptability limits, appropriate steps are taken.

A. Repeat QC run using new QC material
B. Repeat patient testing
C. Compare patient means for the run in question to historical patient means
D. Review of selected patient results against previous results to see if there are consistent biases for the tests in question

QC Confirmation of Acceptability

Monthly QC Review

The departmental supervisor has been delegated by the Laboratory Medical Director to review and

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assess quality control data including records for following up outliers, trends, or omissions that were not previously addressed. These documents are retained for three (3) years.

Inter-Laboratory Comparison

The Laboratory participates in inter-Laboratory comparison programs for most of the analytes. The specimens are integrated into the routine workload and analyzed by the same staff and methods used for patient samples. All comparison results are reviewed by the Department Supervisor in consultation with the Laboratory Manager.

Augmenting these controls are Proficiency Testing samples, patient controls, patient delta checks, and test linearity parameters.

All Revision Dates

1/26/2026, 12/1/2016

Approval Signatures

Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator, VCMC & SPH	1/26/2026
Laboratory Services Department	Erlinda Roxas: Director, Laboratory Services	1/24/2026
Laboratory Services Department	M. Anwar Molani: Medical Director, Laboratory Services	10/7/2025
Laboratory Services Department	Gayle Haider: Supervisor-Quality Assurance, Laboratory Services	10/7/2025

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Status **Active** PolicyStat ID **16307565**

Origination	6/1/1989	Owner	Gayle Haider: Supervisor-Quality Assurance, Laboratory Services
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Effective	1/26/2026	Policy Area	Laboratory Services
Last Revised	1/26/2026		
Next Review	1/26/2028		

L.33 Laboratory Analyzer and Equipment Utilization

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POLICY

The Laboratory Department relies heavily on automated analyzers and equipment in the performance of its duties. All analyzers and equipment must be maintained in optimal condition to ensure the reliability and accuracy of laboratory test results.

PROCEDURE

A. Laboratory analyzers and equipment will be installed and serviced according to manufacturer specifications. Before being placed into service, the Biomedical Department at Ventura County Medical Center (VCMC) & Santa Paula Hospital (SPH) will do a safety check and place an identification number on each piece of equipment.

B. In most cases, major items will be installed and serviced by a factory authorized service representative. Any equipment which produces clinical results requires that all regulatory standards be maintained in the installation of such equipment. This may include, but not be limited to, the correlation of methodologies as well as the verification or establishment of reference ranges.

Test system - The process that includes pre-analytic, analytic, and post-analytic steps used to produce a test result or set of results. A test system may be manual, automated, multi-channel or single-use and can include reagents, components, equipment and/or instruments required to produce results. A test system may encompass multiple identical analyzers or devices. Different test systems may be used for the same analyte.

Analytical validation - The process used to confirm with objective evidence that a laboratory-developed or modified FDA-cleared/approved test method or instrument system delivers reliable results for the intended application.

Device - Any reagent, reagent product, kit, instrument, apparatus, equipment or related product, whether used alone or in combination, intended by the manufacturer to be distributed for use in vitro for the examination of human specimens

Analytical verification - The process by which a laboratory determines that an unmodified FDA-cleared/approved test performs according to the specifications set forth by the manufacturer when used as directed.

Instruments and Equipment

A. Instruments are analytical units that use samples to perform chemical or physical assays (e.g. chemistry and hematology analyzers).
    1. Instrument platform is any of a series of similar or identical analytical methods intended by their manufacturer to give identical patient results across all models

B. Equipment is a single apparatus or set of devices or apparatuses needed to perform a specific task (e.g. centrifuges, mechanical pipettes, fume hoods, microscopes, heat blocks, water baths, etc.)

C. Performance of all instruments and equipment are verified according to manufacturer's instructions to ensure they perform according to expectations for the intended use and within defined tolerance:
    1. Prior to initial use,
    2. After major maintenance or service,
    3. After replacement of critical components,
    4. After relocation, appropriate function checks are performed to ensure that the move to a new environment did not adversely affect performance.

D. A function check to confirm that an instrument or equipment operates according to manufacturer's specifications prior to iinital use, at prescribed intervals, or after minor adjustment ((e.g. base line calibration, balancing/zero adjustment, thermometer calibration, reagent delivery).

Orientation and Training

A. Orientation and training program will be established for each laboratory equipment. Laboratory records include initial training checklists, to document training for each equipment operator.

B. Operator/users manuals are accessible to all operators and users.

C. Departmental Clinical Laboratory Scientist IIIs are responsible for training and competency assessments for operators and users.

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Instrument and Equipment Function Checks and Preventive Maintenance

Preventative Maintenance

Maintenance - Activities that prolong the life of an instrument or minimize breakdowns or mechanical malfunctions. Examples include cleaning, lubrication, electronic checks, or changing parts, fluids, or tubing, etc.

Preventative maintenance schedules will be based on the manufacturer specifications, the recommendations of the Biomedical Department and/or other scientifically sound or generally accepted sources. Records of temperatures for all refrigerators, freezers, water baths, and heat blocks will be kept as specified in each department and for the duration that is stated in policy *L.42 Preservation of Laboratory Records and Specimens*.

Preventive Maintenance schedules, Preventive Maintenance Logs and Corrective Action logs are available in each Department in the Laboratory. Copies of all maintenance performed by an outside service company excluding the manufacturer will be kept onsite in the Laboratory Department.

Biomedical Engineers shall provide records of completion to respective section CLS III/Technical Supervisor for review and record-keeping.

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Instrument and Equipment Troubleshooting

Instrument and Equipment Records

Reagents, Controls and Calibrators

All reagents, controls and calibrators must be stored in accordance with the manufacturer's recommendations and used within the manufacturer's indicated expiration date.

When an expiration date is not provided by the manufacturer or when calibrators, controls or reagents are prepared by the Laboratory, an expiration date will be assigned based on known stability, frequency of use, storage conditions and risk of deterioration. Reagent preparation instructions, reagent handbooks, textbooks or pertinent articles may be used for this purpose.

All controls, calibrators and reagents, once opened for use, must be labeled with a "**new expiration date**" when so required. This is necessary to be in compliance with College of American Pathologists Laboratory Accreditation Requirement (CHM.12400), which states that *"a new expiration date must be recorded on the container if opening the container changes the expiration date"* (the date that is printed on the product label by the manufacturer).

The manufacturer's insert should be reviewed for all Reagents, Controls, and Calibrators for storage and stability once they are opened or reconstituted for use. Policies and procedures are updated as required.

Note: Reagents in the Laboratory which have not been assigned an expiration date by the manufacturer will be assigned a five (5) year expiration date from the date of receipt.

Expired Reagents, Controls, and Calibrators

It is a violation of CAP standards to use expired reagents. Expired Reagents, Controls, and Calibrators will NOT be used. The only exception is in the Blood Bank where reagents may be used under very limited circumstances in strict compliance with the Blood Bank policy for use of expired reagents. This is necessary to be in compliance with CAP COM.30400 Reagent Expiration Date.

Problems and Failures

Any time there is a significant delay in the Laboratory's ability to produce critical lab results, the supervisor on duty or their designee shall communicate (phone or TigerText) the delay directly to the departments that are impacted and contact the Director of Laboratory Services and the Nursing Supervisor on Duty.

During normal business day shift hours, the Director of Laboratory Services or supervisor on duty will communicate the issue and expected time of resolution initially and at reasonable periods of time to the following via phone call or TigerText:

- Director Laboratory Services or Clinical Laboratory Scientist III in charge in the absence of a Director Laboratory Services
- Nursing Supervisor
- Administrator on Duty
- Medical Director Laboratory Services or Pathologist in charge in the absence of the Medical Director Laboratory Services.

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When delays are outside of normal business day hours, the Director Laboratory Services or supervisor on duty will communicate the issue and expected time of resolution initially and at reasonable periods of time to the Nursing Supervisor and Administrator on Duty, as well as via e-mail to the following:

- Director Laboratory Services or Clinical Laboratory Scientist III in charge in the absence of a Director Laboratory Services
- Nursing Supervisor
- Administrator on Duty
- Medical Director Laboratory Services or Pathologist in charge in the absence of the Medical Director Laboratory Services.

In the event the chemistry analyzer at Santa Paula Hospital is not functional, the iStat device may be deployed to run approved chemistry labs. The iStat device and its reagents shall be stored and maintained in the SPH Laboratory department. SPH Nursing Supervisors and Respiratory Therapists shall be trained to use the iStat device.

Documentation of all instrument problems and their resolution will be kept. The procedure specific to that instrument will define exactly how instrument problems are communicated. Instrument specific log

sheets, manufacturer service receipts, departmental communication logs and maintenance sheets are all examples of currently used methods to communicate instrument problems.

Documentation and Review

All phases of Equipment Maintenance will be documented on the appropriate forms. The records will be reviewed each month by the appropriate Department Supervisor. Problems, overdue maintenance, continuing education needs and excessive instrument downtime will be identified at this time. This review will be recorded on each Log and these records are stored for three years. Information on significant downtime events in the Laboratory will be collated on a monthly basis and presented to the Medical Director Laboratory Services.

REFERENCES

All Common Accreditation Checklist. College of American Pathologists, August 2023.

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All Revision Dates

1/26/2026, 9/26/2022, 9/1/2022, 11/1/2016, 6/1/2015, 2/1/2006

Approval Signatures

Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator, VCMC & SPH	1/26/2026
Laboratory Services Department	Erlinda Roxas: Director, Laboratory Services	1/24/2026
Laboratory Services Department	M. Anwar Molani: Medical Director, Laboratory Services	10/7/2025
Laboratory Services Department	Gayle Haider: Supervisor-Quality Assurance, Laboratory Services	10/7/2025

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Last Revised	2/24/2026
Next Review	2/24/2028
Owner	Kathrina Barcena: Supervisor-Blood Bank, Laboratory Services
Policy Area	Laboratory Services - Blood Bank

L.BB.102 Safe-T-Vue® 6 and Safe-T-Vue® 10 Quality Control

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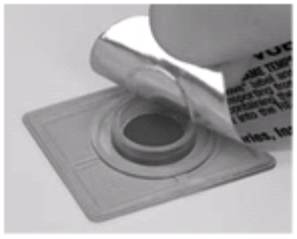
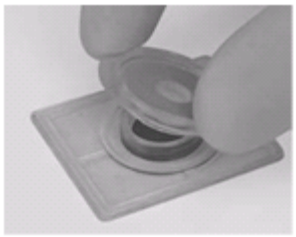
PURPOSE:

The purpose of this procedure is to measure and interpret color-related temperature changes in Safe-T-Vue® 6 and Safe-T-Vue® 10 when used as a temperature monitoring indicator on blood products contained in flexible plastic bags.

MATERIALS/EQUIPMENT:

1. A refrigerator with temperature control between 1° and 6° C for Safe-T-Vue® 6.
2. A refrigerator with temperature control between 1° and 6° C for Safe-T-Vue® 10;
3. A simulated blood bag consisting of a common, flexible plastic blood bag filled with the appropriate volume of saline (to simulate blood mass and volume) or outdated blood.
4. An electronic thermometer with an immersion probe or a similar temperature measuring instrument that can be calibrated;
    i. The temperature measuring probe is inserted into the bag so that it is in the approximate center of the blood bag liquid to assure temperature measurement of the "core" temperature of the liquid mass.
5. Safe-T-Vue® quality control form
6. Safe-T-Vue® quality assurance document for respective lot number.

PROCEDURE: Safe-T-Vue® 6

Step	Action	Comment
1	Simulated blood bags and Safe-T-Vue® 6 (STV 6) indicators must be stored in refrigerator at 1° to 6° C for at least 24 hours prior to test.	All Safe-T-Vue blood indicators will be refrigerated (1°-6° C) upon receipt.
2	To begin the validation, remove the simulated blood product (or outdated blood) from refrigerator.	
3	Insert the temperature probe in the blood product and position it so that it is in the approximate center of the blood bag liquid.	Assures temperature measurement of the "core" temperature of the liquid mass.
4	Remove one STV 6 from refrigerator.	Take care to handle by the edges.
5	Peel off the "Remove" label to expose the adhesive and attach STV 6 directly to the blood bag where there is the greatest volume of liquid and immediately above the measurement probe; DO NOT ACTIVATE.	
6	Store simulated blood bag with STV 6 temperature indicator(s) attached and with measurement probe in place in refrigerator at 1° to 6° C for at least 15 minutes or longer.	
7	After refrigerating for 15 minutes or longer, remove blood bag from the refrigerator. a. Stabilize STV 6 against the bag with fingertips and peel off the tip foil lid to expose the red and white rounds; b. Activate by folding the white round into the red round and pressing firmly together by pressing only on the colored, round label.	 
8	Observe the color change process and record the corresponding temperature from an all-white color to an all red-color, which typically takes place over about 1°C.	

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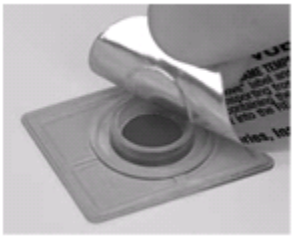
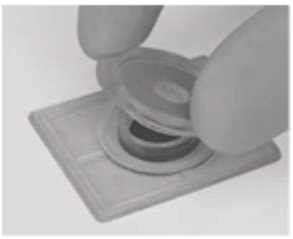
PROCEDURE: Safe-T-Vue® 10

Step	Action	Comment
1	Simulated blood bags and Safe-T-Vue® 10 (STV 10) indicators must be stored in refrigerator at 1° to 6° C for at least 24 hours prior to test.	All Safe-T-Vue® blood indicators will be refrigerated (1°-6° C) upon receipt.
2	To begin the validation, remove the simulated blood product (or outdated blood) from refrigerator.	
3	Insert the temperature probe in the blood product and position it so that it is in the approximate center of the blood bag liquid.	Assures temperature measurement of the "core" temperature of the liquid mass.
4	Remove one STV 10 from refrigerator.	Take care to handle by the edges.
5	Peel off the "Remove" label to expose the adhesive and attach STV 10 directly to the blood bag where there is the greatest volume of liquid and immediately above the measurement probe a. Stabilize STV 10 against the bag with fingertips and peel off the top foil lid to expose the red and white rounds; b. Activate by folding the white round into the red round and pressing firmly together by pressing only on the colored, round label.	  
6	Observe the color change process and record the corresponding temperature from an all-white color to an all red-color, which typically takes place over about 1°C.	
7	Repeat the validation process with two additional STV 10 temperature indicators.	Demonstrates process will consistently produce results meeting the specifications

CALIBRATION:

Digital thermometer with probes should be calibrated yearly.

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CALCULATIONS:

N/A

QUALITY CONTROL:

1. Quality Assurance documents included with the Safe-T-Vue® products.

RESULTS:

Observe the color change process and record the corresponding temperature from an all-white color to an all red-color, which typically takes place over about 1°C.

1. "Red Spots – Random" – Small, red spots around the edges of the white area and/or within the white area.
2. "Red Filling In" – areas of red spots coalescing into areas of red.
3. "Completely Red" – The entire white area is red, indicating attainment of 6°C or 10°C. A positive control is helpful for color comparison.

LIMITATIONS:

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Critical process variables:

1. Refrigerator temperature range;
2. Calibration of temperature-measuring instruments
3. Handling of samples

Conditions to be Monitored

1. Safe-T-Vue® 6 and Safe-T-Vue® 10 may be kept in the blood bank refrigerator for up to 2 months. After 2 months, remove STV 6 and STV 10 from the refrigerator for 24-48 hours, and then return to the blood bank refrigerator. This cycling may be repeated every 2 months.
2. Storage of STV 6 and STV 10 in refrigerator so that "warm air wash" from normal opening and closing of the door does not warm the indicators above threshold prior to use.
3. Training to ensure consistent handling and application of STV 6 and STV 10.

REFERENCES:

1. *Association for the Advancement of Blood and Biotherapies (AABB)* **Standards for Blood Banks and Transfusion Services**, **Reissue of Blood and Components**.
2. *TEMPTIME* Corporation, 116 American Road, Morris Plains, NJ 07950; ***Suggested Validation Procedure for Safe-T-Vue 6*** (Product No. 7206) and ***Suggested Validation Procedure for Safe-T-Vue 10*** (Product No. 7201), 2016-01-15.
3. Current Package insert "*Instructions & FAQs.*"

All Revision Dates

2/24/2026, 12/1/2016, 4/1/2016

Attachments

Image 02

Safe-T-Vue Non-Reversible Blood Bag Temperature Indicators Quality Control

Approval Signatures

Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator, VCMC & SPH	2/24/2026
Laboratory Services Department	Erlinda Roxas: Director, Laboratory Services	2/24/2026
Laboratory Services Department	Kathrina Barcena: Supervisor-Blood Bank, Laboratory Services	2/5/2026
Laboratory Services Department	Linda Lee: Medical Director, VCMC Blood Bank	1/26/2026

Status **Active** PolicyStat ID **19191816**

VENTURA COUNTY HEALTH CARE AGENCY

Origination	6/16/2000
Last Approved	1/23/2026
Effective	1/23/2026
Last Revised	1/23/2026
Next Review	1/23/2028
Owner	Kathrina Barcena: Supervisor-Blood Bank, Laboratory Services
Policy Area	Laboratory Services - Blood Bank

L.BB.75 Supplying Blood in Blood Transport Coolers

COPY

PRINCIPLE:

To define guidelines for packing, issuing, delivering, monitoring, and return of coolers used for blood transport and temporary storage.

SCOPE:

This procedure applies to coolers shown to maintain a temperature range of 1-6°C when used to store blood products after transport to locations where patient care necessitates the presence of readily available refrigerated blood products.

POLICIES:

Item	Description
1	Only approved blood coolers that have been validated for transport and temporary blood storage can be used.
2	All approved coolers will be assigned and labeled with a Blood Bank inventory number.
3	To avoid unnecessary expiration of blood products, blood coolers that are packed and issued by the blood bank will be tracked and monitored for storage time by the blood bank. **Coolers should be exchanged every 4 hours**.
4	Each unit of blood, packed in a blood cooler, will be monitored by placing a blood temperature indicator on the unit. • **Safe-T-Vue® 10** blood indicators will be used for blood and plasma that may be returned to the blood bank. The cooler is used for transport and for temporary storage duration of 4 hours.
5	Blood storage coolers will be transported by courier to their requested location and delivered to a

	responsible caregiver. They are never left unattended.
6	Blood storage coolers serve as a transport and temporary storage for blood products during trauma, surgery, or excessive bleeding.
7	Blood coolers may be used for the transport of ***one (1) unit of red blood cells*** to the patient care area of the Infusion Center.
8	When blood is issued by the Blood Bank for transfusion, **each** patient **must** have his/her own cooler. It is **NEVER** acceptable to issue a cooler that contains blood that is intended for transfusion to multiple patients.
9	Red cell and thawed plasma products must be stored in validated Max Q MTP coolers.
10	Platelet and cryoprecipitate products must never be placed in a 1-6°C blood cooler.

SPECIMEN COLLECTION:

N/A

EQUIPMENT

ThermoSafe BC15 Blood Transport Cooler	**Plastic product container inserts**
Playmate large Coolers	**Cardboard inserts**
Refrigerator maintained at 1-6°C	**Freezer maintained at ≤ -30°C**
Polar Pack 16 oz Gel refrigerant packs	**Safe-T-Vue ® 10 Nonreversible Blood Temperature Indicators**

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PROCEDURE:

Preparation and Packing of Large Blood Transport Coolers
(Refer to Diagrams 1& 2)

Step	Action	Comment
1	Retrieve a large blood transport cooler, • The large blood coolers have a storage capacity of 1-6 red blood cell / Thawed Plasma units.	
2	Each large blood cooler should have a white/clear container in the cooler.	
3	Place two frozen (≤-30°C) Brite Ice refrigerant bricks in the cooler on each short side.	See diagram 1 and 2.
4	Place one chilled (1-6°C) Brite Ice refrigerant brick in the cooler on the long side.	See diagram 1 and 2.
5	Place a chilled (1-6°C) gel pack in the bottom of the product container.	See diagram 1 and 2.
6	Place 1 to 6 blood products in the product container.	See diagram 1 and 2.
7	Place a chilled (1-6°C) gel pack on top of the packed blood products.	See diagram 1

Step	Action	Comment
		and 2.
8	Close the blood cooler.	
9	Continue with the procedure to complete a ***Blood Cooler Tracking Log*** entry.	

PROCEDURE:

Preparation and Packing of Small Blood Transport Coolers.
(Refer to Diagrams 3 & 4)

Step	Action	Comment
1	Retrieve a small blood cooler, • The small blood coolers have a storage capacity of 1-2 red blood cell/ thawed plasma units.	
2	Each small blood cooler should have a brown cardboard strip to separate the blood from the refrigerant.	
3	Place one (1) frozen (≤30°C) Brite Ice refrigerant pack in the cooler on the long side.	See diagram 3 and 4.
4	Place one (1) chilled (1-6°C) gel pack on the floor of the igloo (the plasma will sit on top of this refrigerant).	See Diagram 3 and 4.
5	Place two (2) chilled (1-6°C) gel pack on either side of the blood.	See diagram 3 and 4.
6	Close the blood cooler.	
7	Continue with the procedure to complete a ***Blood Cooler Tracking Log entry.***	

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PROCEDURES:

PROCEDURE

Completing the Blood Cooler Tracking Log

Step	Action	Comment
1	Complete an entry on the *Blood Cooler Tracking Log* for each cooler issued for a patient.	The *Blood Cooler Tracking Log* is located at the issue bench and monitored by the Issue Technologist. See Addendum 1.
2	Record the following information: • Cooler number • Patient name and chart number • Location • Date/time the cooler was issued • Date/time cooler must be exchanged	

Step	Action	Comment

	• Initials of preparer
	• Type of product (Check one)
	  ◦ RBC for red blood cells
	  ◦ FFP for Thawed Plasma
	• Initials of courier/time of pick up	

The cooler is ready for transport and blood storage for up to 4 hours.		

Procedure

Monitoring Issued Blood Storage Coolers

Step	Action	Comment
1	Blood Bank Technologist: • Periodically review the time on the Blood Cooler Tracking Log to determine whether the cooler needs to be exchanged.	
2	When the time that the cooler needs to be exchanged is less than 30 minutes, call the location where the cooler was issued to find out if the cooler is still needed.	
3	If the cooler is no longer needed, have location return the cooler.	

4	If the cooler is still needed:
	• Alert the area staff that a replacement cooler will be brought to them.
	• Prepare a replacement cooler as in *Preparation and Packing of Blood Storage Coolers* above without blood products.
	• Complete an entry on the *Blood Cooler Tracking Log* as in *Completing the Blood Cooler Tracking Log* for the new issued replacement cooler.
	• Check the Safe-T-Vue® blood indicators on each of the remaining units to verify that the products in the original cooler are in the 1-10°C temperature range.
	  ◦ If the blood indicators are red, **return the original cooler and all blood products to the blood bank – the units must not be transfused**.
	  ◦ If the blood indicators are white, put all products from the original cooler into the
		For OR, have one of the staff meet you at the OR front desk.

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Step	Action	Comment
	replacement cooler. • Return to the blood bank with the original cooler and update the *Blood Cooler Tracking Log* by entering the 'Time Returned'.	

Procedure

Unpacking Returned Coolers

Step	Action	Comment
1	Upon arrival in the blood bank, open the blood storage cooler.	
	• If red cell and/or plasma products are returned, check the blood temperature indicators on each unit for verification that the temperature range of 1-10°C was maintained throughout the storage period.	SOP
	• Perform visual inspections on any returned products.	SOP
2	Complete the *Blood Cooler Tracking Log* • Enter the date/time returned • Initials of the inspector • Any Comments	
3	Remove the Brite Ice refrigerant and return to the appropriate storage freezer or refrigerator	1-6°C or ≤ -30°C, do not freeze Brite Ice that is labeled for 1-6°C storage.
4	Remove the gel packs and store in the proper storage refrigerator (1-6°C).	Do not Freeze gel packs.
5	Perform an inspection of the cooler: • Remove any patient identification information added to the cooler. • Disinfect the cooler immediately after unpacking. • Inspect cooler for cracks or leaks inside and outside of the cooler.	If the workload does not permit the cooler to be cleaned immediately upon receipt, place the cooler by the sink for later cleaning. If there are cracks or leaks, remove the cooler from service. Refer the cooler to a supervisor for replacement.
6	Place the cooler in the cooler storage rack	

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Diagram 1

Top View of Large Storage Cooler

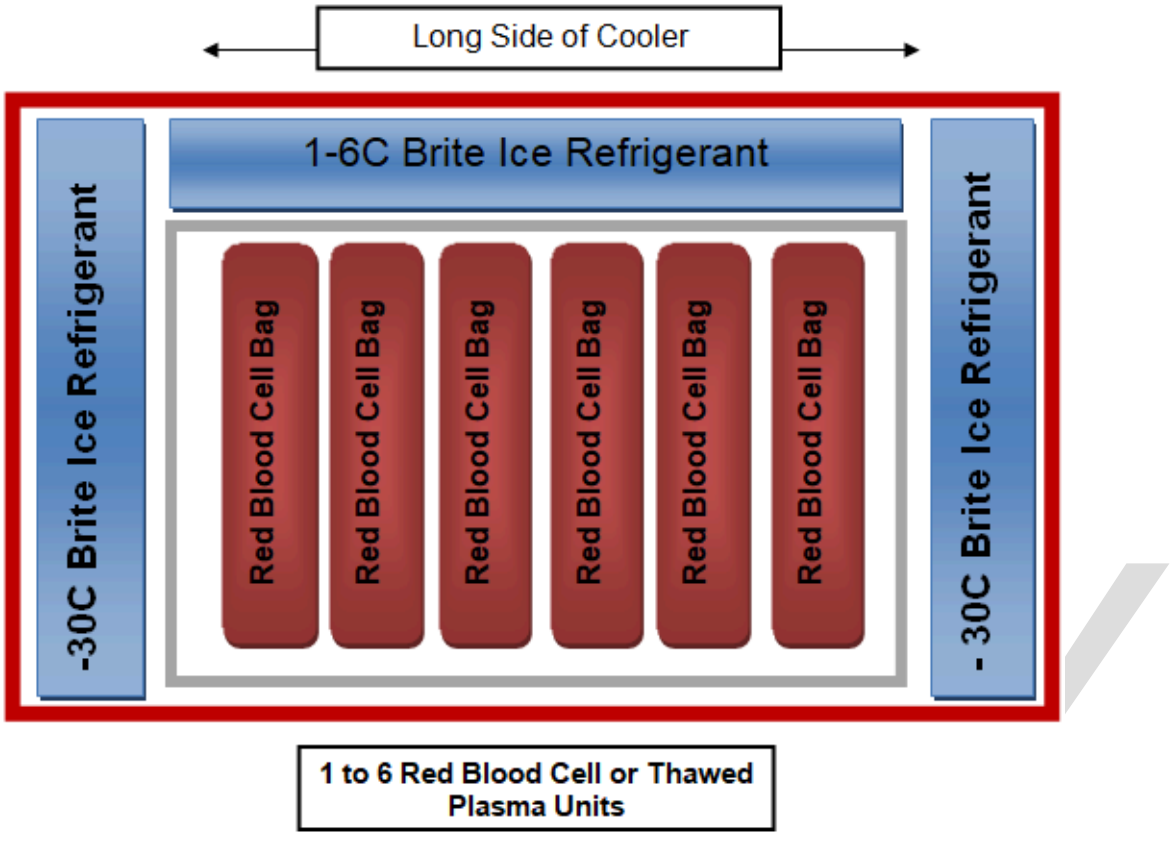

Diagram 2

Side View of Storage Cooler

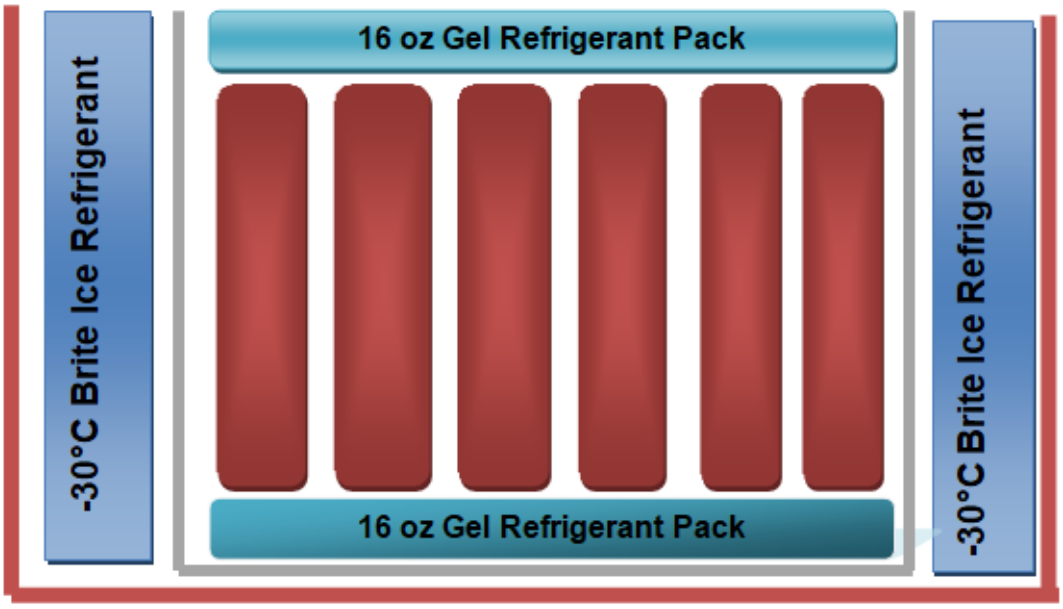

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Diagram 3

Top View of Small Cooler

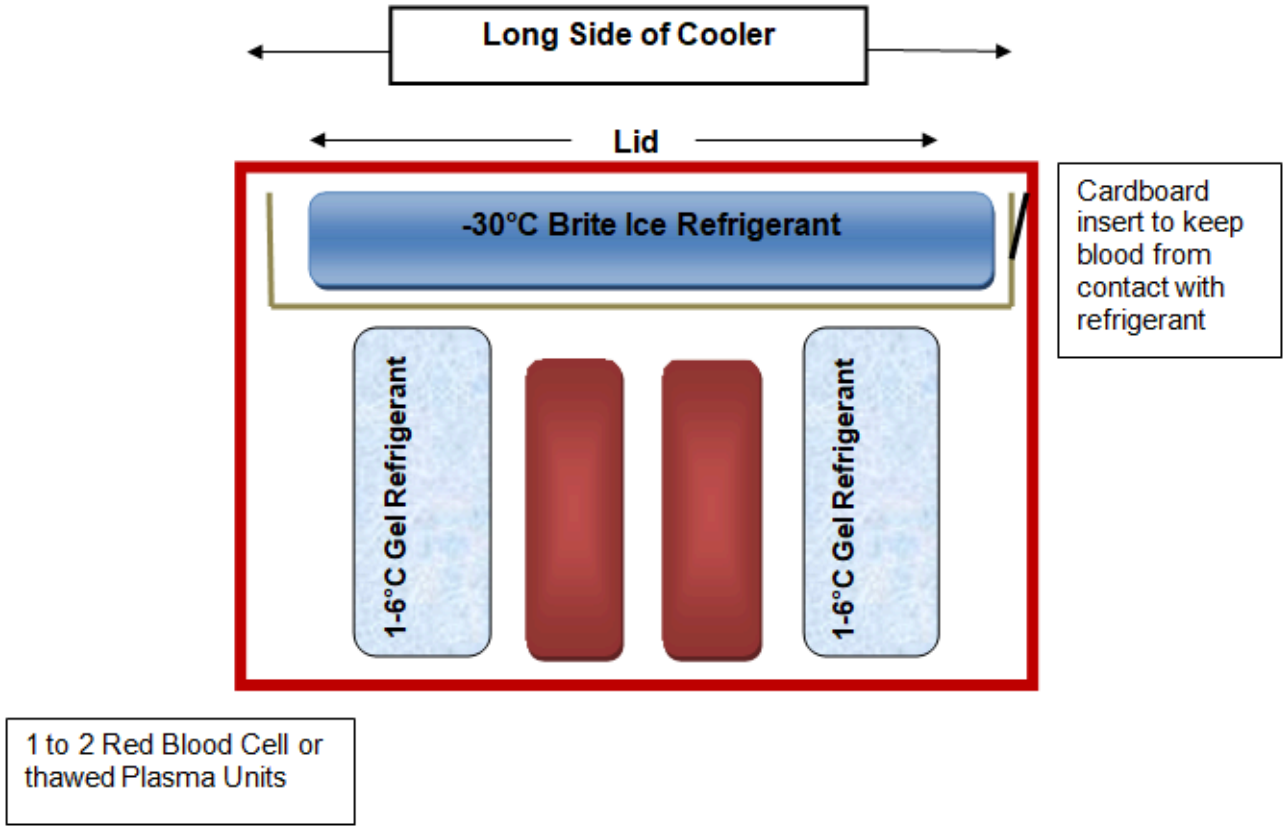
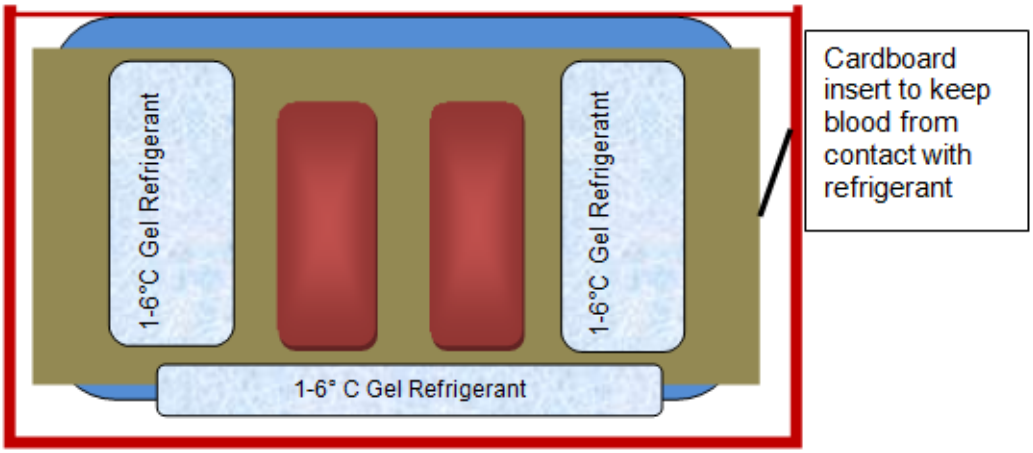


Diagram 4

Side View of Small Cooler



All Revision Dates

1/23/2026, 12/1/2016, 3/1/2010

Attachments

Blood Cooler Tracking Log

Approval Signatures

Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator, VCMC & SPH	1/23/2026
Laboratory Services Department	Erlinda Roxas: Director, Laboratory Services	1/23/2026
Laboratory Services Department	Linda Lee: Medical Director, VCMC Blood Bank	11/4/2025
Laboratory Services Department	Kathrina Barcena: Supervisor-Blood Bank, Laboratory Services	11/4/2025

Status **Active** PolicyStat ID **19747385**

Origination	9/15/2008	Owner	Erlinda Roxas: Director, Laboratory Services
Last Approved	1/23/2026		
Effective	1/23/2026	Policy Area	Laboratory Services
Last Revised	1/23/2026		
Next Review	1/23/2028		

L.SPH.48 HCG Urine Qualitative - Medline hCG Combo

COPY

DESCRIPTION

Medline hCG COMBO PREGNANCY TEST CASSETTE (Serum/Urine) test is a rapid one-step test for the detection of human chorionic gonadotropin (hCG) in serum or urine.

For urine testing, it is a CLIA-Waived test.

For serum, it is moderately complex test.

INTENDED USE

Medline hCG COMBO PREGNANCY TEST CASSETTE (Serum/Urine) is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in serum and urine to aid in the early detection of pregnancy.

SUMMARY

PRINCIPLE

REAGENTS

The test cassette contains mouse anti-beta hCG antibody conjugated to colloidal gold and goat anti-alpha hCG antibody coate on the membrane.

PRECAUTIONS

- For professional in vitro diagnostic ue only. DO NOT USE AFTER THE EXPIRATION DATE.
- The test cassette should remain in the sealed pouch until use and should not be reused.

- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The test cassette should be discarded in a proper biohazard container after testing.

STORAGE AND STABILITY

- Store as package in the sealed pouch at 2 - 30C. Keep test cassette in the pouch until use.
- The test cassette is stable through the expiration date printed on the sealed pouch.
- DO NOT FREEZE,
- DO NOT USE beyond expiration date.

SPECIMEN

Urine Assay

- Urine shall be collected in a dry clean container.
- Random specimen may be used, but a first morning void is preferred, since it contains the highest concentration of the hCG.
- Centrifuge urine specimens exhibiting visible precipitates to obtain clear specimen for testing.

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Serum Assay

- Collect blood aseptically into a clean tube without anticoagulants.
- Sepaate the serum from blood as soon as possibe to avoid hemolysis.
- Use clear, non-hemolyzed spcimens when possible.

Specimen Storage

- Specimens can be stored at 2 – 8 degrees C for up to 48 hours prior to testing.
- For prolonged storage, samples may be frozen and stored at below -20°C. Frozen samples should be thawed and mixed before testing.
- Refrigerated samples must be brought to room temperature before testing.

MATERIALS PROVIDED

1. Test cassettes
2. Disposable sample pipettes
3. Zip lock bag with extra sample droppers
4. Product instructionsfor use

MATERIALS REQUIRED BUT NOT PROVIDED

1. Individually wrapped test strips

2. Sample collection container
3. Calibrated timer

DIRECTIONS FOR USE

Medline hCG Combo+ Pregnancy Cassette Demo Video on Vimeo

INTERPRETATION OF RESULT

Positive

Two distinct red lines appear. One line should be in the control region (C) and another line should be in the test region (T).

Negative

One distinct red line appears in the control region (C). No red or pink line appears in the test region (T).

Invalid

Control line fails to appear.

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CALIBRATION

None required.

QUALITY CONTROL

1. External Positive and Negative controls are run when a new lot of reagents is first opened, or at receipt of a new shipment of an existing lot of reagents..
2. Acceptable external controls are BioRad Liquicheck Urine Chemistry Controls, Level 1 (negative) and Level 2 (positive).
3. If controls are not acceptable, repeat. If still not acceptable open new bottle of control and repeat. If unacceptable still, do not report results, quarantine the lot of reagents and notify a supervisor.

Record test result and presence or absence of the internal control line on the HCG Log Sheet.

Manually enter the valid test result into the LIS per SOP

LIMITS OF PROCEDURE

1. False negative results may occur when levels of hCG are below the sensitivity level of this test.

Sensitivity for urine samples is ≥25 mIU/ml of hCG.

2. Elevated levels of hCG may be found in trophoblastic disease,choriocarcinoma, embryonal cell carcinoma, Islet cell tumors and other carcinomas.
3. Detectable levels of hCG may remain several weeks following normal pregnancy delivery, caesarean section, spontaneous or theraputic abortions.
4. Ectopic pregnancies may produce very low levels of hCG. If suspected, further testing by a quantitative method is recommended.
5. This test provides a presumptive diagnosis for pregnancy.

PERFORMANCE CHARACTERISTICS

Accuracy

Sensitivity

10 mIU/mL or greater in serum and 20 mIU/mL or greater in urine samples

Interfering Substances

See the manufacture's Product Instructions for a complete list of interfering substances.

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REFERENCE

https://punchout.medline.com/sku/item/MDPMPH22025HCG?skuIndex=S3&question=&flowType=&indexCount=

All Revision Dates

1/23/2026, 9/15/2008

Attachments

- MEDLINE hCG COMBO INSTRUCTION.pdf
- Medline hCG Pregnancy Test Cassette SDS.pdf
- QUALITATIVE HCG LOG SHEET.docx
- Urine HCG QC Log SPH Lab.docx

Approval Signatures

Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator, VCMC & SPH	1/23/2026
Laboratory Services Department	M. Anwar Molani: Medical Director, Laboratory Services	1/23/2026
Laboratory Services Department	Erlinda Roxas: Director, Laboratory Services	1/23/2026

COPY

Status **Active** PolicyStat ID **20135463**

VENTURA COUNTY HEALTH CARE AGENCY

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Effective	3/27/2026
Last Revised	3/2/2026
Next Review	3/26/2028
Owner	Amanda Lo: Medical Director, SPH Lab
Policy Area	Laboratory Services - Cytology

L.CYT.1 Cytology Specimen Procurement - Introduction

COPY

PURPOSE

The concept of diagnostic cytology has been greatly influenced by the efforts of Dr. George N. Papanicolaou (hence the term “Pap smear”), whose contributions to our knowledge of the cytologic presentation of cancer have changed the status of cytology from largely theoretical to a widely accepted laboratory procedure. Most important among numerous applications of cytologic technique is the detection and diagnosis of early, clinically silent tumor processes.

Cytology’s value to the physician involves the interdependence of several equally important factors. Within the boundaries of its obvious limitations, it requires competent technical processing and knowledgeable interpretation of material which has been collected with the utmost care from the indicated area. Too frequently the effectiveness of the evaluation is negated by a specimen which did not adequately sample the area of interest, and, to which insufficient regard was given the prime concept in dealing with any cytological technique – the concept that the cell is fragile and must be handled quickly and carefully.

This manual is to be used as a suggested guideline for those procedures routinely ordered at Ventura County Medical Center. It does not necessarily contain the best available methods, nor does it, by any means, contain the only methods, but it does attempt to set forth those which appear to have given the best results in this hospital with its existing facilities. Since cytology is a flexible tool, however, alterations in technique may be utilized in accordance with the physician’s preference or in the patient’s particular problems. In these cases, the Cytology Department should be notified of the change so that the processing steps may be suitably altered.

Suggestions relating to improvements in our techniques are always welcome and may be discussed with the department at any time. The Cytology Laboratory is located on the second floor with the Clinical Laboratory. It is regularly open Monday through Friday from 7:00 a.m. to 5:00 p.m. All specimens should be collected and sent to the laboratory during these hours when at all possible. If the specimen cannot

be collected during these times, it is to be preserved according to the instructions on the following pages.

It is very important that the orders for the cytology specimen be entered into the EHR in the appropriate pathology module.

Specimens submitted for processing by the Cytology Laboratory shall only be accepted from physicians or other hospital/clinic personnel as authorized by law, e.g., nurse practitioners, supervised physician assistants. In case of doubt, Cytology personnel shall refer to the Laboratory Medical Director.

All Revision Dates

3/2/2026

Approval Signatures

Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator, VCMC & SPH	3/27/2026
Laboratory Service Dept	Erlinda Roxas: Director, Laboratory Services	3/26/2026
Laboratory Service Dept	Amanda Lo: Medical Director, SPH Lab	3/18/2026

Status **Active** PolicyStat ID **20135468**

Origination	12/5/2011	Owner	Amanda Lo: Medical Director, SPH Lab
Last Approved	3/27/2026		
Effective	3/27/2026	Policy Area	Laboratory Services - Cytology
Last Revised	3/2/2026		
Next Review	3/26/2028		

L.CYT.10 Cerebral Spinal Fluid (CSF)

COPY

PRINCIPLE:

The cerebrospinal fluid is usually obtained by lumbar puncture at the 3rd or 4th intervertebral space and occasionally by ventricular and occipital punctures with strictly antiseptic technique. The normal position with the spine strictly horizontal.

SPECIMEN:

In cases of increased intracranial pressure as caused by brain tumor and meningeal inflammation, withdrawal of the fluid may cause a fatal pressure cone by cerebral herniation. Therefore, there may be occasions when only two or three milliliters are available for cytodiagnosis. In suspected brain tumor, abscess or hemorrhage, the fluid should be removed slowly under manometric control.

1. Use a properly labeled CSF collection tube.
2. Enter the orders into the EHR, non-gynecology cytology procedure.
3. The specimen should be brought to the lab promptly, without fixative, and handed to the person on duty at the lab front desk.

REFERENCES:

- "The Cyto-Centrifuge and Cerebrospinal Fluid Cytology," by Heine Hansen, et.al., ACTA Cytologica, Vol. 18, No. 3, 1974.
- "Diagnostic Cytology of Cerebrospinal Fluid by the Cytocentrifuge Method," by Ho-Soon Choi, et. Al., American Journal Of Clinical Pathology, Vol. 72, No. 6, 1979.
- "Reading the Signs in Synovia," by Lewis Glasser, Diagnostic Medicine, November/December 1980.

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- “Tapping the Wealth of Information in CSF,” by Lewis Glasser, Diagnostic Medicine, January/ February 1981.
- “Cytospin 2 Operating Instructions,” by Shandon Southern, January 1981.
- Leopold Koss, M.D., Diagnostic Cytology, 2nd Edition.
- Masayoshi Takahashi, M.D., Color Atlas of Cancer Cytology.
- Ishizuka, et. Al., Practical Cytodiagnosis.

All Revision Dates

3/2/2026

Approval Signatures

Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator, VCMC & SPH	3/27/2026
Laboratory Service Dept	Erlinda Roxas: Director, Laboratory Services	3/26/2026
Laboratory Service Dept	Amanda Lo: Medical Director, SPH Lab	3/18/2026

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VENTURA COUNTY HEALTH CARE AGENCY

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Next Review	3/26/2028
Owner	Amanda Lo: Medical Director, SPH Lab
Policy Area	Laboratory Services - Cytology

L.CYT.11 Criteria for the Rejection of Surgical Pathology and Cytology Specimens

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PURPOSE:

In order to maintain a high level of quality, specimens that are unsatisfactory will not be processed.

POLICY:

Unacceptable specimens will not be processed.

PROCEDURE:

1. Each specimen container (or in the case of smears, each smear) must be labeled to include the patient's name. If a specimen from more than one site or source is received from a patient, each specimen container or smear must also include a way of distinguishing the specimen (e.g., description of source of specimen or a number or letter).
2. Each set of specimens from a patient must be accompanied by a pathology or Gyn cytology accession in the computer which includes the patient's name; a hospital ID number or date of birth, or other patient identifying information; the requesting physician's name; the date (and for body fluids, the time) the specimen was obtained; and identification of the source of the specimen(s). For tissue and non-Gyn cytology specimens, pertinent clinical information including a preoperative or postoperative diagnosis is desirable.
3. Each specimen must either be received in the proper fixative (usually 10% formalin or 95% ethyl alcohol). In the event specimens are received unfixed or unrefrigerated for an extended period or are received with the outside container surfaces contaminated, all efforts will be made to salvage the specimen for microscopic examination and the referring physician/clinic contacted to prevent recurrence and be made aware of possible compromise to examination of the tissue. If received fresh (for frozen section, cultures, or other special indication), there

must be a person in the laboratory at the time the specimen is received who is familiar with pathology/cytology procedures and is qualified to process the specimen immediately. If any of the above requirements is not met, the specimen will be returned, the specimen cannot be accessioned and processed. The specimen will be returned to its place of origin (surgery, 3 -west, etc.) and the responsible party specimen (nursing supervisor, requesting physician) will be asked to correct the problem or obtain a new specimen.

If any of the above requirements is not met, the specimen cannot be accessioned and processed. The specimen will be returned to its place of origin (surgery, 3-West, etc.) and the responsible party (nursing supervisor, requesting physician) will be asked to correct the problem or obtain a new specimen.
NOTE: If there is a question about specimen preservation, the specimen will be processed and a statement regarding the adequacy of the specimen will be included in the report when specimen handling is suboptimal. A clotted specimen is not grounds for rejection. A broken slide will be accepted if it can be processed.

All Revision Dates

3/2/2026

COPY

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Step Description	Approver	Date
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Owner	Amanda Lo: Medical Director, SPH Lab
Policy Area	Laboratory Services - Cytology

L.CYT.12 Improperly Labeled Cytology Specimens

COPY

POLICY:

IMPROPERLY LABELED CYTOLOGY SPECIMEN

If a cytology specimen is received in the laboratory which has not been properly identified (i.e. the specimen container is not labeled with the patient's name or the specimen orders have not been entered into the EHR system, or if a slide is submitted that is not labeled), the following procedure will be followed:

1. The case will not be accessioned until properly identified.
   The clinic, nurse or physician submitting the incorrectly labeled specimen will be contacted by pathology or histology and told that there is a problem with the labeling. The physician or nurse will be asked to come to the laboratory and properly label the specimen with the understanding that they assume full responsibility for identifying the specimen as belonging to the patient and that they will be required to fill out a form to verify the identity of the patient. If the accompanying orders have not been entered, the physician, nurse or clinic will be contacted.
2. Histology Staff will notify the pathologist or supervisor that an improperly labeled specimen has been received. The pathologist or supervisor will sign the mislabeled specimen form in the designated area and return to the office. The forms will be saved in a file folder.
3. Once the specimen has been properly identified and the orders are complete, the case will be accessioned and handled in the usual manner.

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L.CYT.13 Accession Numbers and Reporting Non-Gyn Cytology and Cell Buttons

COPY

POLICY:

The purpose of adjoining the cytologic smear and the cell block as a surgical specimen is to allow for better continuity and evaluation of specimens. often times an important diagnostic finding will appear in the cytologic specimen that is not seen in the cell block and vice versa. This can cause confusion if two reports are issued which seem to contradict each other.

POLICY:

Body fluid should be processed in the fresh state. If the specimen can not be processed immediately, it should be processed as per instructions for After Hours, weekends, holidays and when nobody is in the Histology lab.

The specimen should be entered in the LIS and given a non-gynecology (NG) registration number.

SPECIMEN:

1. Give all Non-GYN cytology specimens a Non-gynecological cytology accession number.
2. In the Gross Description, the cytology specimen will be described concerning the color, nature and volume submitted and the number of slides prepared and stained with the Papanicolaou stain.
3. The cell button will be made from any remaining fluid specimen.
4. The cytotechnologist will keep a record of the cytologic preparation for CAP survey.

SMEAR TECHNIQUE:

1. Transfer the fluid to one or more centrifuge tubes.
2. Spin the specimen at approximately 2000 RPM for 5-7 minutes.
3. Decant the supernatant. Have a Coplin jar of absolute reagent alcohol fixative ready.
4. Using completely frosted slides, make 2-4 smears from the sediment by placing 1-2 drops on slides and gently rotating one slide over the other.
5. Fix smears immediately in alcohol fixative. Fix at least 15 minutes before staining.
6. Use the remainder of sediment for a cell button: Spin down at 2000 RPM for 5 minutes and follow the procedure for cell block preparation using HistoGel.
7. Dispose of contaminated material in red trash bag for incineration.

CYTOSPIN METHOD (FOR LOW-CELLULARITY FLUIDS):

1. Centrifuge the specimen.
2. Pour off supernatant
3. Assemble cytospin apparatus – chamber, filter slide clip and slide labeled with patient's identification. Have ready a Coplin jar of absolute reagent alcohol fixative.
4. Add 2 or 3 drops of sediment to chamber, put on plastic cap and place apparatus opposite of balance unit.
5. Spin at 2500 RPM for 10 minutes.
6. Remove slide from apparatus and place immediately in alcohol fixative

COPY

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Owner	Amanda Lo: Medical Director, SPH Lab
Policy Area	Laboratory Services - Cytology

L.CYT.14 Cytology Specimens That May Be Contaminated With M. tuberculosis or Other Highly Infectious Organisms

COPY

POLICY:

Using surgical gloves and working under the protective hood in the microbiology department withdraw specimen with pipette or applicator stick and apply to glass slide. Drop immediately in Coplin jar with absolute reagent alcohol. Dispose of any remaining specimen in red trash for incineration

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Owner	Amanda Lo: Medical Director, SPH Lab
Policy Area	Laboratory Services - Cytology

L.CYT.15 Body Fluid, Cyst Fluid, Urine, and Cerebrospinal Fluid Processing

COPY

POLICY:

Body fluid should be processed in the fresh state. If the specimen can not be processed immediately, it should be processed as per instructions for After Hours, weekends, holidays and when nobody is in the Histology lab.

The specimen should be entered in the LIS and given a non-gynecology (NG) registration number.

PROCEDURES:

Smear Technique:

1. Transfer the fluid to one or more centrifuge tubes.
2. Spin the specimen at approximately 2000 RPM for 5-7 minutes.
3. Decant the supernatant. Have a Coplin jar of absolute reagent alcohol fixative ready.
4. Using completely frosted slides, make 2-4 smears from the sediment by placing 1-2 drops on slides and gently rotating one slide over the other.
5. Fix smears immediately in alcohol fixative. Fix at least 15 minutes before staining.
6. Use the remainder of sediment for a cell button: Spin down at 2000 RPM for 5 minutes and follow the procedure for cell block preparation using HistoGel.
7. Dispose of contaminated material in red trash bag for incineration.

CYTOSPIN METHOD (FOR LOW-CELLULARITY FLUIDS):

1. Centrifuge the specimen.
2. Pour off supernatant
3. Assemble cytospin apparatus – chamber, filter slide clip and slide labeled with patient's identification. Have ready a Coplin jar of absolute reagent alcohol fixative.
4. Add 2 or 3 drops of sediment to chamber, put on plastic cap and place apparatus opposite of balance unit.
5. Spin at 2500 RPM for 10 minutes.
6. Remove slide from apparatus and place immediately in alcohol fixative

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COPY

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Policy Area	Laboratory Services - Cytology

L.CYT.16 Cytospin 2

COPY

PRINCIPLE:

The Cytospin 2 operation is based on the fact that the cell is more dense than the suspending fluid, and under an applied force, the cell will have greater momentum than the fluid. This condition means that after passing through the sample chamber, the cell will be projected toward the microscope slide with sufficient momentum to cross the gap formed by placing a filter card between the sample chamber and glass slide. The suspended fluid is absorbed into the filter card by capillary action.

REAGENTS AND EQUIPMENT:

1. Cytospin 2
2. Cytospin 2 apparatus – chamber, filter cards, slide clip.
3. Glass slides.
4. ETOH – to clean slides.
5. Disposable pipettes and rubber bulb.
6. Isotonic saline – if dilution necessary.
7. Slide stainer.
8. 22% bovine albumin

PROCEDURE:

To Prepare Slide Clip:

1. Using the pressure release tool provided, release pressure so as to insert the card and slide

into the holder

2. Place a microscopic slide on face of backing plate.
3. Take the sample chamber and align the filter card against the face of the chamber. Insure that the locking stud locks into one hole and the lower hole is in line with the sample chamber outlet port.
4. Position the sample chamber and filter card in the slide clip, so they are aligned with the glass slide.

Holding the components together, remove the pressure release tool.

Loading the Sample Chamber:

1. Only load chamber when the whole assembly is positioned in Cytospin 2. (We do not want to wet the filter card before spinning.)
2. Add appropriate amount of fluid depending on cell count:
    a. If WBC less than 1,500 – make 1:2 dilution with isotonic saline.
    b. If WBC is 500-1000, use 0.2 to 0.3 cc sample.
    c. If WBC is less than 500, us 0.5 cc.
    d. If WBC is over 50, use 0.5 cc fluid and one drop of 22% bovine albumin, for CSF only.
3. Put plastic lid on the sample chamber.
4. Insert sample assembly and the balance assembly into the centrifuge.
5. Switch power on.
6. Place lid on the rotor and snap the latch tight.

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Programming and Starting the Cytospin 2:

1. Press “SET TIME”
2. Press “1” and “0”
3. Press “ENTER”
4. Press “SET SPEED”
5. Press “1”, “2”, “5”
6. Press “ENTER”
7. Press “ACCEL” so the “HI” light is lit.
8. Close lid.
9. Press Start.

Unloading the Chamber:

1. Remove the slide clip assembly and using the pressure release tool again, release the pressure so as to remove the slide and card.
2. Remove slide, filter card and sample chamber as one unit. Peel the filter card away from the slide taking care not to smudge the cell prep.
3. Immediately place slide in Coplin jar with absolute reagent alcohol.
4. Rinse sample chamber with amphyl and distilled water immediately. Air dry.

NOTE: All fluids should be handled with care as many diseases can be transmitted through them.

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Policy Area	Laboratory Services - Cytology

L.CYT.17 Bronchial Esophageal and Gastric Washings Processing

COPY

PROCEDURE:

These washings contain small amounts of mucoid and cellular material mixed with normal saline solution. Separate material by spinning the specimen down at about 2000 RPM for 5-7 minutes. The supernatant is decanted and smears are made from the sediment. Using completely frosted slides, spread a small amount on two slides. Have a container of absolute reagent alcohol ready, placing prepared slides in this fixative.

If a cell button is desired, spin down the sediment at 2000 RPM for 5 minutes and follow the procedure for cell button preparation using HistoGel.

Dispose of any remaining contaminated material in the proper container for incineration (red trash bags).

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L.CYT.18 Sputum Specimen Processing

COPY

POLICY:

1. After the specimen has been collected, process as soon as possible. If there is a delay in processing, add saccammono fixative and mix well. The specimen does not need to be refrigerated. Give the specimen a surgical pathology accession number. Label slides with patient's name, and accession number. Have a container (Coplin jar) of absolute reagent alcohol ready for fixation.
2. Select suspicious areas (bloody or discolored) of the specimen; or if there are no such areas, randomly select material and place on the slides. Use an applicator stick to spread material as evenly as possible over the slides, then place immediately in the alcohol. Fix at least 15 minutes before staining. Sputum in saccammono fixative should be placed on the shaker for at least 3 hours. It is then centrifuged down and 2 cytospins and a cell block, if needed, are prepared. The cell block is prepared by placing the specimen in the centrifuge for 5 minutes at 2000 RPM, and following the procedure for cell button preparation using HistoGel.
3. Dispose of any remaining contaminated material in the proper container for incineration (Red Trash Bags).

Examination of possible highly infectious specimens:

Using surgical gloves and working under the protective hood in the microbiology department, withdraw specimen with pipette or applicator stick and apply to glass slide. Drop immediately in Coplin jar with absolute reagent alcohol. Dispose of any remaining specimen in red trash for incineration.

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Policy Area	Laboratory Services - Cytology

L.CYT.19 Histogel Cell Block Procedure

COPY

PRINCIPLE:

HistoGel is an aqueous gel which is solid at room temperature. It can be used with ethanol preserved cell suspensions, formalin fixed tissue or unfixed tissue for preparation of a cell block.

HistoGel should be refrigerated when not in use and should be used before the expiration date. It should be a consistently translucent gelatin material with a slightly pink color. Do not use if it appears to have mold growth.

POLICY:

Instructions for use:

1. Liquify a small aliquot of HistoGel, by placing it in a glass test tube in the Histology incubator at 60-65 degrees for 7 to 10 minutes or until liquefied.
2. Centrifuge the cell suspension at 2000 RPM for 5 minutes. Repeat if needed.
3. Remove the supernatants from the centrifuge tube.
4. Add 4-6 drops of liquefied HistoGel with a pipette to cell pellet at bottom of centrifuge tube.
5. Carefully mix cells and HistoGel together by lightly shaking the tube in a swirling motion or by allowing HistoGel to settle on the bottom of the tube. If the specimen has disaggregated, it can be spun down again at 2000 RPM for 5 minutes.
6. Allow the cell block containing the HistoGel to cool to near room temperature. This can be done by cooling naturally or by placing the specimen on an ice pack.
7. Remove the HistoGel pellet containing the specimen and place inside a microbiopsy cassette.
8. Histologically process HistoGel button containing the cell block as a standard histology specimen without wrapping it in lens paper.

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REFERENCES:

- Richard-Allan Scientific, ***HistoGel Specimen processing gel. Specimen Collection & Grossing***. Kalamazoo, MI.
- Koss, Leopold G: ***Diagnostic Cytopathology and Its Histopathologic Bases***. J.B. Lipincott, Third Edition, Philadelphia, 1979, p.

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Owner	Amanda Lo: Medical Director, SPH Lab
Policy Area	Laboratory Services - Cytology

L.CYT.2 Specimens Which May be Excluded from Routine Submission to the Cytology Department

COPY

POLICY:

The Pathology Department as a policy prefers that all cytological specimens either exfoliation or fine needle aspiration be submitted to the cytology department for review.

Possible exceptions may include:

- Clear fluid from aspirated breast or thyroid cysts at the discretion of the obtaining physician.
- This does not include blood tinged or turbid fluids which should all be submitted for cytology.
- Fine needle aspirations of abscesses for culture only.
- Urines for urine analysis or culture.

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Owner	Amanda Lo: Medical Director, SPH Lab
Policy Area	Laboratory Services - Cytology

L.CYT.20 Preparation, Labeling, and Storage of Reagents

PROCEDURE:

COPY

Absolute reagent alcohol is stored in the flammable storage cabinet at the rear of the Laboratory. Prepared reagent containers are stored in cabinet under staining area.

Alcohol 70%, 95%, 100% and acid alcohol as well as Harris' Hematoxylin, OG 6, and EA 50 stains and Hemo De (xylene substitute) are supplied by vendor/manufacturer, and labeled with the appropriate expiration date by vendor.

All reagents are stored at room temperature or in a monitored refrigerator as recommended by the manufacturer and used within their indicated expiration date.

Reagents lacking a manufacturer's expiration date or made in the laboratory are labeled using preprinted reagent labels stored in the histology laboratory with an expiration date of one year. These assigned expiration dates are based on known stability, frequency of use, storage conditions and risk of deterioration. Sources such as MSDS sheets and/or internet searches are also used for this purpose. After this time, remaining reagent is discarded in an appropriate manner.

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Policy Area	Laboratory Services - Cytology

L.CYT.21 Papanicolaou Staining Procedure

COPY

PURPOSE:

For routine diagnostic cytology the method of staining suggested by Papanicolaou (1942) gives the most satisfactory results. Although a long series of staining steps is necessary, the procedure is quite simple and can be completed within 20 minutes. Even thick smears can be examined because of the transparency of the stain. Characteristics of this stain consist of polychromic action by mixture of cationic, anionic and amphoteric dyes. Each layer of stratified squamous epithelium produces a graded color pattern; i.e., from deep blue-green at the basal layer to bright orange at the superficial layer. Color differentiation is also useful for cell-typing of malignant cells.

POLICY:

Cellular specimens from all tissue sites may be stained by the Papanicolaou method. Most often this stain is utilized for the examination of gynecologic (cervical) results which will be obtained if the specimen has been properly preserved with a suitable cytology fixative such as absolute reagent alcohol or spray Pap fixative. Variations in amount of time specimens are allowed to remain in the various stain components will be found to produce optimum visual

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L.CYT.22 Non-GYN Staining Procedure

COPY

PURPOSE:

To create a uniform policy and procedure for Non-GYN staining technique.

PROCEDURE(S):

Non-Gyn Staining Procedure

#	Step	Repititions/Length
1	Absolute Reagent Alcohol	10 dips
2	Absolute Reagent Alcohol	10 dips
3	80% Absolute Reagent Alcohol	10 dips
4	70% Absolute Reagent Alcohol	10 dips
5	Distilled H20	10 dips
6	Harris Hematoxylin	1 Minute
7	Tap H20	10-15 dips
8	Ammonia H20	2 dips
9	Running Tap H20	1 Minute
10	Distilled H20	10 dips
11	70% Absolute Reagent Alcohol	10 dips

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12	80% Absolute Reagent Alcohol	10 dips
13	Absolute Reagent Alcohol	10 dips
14	OG-6 Stain	1.5 minutes
15	Absolute Reagent Alcohol	10 dips
16	Absolute Reagent Alcohol	10 dips
17	EA-50 Stain	1.5 minutes
18	Absolute Reagent Alcohol	15 dips
19	Absolute Reagent Alcohol	15 dips
20	Absolute Reagent Alcohol	15 dips
21	Absolute Reagent Alcohol	4 minutes
22	Clear-rite	10 dips
23	Clear-rite	10 dips
24	Clear-rite	10 minutes
25	***MOUNT***	

NOTE:

- Staining times may vary with quality of stain (intensity per batch)
- GYN Specimens are to be stained separately from non-GYN specimens.
- Body fluid sediment smears, Sputum, Bronchial brushing, washing, Aspiration Biopsy, Urine, CSF, Low Cellular Fluids.

COPY

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L.CYT.24 Laboratory Performance Improvement

COPY

PURPOSE:

Program Objectives:

The Performance Improvement plan includes all the systems and procedures required to insure accurate patient results. The Laboratory is committed to providing appropriate high-quality services that are adequate in scope and complexity, and performed in a cost-effective, safe manner by qualified personnel.

The objectives of the Laboratory Performance Improvement program are:

1. Educate staff to improve performance and competence.
2. Identify standards for patient care.
3. Monitor and evaluate the quality and appropriaateness of patient care.
4. Identify and resolve problems using structured techniques.
5. Disseminate results, conclusions and recommendations.
6. Improve communications between departments.

SCOPE:

A variety of physicians utilize the Laboratory including Family Practice Residents, attending physicians, community physicians and specialists from outside the area.

The laboratory operates 365 days per year, 24 hours per day.

Services are provided from the following departments:

- **Clinical Laboratory**
    - Chemistry, Hematology, Coagulation, Serology, Urinalysis
- **Microbiology**
    - Bacteriology, Mycology, Mycobacteriology, Parasitology, Virology
- **Blood Bank**
    - **Testing:**
        - Type/RH, Antibody Screen & ID, Crossmatch, HDN Screening
    - **Products:**
        - RBCs
        - Pediatric units
        - FFP, Platelets
        - Cryoprecipitate
        - Low-Titer O Positive Whole Blood
- **Anatomic Pathology**
    - Histology, Cytology

COPY

The Laboratory processes specimens from various wards, clinics, and private physician offices. Processing of specimens from Ventura County Health Care Plan patients has continued to increase. The Assistant Chief Operations Officer coordinates a courier service for these specimens and reports. The phlebotomy team is responsive to the Emergency Room, Trauma Room, Intensive Care Unit, Cardiac Care Unit, Pediatrics, Intensive Care Nurseries, Obstetrics, and outpatients from physician offices and both on-site and off-site clinics. The laboratory also participates in various health screening programs throughout the county.

INDICATORS:

The laboratory is organized into multiple, overlapping and interacting areas. Performance Improvement Reports reflect this, although most indicators are narrowed to focus on a single aspect of the specimen or information flow. Performance Improvement is performed, but not limited to, the following areas: laboratory utilization, test processing and reporting of results, evaluation of new and existing test procedures, blood bank product utilization, personnel licensing and qualifications, laboratory information system, and specimen requests, procurement, transport and receipt.

The laboratory information system has made feasible the gathering of large amounts of data.

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COPY

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L.CYT.26 Quality Assurance for Pathology and Non-Gynecological Cytology

COPY

POLICY:

Quality assurance for surgical pathology, cytology, and autopsies is important. The following quality assurance protocol for surgical pathology, non-gyn cytology, and autopsies has been implemented.

A. All difficult, controversial, or unusual cases will be shown to other pathologists or will be sent directly to a recognized authority for consultation.

B. Non-gynecological cytology findings should be correlated with histological and/or clinical findings. There should also be correlation with specialized studies such as immunohistochemistry, molecular studies, flow cytometry and outside consults.

    1. In many cases, especially those with a benign cytology diagnosis, there may be considerable delay between obtaining the cytology specimens and a later histological specimen or else obtaining significant clinical followup. In all histological cases, in which a previous cytology specimen was received, the cytology should be reviewed and any significant disparities should be reconciled and commented on in the current histology report. An amended report should be issued when the disparity would affect patient care. In cases in which additional clinical information should come to light at a later date, the cytology should also be reviewed.

C. A pathologist will review all non- gynecological cytopathology slides and sign out all non-gynecological cytology reports.

D. All frozen section diagnoses will be compared with the final diagnoses at the time the pathology report is dictated and any significant discrepancies will b examined in writing in the pathology report.

E. A summary of the number of cases reviewed by in house pathologists, the number of cases

sent to outside experts for consultation, the number of discrepancies in the diagnosis rendered by VCMC pathologist(s) and the consulting pathologists, and the number of frozen section diagnosis and the final diagnosis will be sent at least annually to the Medicine Committee and the Executive Committee.

F. Any cases with clinically significant discrepancies between the frozen section and the permanent section diagnosis, between the VCMC pathologist(s) and the consulting pathologists, and any corrections or changes in diagnosis due to diagnostic errors (missed cases) will be sent by the pathologist to the appropriate medical staff committee for review.

G. In addition to the above quality assurance protocols, the pathologic findings of each autopsy will be correlated with the clinical impressions and clinical findings. This will usually be done in a correlative note to the autopsy report. In addition, the correlation and autopsy findings may be part of a formal teaching conference or the autopsy findings may serve as the impetus for a more didactic teaching conference.

H. A copy of the final autopsy report will be sent to the medial staff quality assurance committee for incorporation into the hospital quality assurance program.

I. In cases where the pathology or cytopathology diagnoses are considered particularly significant or unexpected, the submitting clinician should be notified of the diagnosis. This should be documented in the pathology report. In cases where the submitting physician is not available such as the Emergency Room or a clinic, the message should be conveyed to the attending physician covering that area. In some cases, the message can be left with a nurse. In all cases, the name of the person who is notified should be noted in the pathology report.

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L.CYT.27 Sending Pathology/Cytology Material to Outside Institutions, consultants, or other Entities

COPY

PURPOSE:

Pathology and cytology slides, tissue blocks and specimens often need to be sent to outside laboratories or hospitals for additional testing, expert consultation or in the case of a patient going to a different institution for a second opinion or treatment. Pathology reports, slides and blocks may also be required in legal cases.

POLICY:

A. In order to comply with current regulations, good medical practice, and good medical-legal judgment, proper record keeping is essential, and it is preferable, when possible that diagnostic material (preferably both microscopic slides and tissue blocks) be retained in the laboratory. It is also important that the institution, consultant or entity to which the pathology/ cytology material is sent be given representative and diagnostic material. In order to satisfy these demands, it is necessary to have a pathologist review all of the microscopic slides and blocks so that both the laboratory and the outside institution, consultant, or other entity are assured of having representative and diagnostic material.

B. For the above reasons, any request to send pathology/cytology slides or blocks to an outside institution, consultant, or entity, must be directed through the hospital pathologist. At no time are microscopic slides or blocks to leave the laboratory without first being reviewed and approved for send out by the pathologist.

C. An accurate and complete tracking of all tissues, microscopic slides and blocks sent to any outside institution, consultant, or entity must be maintained in the laboratory. This is done in EHR under inventory management and includes the name and address of the institution, consultant or entity to which material is sent, the date the material is sent and returned and the date of the consultant's report and complete inventory of all sent out and returned slide(s) or

block(s). All materials sent to outside institutions or laboratories, other than our contracted reference laboratories, will include a form requiring the return of all materials within 30 days. The EHR generates a report periodically of outstanding slides and blocks. The

D. In cases where the pathologist sends out slides and blocks to outside institutions for diagnostic consultation or further testing the pathologist will ensure that the necessary forms and paperwork are filled out and signed by a physician. When staff clinicians request any additional testing, they are required to send the department written requests listing the required studies. Outside physicians or institutions may also request slides or blocks for patients under their care. These requests need to be on official letterhead paperwork and include appropriate permission forms. The paperwork will be scanned into the patient's EHR.

E. There may also be occasions when slides or blocks may be subpoenaed by an attorney or other entity. When notice of a possible legal action is received in the pathology office, the relevant reports should be printed out and the slides and blocks should be retrieved from the files and retained in the Pathology office labeled as Legal Hold. The medical staff office should be notified of this and sent all of the relevant correspondence. The medical staff office will refer this matter to Risk Management or other relevant departments in keeping with the Ventura County Medical Center policies and procedures. The Pathology department will then proceed as directed by the medical staff office. Any materials sent out should be reviewed by a pathologist and all materials sent out should be inventoried in the EHR in keeping with the departmental policies.

F. In some cases unprocessed tissue is sent out to outside laboratories for specialized studies including specimen processing and interpretation. This includes renal, muscle and nerve biopsies and tissues for immunofluorescence. In these cases, the specimen is described in the gross pathology report and notation is made that the material is sent out and name of the other institution or laboratory. Copies of all of the relevant forms are kept and scanned into the EHR. In these cases, the tissue blocks and slides prepared by the outside facility are retained by them.pathology office will follow up on these notifications until such time as the material is returned to our institution.

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VENTURA COUNTY HEALTH CARE AGENCY

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Policy Area	Laboratory Services - Cytology

L.CYT.28 Biohazard and Contaminated Waste Disposal

COPY

PURPOSE:

To promote and maintain employee health and safety.

POLICY:

Hospital waste for which special precautions appear prudent include microbiology, pathology, and all blood and body specimens which may be found in the entire laboratory. The following categories will give specifics as to overall disposal procedures.

PROCEDURE 1:

Non-Infectious Waste: Material not contaminated with blood or body secretions are to be placed in a large brown plastic trash bag in trash receptacles. The custodial service will remove, replace and discard appropriately.

PROCEDURE 2:

1. Needles, knife blades and other sharp objects: These are placed in puncture-proof sharps containers. When the containers are full, they are securely closed and disposed of as infectious waste for pickup and safe disposal. Housekeeping will discard and safely remove the material according to their protocol.
2. Bulk blood, bloody fluids, excretions, suctioned materials and secretions may be carefully, to avoid aerosols, poured down a drain connected to a sanitary sewer. This guideline is taken from “Morbidity and Mortality Weekly Report,” August 21, 1987, Vol. 36/No S2.
3. Glass is disposed of in puncture proof Sharps containers. When full or at timely intervals, it is given to the housekeeping department for disposal according to their stated protocol.

4. Tissue specimens or body parts and wet tissue used in pathology or remaining after processing are placed in plastic tissue storage barrels for placement in the lower storage area. The tissue is stored for at least one month. After an appropriate interval, the specimens are discarded, to be destroyed by incineration by a medical waste disposal company.
5. Bio-hazardous materials such as formalin and xylene are carefully poured into a waste receptacle, labeled “BIOHAZARD”. This container is stored in a bio-hazard cabinet located outside of the laboratory and is then collected for disposal by a commercial disposal company.

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L.CYT.29 Handling Highly Infectious Specimens

COPY

PURPOSE:

Written instructions for handling highly infectious specimens for cytology should reduce the risk of transmission of these infections to laboratory personnel.

POLICY:

Universal blood/body fluid precautions will be followed in the handling of all tissue, blood and body fluid specimens. Gloves, plastic aprons, masks and goggles are available. Masks must be worn in the handling of all specimens suspected of harboring M. tuberculosis or other mycobacteria. All non-disposable instruments, containers and equipment (including the centrifuge and the cryostat) which come in contact with highly infectious specimens must be decontaminated according to the instructions in this manual (see “Cleaning of Surgical Pathology Grossing Area and Instruments) item 4.

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L.CYT.3 After-Hours Instructions for Cytology/Histology Specimen Handling

COPY

POLICY:

The key to obtaining diagnostic cytological specimens lies in appropriate fixation. Gynecological cytology specimen, brushings, and fine needle aspirates are immediately placed in fixative at the time of collection. Body fluids are best processed immediately after they are obtained. Non-gynecological cytology fluids received after hours, on weekends, holidays, or at any time when no one is working in histology needs to be processed as follows:

- The non-gyn cytology form should be completed for each specimen.
    - (See the non-gyn cytology fluids form in a separate sleeve.)
- At no time, should an unfixed specimen be left on the desk in histology without taking the appropriate action.
- Cerebrospinal fluid should be processed within 30 minutes of the collection time. Two cytocentrifuged slides should be prepared and immediately placed in 95% alcohol. Add an equal volume of 95% ethyl alcohol to the remaining fluid and leave on the counter in histology.
- Sputum only should be placed in Saccomanno's fixative, shaken firmly and placed on the counter in histology.
- Urine and other body fluids (pleural, ascites, bronchial washings, etc.). Add an equal volume of 95% ethyl alcohol to the specimen container or to a 50 ml aliquot of the fluid if the volume is greater than 50 ml and leave on the counter in histology.
- Fluids received in the 1000 ml evacuated containers should be placed in the refrigerator in the front office following the established protocol for notification of the front desk. A non-gyn cytology fluid form should be filled in and placed on the counter in histology.

(See Attached Below Form - 3B After Hours Instructions for Specimens – Cytology / Histology)

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Attachments

After_Hours_Cytology_Histology_Form.pdf

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L.CYT.31 Outside Slides

POLICY:

COPY

Slides from other institutions are sometimes received for patients undergoing treatment at this hospital. On every case there must be, in writing, identification of the patient by name and outside pathology accession number(s). This identification is accomplished by, in order of preference:

1. An accompanying report with matching name and number on it.
2. A letter of identification from the outside pathologist.
3. Identification on our requisition form from the referring clinician.

The gross description should be a description of the pathological material received, its accession number, a statement about the type of identification, and the name of the certifying person. Example: Received are 2 slides labeled, “OS-94-1, A&B, Outside Memorial Hospital, Townsville, CA”. They are identified in a protocol from Outside Pathologist MD as being slides of tissue of A.B. Jones.

A covering letter, copy of our reports as well as any pertinent follow-up information should accompany the slides, which are to be returned to the outside hospital. In cases in which the outside hospital has given permission for the slides to be retained by our institution, the slides should be labeled with our accession number, in such a way so as not to obscure the outside hospital accession number, are filed with our slides. A copy of our report and follow-up information should be sent to the outside hospital.

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L.CYT.34 Communication of Significant or Unexpected Cytological Findings

COPY

POLICY:

Any cytopathology diagnoses which are significant and unexpected (see list below) or are felt to be so by the pathologist, should be addressed in a timely fashion. The submitting clinician should be contacted at the office, or by means of a pager or cellphone. The electronic health records could be consulted as to the patient's prior history, and as to who is the current treating physician. Examples would include a specimen obtained on an outpatient basis from a patient who is now an inpatient. These communications should be mentioned in the comment section of the cytology report, and should include the name of the person contacted as well as the date.

Examples of unexpected or significant findings include, but are not limited to the following:

- Any unexpected malignancy in a patient with no prior history of such; Invasive carcinoma in a cervicovaginal specimen, or any findings of high grade squamous intraepithelial lesions.
- Infectious agents which may require prompt initiation of treatment.

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Owner	Amanda Lo: Medical Director, SPH Lab
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L.CYT.35 Cytology Assessment Record

COPY

POLICY:

At times a pathologist may be asked to review a cytology specimen at the time of collection for specimen adequacy, a preliminary diagnosis, or recommendation for additional studies. In these cases a “SURGICAL PATHOLOGY REQUISITION” form is to be completed (see example). A copy can be handed to the clinician asking for the review. The completed form is submitted to scanning and will be available in their EMR in power chart for review. The form needs to be completed with two patient identifiers, the location and the submitting physician. It should include a pre-operative diagnosis, history, and specimen submitted. The pathologist should indicate in the form that it represents a preliminary diagnosis. The report should include the specimen number as well as the reviewing pathologist’s signature with the date and time.

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L.CYT.36 Cytology Workload Policy

COPY

POLICY:

The final rule implementing the Clinical Laboratory Improvement Amendments of 1988 (CLIA 1988) requires that each individual Cytotechnologist evaluating cytology preparations by non-automated microscopic technique must examine no more than 100 slides (gynecologic and non-gynecologic or both) in a 24-hour period. Records must be maintained showing the total number of slides examined by each individual during each 24-hour period. The pathologist must establish the maximum workload (based on capability/documented performance evaluation) for each individual examining slides and the limit must be reassessed at least every 6 months. The maximum workload of 80 slides can be completed in no less than an 8-hour workday. Part-time employee's workload must be prorated based on screening time and an 8-hour day.

Pathologists who screen previously unscreened gynecologic slides and non-gynecologic slides (including FNA direct smears) must adhere to and record the above workload limit.

The following are not subject to the workload limit for pathologists:

1. Previously screened reactive/repair, atypical, premalignant and malignant gynecologic slides
2. Re-screened five-year look-back slides
3. 10% re-screen of negative gynecologic slides
4. Previously screened non-gynecologic and FNA slides
5. FNA slides evaluated solely for the purpose of adequacy.

A Cytology Workload Pathologist Daily Log will be maintained in the Histology Laboratory with the total number of cytology slides given to each Pathologist for screening. See attachment below

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L.CYT.37 Quality Management

COPY

PURPOSE:

The Laboratory Quality Management Program includes active surveillance of laboratory activities starting with specimen identification, preservation, and data entry, specimen processing and specimen reporting. The data from this surveillance is studied and used on an ongoing basis to correct any problems detected and used to improve the overall quality of patient care. The Quality Management Program encompasses the Performance Improvement Program, the Quality Improvement Program, the Competency Assessment Program and the Quality Assurance Program. The following indicators are monitored on an ongoing basis:

POLICY:

DATA ENTRY

At the time of entering the specimens into the HER, the Orders are checked with the specimen container for accuracy in patient identification and specimen source.

SPECIMEN PROCESSING

At this time, gynecological slides are sent to an outside laboratory for processing and interpreting.

SLIDE INTERPRETATION AND REPORTING

All pathologists and cytotechnologists participate in GYN and non-GYN inter-laboratory peer comparison programs (Pap and CAP non-GYN programs).

Records of inter- and intradepartmental consultations will be maintained. Discrepancies will be resolved.

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L.CYT.38 Submitting Pap Smears to Quest

COPY

PRINCIPLE:

Cervico-vaginal Pap smear specimens will be submitted to Interscope Pathology for initial review. They will then be returned to Ventura County Medical Center for final sign out.

The specimens will be entered into the computer using the protocol as indicated in the manual. A worksheet will be generated for each case.

Interscope will pick up Paps as needed. The front desk will enter the Paps and leave the specimens, proof reports, worksheets and labels in the Pap collection box in Cytology. Prepare them as follows:

PROCEDURE:

1. Separate the strips of labels and keep them in order by accession number (lowest to highest).
2. Check the proof reports against the computer orders to make sure the information has been entered in the computer correctly. If you find typos or if you find that information has been entered incorrectly or omitted, make the correction in the computer. **Staple multiple pages on same patient together**. Clip all proof reports together, making sure they are in accession order.
3. Make up a Big Brown paper bag by labeling it with "**INTERSCOPE PICKUP**" AND THE DATE OF PICK UP.
4. Place a label on the specimen jar, checking to make sure the names match. Place in the brown bag.
5. If a specimen container is received in the lab without orders in the EHR, the clinic or submitting clinician is called and asked to rectify this.
6. If an HPV order is also received, an HPV form is filled out and submitted together with the

specimen.

7. To ensure that all Pap smear specimens with additional HPV orders are appropriately submitted, the computer is checked for outstanding orders at appropriate intervals, at least one weekly.

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L.CYT.39 Specimen Rejection Criteria

COPY

PURPOSE:

In order to maintain a high level of quality and patient safety, specimens that are unsatisfactory will not be processed. All procedures must be followed to minimize the risk of specimen rejection and delays in processing.

POLICY:

Unacceptable specimens will not be processed.

1. Each specimen container (or in the case of smears, each smear) must be labeled to include two patient identifiers including the patient's name and the medical record number or date of birth. If a specimen from more than one site or source is received from a patient, each specimen container or smear must also include a way of distinguishing the specimen (e.g., description of source of specimen or a number or letter).
2. Each set of specimens from a patient must be accompanied by a pathology or Gyn cytology accession in the computer which includes the patient's name; a hospital ID number or date of birth, or other patient identifying information; the requesting physician's name; the date (and for body fluids, the time) the specimen was obtained; and identification of the source of the specimen(s). For tissue and non-Gyn cytology specimens, pertinent clinical information including a preoperative or postoperative diagnosis is desirable.
3. Each specimen must either be received in the proper fixative (usually 10% formalin or 95% ethyl alcohol). In the event specimens are received unfixed or unrefrigerated for an extended period or is received with the outside container surfaces contaminated, all efforts will be made to salvage the specimen for microscopic examination and the referring physician/clinic contacted to prevent recurrence and be made aware of possible compromise to examination

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of the tissue. If received fresh (for frozen section, cultures, or other special indication), there must be a person in the laboratory at the time the specimen is received who is familiar with pathology/cytology procedures and is qualified to process the specimen immediately.

NOTE:

- If any of the above requirements is not met, the specimen cannot be accessioned and processed. The specimen will be returned to its place of origin (surgery, 3-West, etc.) and the responsible party (nursing supervisor, requesting physician) will be asked to correct the problem or obtain a new specimen.
- If there is a question about specimen preservation, the specimen will be processed and a statement regarding the adequacy of the specimen will be included in the report when specimen handling is suboptimal. A clotted specimen is not grounds for rejection. A broken slide will be accepted if it can be processed.

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L.CYT.4 Sputum Collection and Handling

COPY

PURPOSE:

Most studies indicate a lung cancer detection rate of approximately 30% utilizing a single specimen for cytological study. 50% to 60% detection is found with two specimens and 70% to 80% with three or more. Therefore, a sputum series consists of fresh, unfixed specimens obtained daily in the morning for three days.

PROCEDURE:

SPUTUM CONTAINER:

1. Use a clean, dry sterile cup specimen container.
2. Fill out cytology request form with proper patient identification, age, source of specimen, and pertinent clinical data.

NOTE: Some patients may submit daily series of early morning sputum specimens. In these cases, a separate request form must accompany each individual specimen.

SPUTUM COLLECTION AND HANDLING PROCEDURE:

Patients unable to produce satisfactory sputum:

1. Give patient a clean, dry specimen container the night before.
2. Instruct the patient to cough deeply upon awakening and expectorate all sputum (not saliva) into the container.
3. Enter the relevant orders into the EHR system.

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4. Take the specimen to the Laboratory.
5. Repeat the above for three consecutive days.

Patients unable to cough up a representative sputum specimen due to partial obstruction, severe inflammation, or both:

1. Administer a regimen of broad spectrum antibiotic, expectorant and bronchodilator for five (5) days.
2. On the third day of therapy begin a sputum series as in #1 above.

NOTE:

- A good specimen for cytology frequently is obtained immediately post IPPB therapy. If both procedures are requested on a particular patient, they may be advantageously combined and ordered through Physical Therapy.
- If the specimen is collected after lab hours, please add Saccomanno fluid (available in histology laboratory) to the specimen and mix well. It does not need to be refrigerated.

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Policy Area	Laboratory Services - Cytology

L.CYT.40 Gastric Washings

COPY

PRINCIPLE:

Successful gastric cytology examination is dependent upon preparation of the patient.

The patient may have a light supper the night prior to the test, but no breakfast the morning of the test.

The patient is not to NPO overnight, but instead should be well hydrated. **Encourage a large fluid intake** until approximately one hour before the test begins.

If retention is encountered, the stomach may be emptied by overnight Wagensteen suction.

If it is necessary to cleanse debris from the stomach with large volumes of saline, the examination must be postponed until the following day, since exfoliated cells will also be washed away.

Gastric cytology is contra-indicated for 3 to 4 days following a Diagnex Blue test. The dye crystals negate the cytologic findings.

SPECIMEN:

1. Use a 16 or 18 Fr. Levine tube, emesis basin, and cell-U-wipes.
2. Fill out Cytology Request forms with proper patient identification, age, source of specimen and pertinent clinical data.
3. **Intubation**: A 16 or 18 Fr. Levine tube should be passed by mouth a distance of 60 cm from the incisor teeth. The tube should not be passed through the nose, because respiratory epithelial cells are easily confused with gastric epithelial cells. The patient should be told not to swallow saliva during the procedure, but to spit it out in the emesis basin.

4. **Lavage**: Lavage with 500 ml or more, if necessary, normal saline to get rid of excess mucus. Lavage with a second 500 ml normal saline or Ringer's solution. This portion contains the best preserved cellular material.

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Policy Area	Laboratory Services - Cytology

L.CYT.5 Material Obtained at Bronchoscopy or Endoscopy

COPY

PRINCIPLE:

Specimens for cytologic examination may be obtained during bronchoscopy by aspirating secretions, by brushing suspicious areas of the bronchial or gastric mucosa and by washing the area with saline. Because the method used depends upon the bronchoscopic or endoscopic findings and because the findings cannot be predicted before the procedure, the physician must be prepared to use any one or a combination of the three methods.

SPECIMEN:

1. Use frosted end glass slides.
2. Obtain fixative, either a spray type or a Coplin jar with absolute reagent alcohol.
3. Obtain bottles of 10% formalin, obtained from the Tissue Laboratory, for biopsies or tissue fragments which may be encountered.
4. Use chemically clean containers for collecting aspirations or washings. (The sterile tubes which accompany the bronchoscopy setup are satisfactory. No preservative is necessary.)
5. Obtain brushes used for the bronchoscopy or endoscopy procedure.
6. Enter the relevant orders in the EHR system.

PROCEDURES:

Aspirations (Bronchial or Gastric)

1. Aspirate secretions as they are encountered and collected in a chemically clean container.
2. Label the container with the patient's name and area from which specimen was obtained.

Direct Smears (Bronchial or Gastric)

1. Brush the surface of suspicious areas.
2. Roll the brush on the glass slide and immediately apply fixative. Label the slide with the patient's name and the areas from which the specimen was obtained.

Bronchial Washings

1. Turn the patient so that the bronchus in question is independent.
2. Fill the bronchus to its carina with normal saline.
3. Allow the saline to stay in contact as long as possible.
4. Aspirate the washings into a clean container labeled with the patient's name.

RUSH all fresh specimens and smears to the Cytology Laboratory to prevent the degeneration of cells.

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L.CYT.6 Body Cavity Fluids (Pleural, Peritoneal, Pericardial)

COPY

PRINCIPLE:

Body fluids should be submitted fresh and unfixed.

Exfoliated cells deteriorate very rapidly in effusions and speed in processing is essential to obtain representative material.

The entire tap (not just an aliquot) may be submitted to the Cytology Laboratory.

POLICY:

SPECIMEN:

1. Have ready a container for collection. Label with proper patient identification and source of specimen.
2. Obtain equipment for paracentesis, thoracentesis, etc. from Central Supply.

ROUTINE PROCEDURE:

1. Perform tap in the usual manner.
2. Without delay, send the specimen to the Histology Laboratory.
3. Enter the relevant orders into the patient's chart.

AFTER-HOURS PROCEDURE:

To be followed at night, on weekends or anytime the Histology Laboratory is unattended.

1. Follow Routine Procedure, steps 1 and 2, above.
2. Hand the specimen to the person at the front desk of the Laboratory.
3. **NOTE**:
    1. If the tap is an exceptionally large one, submit an aliquot of 200-300 cc.
    2. Some fluids may be unsatisfactory for evaluation even with attempts at preservation and refrigeration, so all efforts should be made to perform taps on Monday – Friday between the hours of 0700 and 1700 when the Cytology Laboratory is open.

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L.CYT.7 Urinary Tract Specimens

COPY

PRINCIPLE:

The urine may contain tumor cells from the bladder, ureter, renal pelvis or kidney. Voided urine from males is satisfactory for cytologic examination but bladder urine from females should be obtained by catheterization or by a “clean catch” to prevent contamination by vaginal cells. When neoplasms of the upper urinary tract (ureter or kidney) are suspected, ureteral catheterization is helpful in determining which side is involved.

SPECIMEN:

Except for ureteral catheterized specimens, which are usually of smaller volume, 50 to 100 cc is considered sufficient. A specimen collected over a period of time is not desirable. Fresh urine, unfixed, is satisfactory, but if any delay in processing the specimen is anticipated, an approximately equal volume of reagent alcohol should be added and the specimen refrigerated for preservation of the cells.

1. Provide a clean container to collect the urine.
2. Enter the orders for a non-gynecological cytology in the EHR system.
3. Submit specimen and forms to the Cytology Laboratory.

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Policy Area	Laboratory Services - Cytology

L.CYT.9 Image Guided Thyroid Fine Needle Aspiration

COPY

PURPOSE:

Image guided thyroid fine needle aspiration is a minimally invasive diagnostic procedure designed to obtain representative cellular material from thyroid nodules for cytologic evaluation using ultrasound guidance. Diagnostic reliability depends on proper needle technique, gentle handling of fragile cells, immediate slide preparation, and appropriate fixation. Rapid processing preserves cellular morphology, reduces air drying and clot artifact, and optimizes material for both direct smears and ancillary studies such as cell block preparation.

PROCEDURE:

MATERIAL FROM LAB REQUIRED:

1. Coplin jars with 95% alcohol for Pap smears
2. 95% Alcohol containing tube for cell block and holder for stability
3. Slide folder
4. Glass slides

FINE NEEDLE ASPIRATE AND BIOPSY GUIDELINES:

1. Open all containers before start of procedure.
2. Use one needle for multiple passes into each discrete nodule/lesion.
3. Prepare 2-3 smears and place immediately into the Coplin jar with 95% alcohol (fixer solution).
4. Prepare 2-3 air dried smears, let them completely dry and place in the slide holder.

5. Aspirate some of the 95% alcohol from the conical tube into the syringe and vigorously rinse the needle with this alcohol. The residual aspirate and needle rinse material should be squirted into the conical tube. This will be used for a cell block if adequate.
6. If a needle core biopsy is obtained, the tissue should be put in a nylon bag and the bag put into a specimen container with formalin. If multiple core biopsies are obtained from the same lesion, they should all be placed in the same nylon bag and there should only be one formalin container per discrete nodule/lesion.

THE FOLLOWING SHOULD BE SUBMITTED TO PATHOLOGY/ CYTOLOGY FOR EACH DISCRETE LESION/MASS:

1. 2-3 air dried smears, labeled with patient's name.
2. 2-3 fixed smears (in Coplin jar), labeled with patient's name.
3. Any residual aspirate and needle rinse in 95% alcohol containing conical tube, properly labeled.
4. Any needle core biopsies in nylon bag placed in a formalin filled container, properly labeled.

COPY

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L.HIST.01 Specimens Exempt from Pathology Examination

POLICY:

COPY

Specimens removed during a surgical procedure are ordinarily sent to the pathologist for evaluation. Limited categories of specimens may be exempted from this requirement because these specimens by their nature or condition do not permit productive examination or rarely, if ever, show pathologic change.

If such a specimen is submitted for pathologic examination, the operating physician must document the nature of the specimen in the medical record and accept full responsibility for exempting the specimen from examination by a pathologist. At the discretion of the operating physician, the following list of specimens may be exempt from pathologic examination:

- Cataracts
- Orthopedic hardware and prosthetic devices
- Therapeutic radioactive sources
- Breast implants
- Foreign bodies (e.g., bullets) that for legal reasons are given directly, in the chain of custody, to a law enforcement representative
- Foreskins from circumcision of a newborn infant
- Placenta that are grossly normal and have been removed in the course of operative and nonoperative
  obstetrics
- Excised scars from previous cesarean sections
- Scribner shunts, Hickman catheters, or other vascular access devices
- Sutures removed at surgery.

Specimens that fall under these categories should be disposed of by the department from which they . - came according to that department's specific policy and procedure.

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L.HIST.03 Collection and Handling of Tissue Specimens

COPY

PURPOSE:

Accurate pathologic diagnosis requires good cellular preservation and proper specimen identification. The following procedure should be adhered to insure proper handling and identification of tissue specimens.

PROCEDURE:

1. All surgically removed material, unless specifically exempted from pathologic examination by the medical staff, must be sent to the laboratory. A list of those specimens exempted from pathological examination is available in the laboratory and in the medical staff office and in Policy Stat under policy title "*Specimens Exempt from Pathology Examination*".
2. Each tissue specimen must be placed in a properly labeled container, which bears the name of the patient, tissue source, and additional patient identification such as hospital identification number, date of birth, or social security number. Tissue from doctor's offices will be accepted if there is enough information on the specimen container to permit definite identification of the patient from which the tissue was obtained.
3. When tissue is obtained from more than one site, the tissue from each separate site will ordinarily be placed in a separate properly labeled container, which clearly distinguishes the source of each portion of tissue.
4. Tissue specimens for routine pathological examination should be placed in a proper size container and submerged in 10% formalin. There should be at least five parts formalin to tissue by volume.
    i. **Note: C**ertain tissue specimens require special handling (frozen section, hormone receptors, electron microscopy, immunofluorescence) as described below.
5. Tissue specimens for which microbiological cultures are requested should not be placed in

formalin, but should be placed in sterile container without fixative and transported to the laboratory immediately.

Alternately, a portion of the specimen may be removed in the operating room under sterile conditions and submitted separately for cultures. The remaining portion of tissue may then be placed in formalin and submitted for routine processing.

6. Certain tissue specimens may require special handling and discussion with the pathologist prior to placement of the tissue in any fixative is recommended. Special instructions exist for the tissue for electron microscopy, frozen section, and other special studies.
7. Specimens which are too large to fit into a container should be wrapped in plastic or fabric towels, properly labeled, and sent to the laboratory as soon as possible. Laboratory personnel will then put the fresh specimen in the microbiology refrigerator immediately upon receipt of the specimen. Laboratory staff will notify on call grossing pathologist of the specimen or leave a written note on the grossing area desk, which clearly states "specimen in micro refrigerator," with the specimen number, and date.
8. Specimens collected during off-hours (when the laboratory is not staffed) and which are too large to place in formalin within the usual specimen containers, must be placed in the microbiology refrigerator in the laboratory by nursing (or someone assigned the task by nursing). The person who puts the specimen in the refrigerator must write "specimen in micro refrigerator" on the "After Hours- Non GYN Cytology Fluids" instruction sheet located in the pathology lab at the cytology counter, this form is to be placed on the counter for the histologist.
9. All tissue specimens must be accompanied by a proper specimen label both affixed to the specimen and the residual labels placed in dry pouch of the biohazard specimen bags. These labels have patient identifiers with or without bar code, but must contain patient name, date of birth, the date and time the tissue was obtained, the source of the tissue, the name of the physician who performed the procedure, preoperative and/or postoperative diagnosis, and any additional relevant clinical information to be obtained in LIS.
10. When accessioning the specimens, if possible, accession the specimens from the same organ system together as a separate group from the specimens from other organ systems to minimize the possibility of mixing up the specimens (1.e., gastrointestinal specimens should be given alternating numbers, with the intervening specimens being something like gallbladder, placenta, or cervical biopsies or skin tissue, etc.).
11. After placing the label on the slide, if the tissue does not meet all expectation peel the label back to make sure the number and name on the slide concurs with the number and name on the label.
12. Frozen sections should be processed and reported to the surgeon in an expeditious manner (usually less than 20 minutes in routine cases). These frozen section slides are to be made up of permanent slides retained in pathology.
13. A written report will be sent to the surgery suite to be uploaded and attached to the patients chart with the second copy to be retained in the surgical pathology department to accompany the surgical pathology report.
14. The empty specimen containers will be retained in pathology for at least four (4) weeks after the case has been grossed.

COPY

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L.HIST.04 Specimen Identification

COPY

PURPOSE:

To ensure adequate identification of every specimen at all times during the process and examination steps.

POLICY:

RECORDS:

All specimens received will be entered-and accessioned in LIS. The specimen will be assigned an accession number. If two or more specimens are submitted for the same patient, the letters "A", "B", etc., will be added to the accession number. The information recorded shall include the patient's name, age, source of specimen, and the physician requesting the test.

Minimum information provided by the submitter must include:

- Source of Specimen (Anatomic site)
- Patient's Full name
- Date of Birth
- Medical Record Number
- Date and Time of Collection

Each report shall identify the pathologist who examined and evaluated the specimen.

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L.HIST.05 Accessioning Surgical Specimens

COPY

PROCEDURE:

Accessioning Steps:

1. After logging in to Cerner open the **Maintain Case** and **Specimen Log-In** icons.
2. In the M**aintain Case** window, click **Cancel**
    a. Select the "Log in Specimens" icon in the top left comer
    b. Look up the patient by MRN or name
    c. Select the correct encounter for the patient according to the date of collection
    d. Select the prefix **T**
3. In the **Specimen Log-In** window click **Retrieve**
    a. Enter the accession number located in the **Maintain Case** window and verify at least two patient identifiers and the specimen source
    b. Select **Log-in**
4. Continue in the **Maintain Case** window
    a. Delete the blank **Special Stains and Requests** and select **Save**
    b. Select the Grossing Pathologist
    c. Double click **Source**
    d. Select the source of the specimen from the drop-down menu
    e. In the "Description" enter the corresponding ID letter
    f. Verify the date of collection and select **OK**
    g. Save the case

h. Write the ID letter and Case Number on the top of the lid then affix the label on the side of the container

i. Choose cassette size: **H1 = large, H2= small**

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L.HIST.06 Outside Slides

COPY

POLICY:

Slides from other institutions are sometimes received for patients undergoing treatment at this hospital. On every case there must be, in writing, identification of the patient by name and outside pathology accession number(s).

This identification is accomplished by, in order of preference:

1. An accompanying report with matching name and number on it.
2. A letter of identification from the outside pathologist. Identification on our requisition form from the ref erring clinician.
3. Identification on our requisition form from the referring clinician.

The gross description should be a description of the pathological material received, its accession number, a statement about the type of identification, and the name of the certifying person.

Example: Received are 2 slides labeled **OC-17-1, A & B**, Outside Memorial Hospital, Townsville, CA. They are identified in a protocol from Outside Pathologist MD as being slides of tissue of A.B. Jones.

A cover letter, copy of our report, as well as any pertinent follow-up information, should accompany the slides, which are to be returned to the outside hospital.

In cases in which the outside hospital has given permission for the slides to be retained by our institution, the slides should be labeled with our accession number, in such a way so as not to obscure the outside hospital accession number, are filed with our slides.

A copy of our report and follow-up information should be sent to the outside hospital.

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L.HIST.07 Preparation of Tissues

COPY

PURPOSE:

Proper fixation of all tissue received in the histology laboratory

PROCEDURE:

1. The foundation of all good histologic preparation is adequate and complete fixation. Fixation is required to:
    a. Prevent postmortem changes such as putrefaction and autolysis.
    b. Preserve various cell constituents in as life-like manner as possible.
    c. Protect by hardening the naturally soft tissue, thereby allowing easy manipulation during subsequent processing. ,
    d. Convert the normal semi-solid consistency.
    e. Aid in the visual differentiation of structure by application of biological dyes and chemicals.
2. To accomplish these objectives the tissue should be placed in the fixative immediately upon removal from the body or as soon after death as possible.
3. The choice of fixing agent should be determined by the purpose for which the tissue is to be stained or preserved.
4. The fact that many specimens may be ruined, by poor handling subsequent to proper fixation, has been proven. This generally occurs when one fails to realize that the different fixatives require varied times to effect complete fixation; and the specimen may require a particular treatment, immediately following fixative, to ensure retention of specific staining properties.

FIXATIVES AND THEIR PROPERTIES

- 10% Formalin:
    - 10% Formalin is the most used and perhaps the best fixative for general use. It is rapid in action and permits the use of a broad spectrum of staining methods.
- Full-strength formaldehyde (34-40%) - 10 mL
- Distilled Water - 90 mL

REFERENCE:

Armed Forces Institute of Pathology, (1960, p. 3)

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L.HIST.09 Processing Tissue

COPY

POLICY:

1. Processing of tissue includes dehydration, clearing, impregnation and embedding. A specimen brought to the laboratory is given an identifying number. Keep this number with the specimen throughout processing.
2. Processing by paraffin technique is accomplished most rapidly and gives the best results when thin sections of soft tissue are desired. Since paraffin is not miscible with water, the tissue must be dehydrated and then cleared in solutions miscible with paraffin before impregnation.
3. Well processed tissue is achieved by a step by step infiltration of the required reagents, each preparing the tissue for the one to follow, so that the end result will be a section closely resembling the living state of the specimen. Every cell should be recognizable as to type, enabling the pathologist to focus all his attention on the cell pattern that determines the diagnosis. Properly fixed tissue is essential, as the following steps of processing build upon it.
4. Dehydration is the removal of extractable water. Alcohol is the most commonly used dehydrant starting with 70%, continuing through 95%, and then 100% alcohol.
5. Clearing reagents must be miscible with the dehydrant and the paraffin. As the dehydrant is removed, the tissue clears, becoming translucent signifying the completion of the process.
6. Impregnation is the complete removal of the clearing reagents by substitution, as the paraffin penetrates the tissue with the use of two paraffin baths. Our laboratory uses paraffin with a melting point of 56 to 58 degrees C.
7. Embedding is the orientation of tissue in melt provides a Parts of the tissue intact when sections are cut.
8. The Tissue Tek-VIP is the name of a machine that automatically fixes, dehydrates, clears and impregnates tissue.

PROCEDURE:

TISSUE TEK-VIP PROCEDURE

Step #	Description	Timing (hours+minutes)	Solution
1		30m	10% Formalin
2	Fixation	2h 30m	10% Formalin
3		30m	70% Alcohol
4	Dehydration	30m	95% Alcohol
5		30m	95% Alcohol
6		30m	100% Alcohol
7		30m	100% Alcohol
8		40m	100% Alcohol
9	Clearing	40m	Xylene
10		40m	Xylene
11		30m	Paraffin
12		30m	Paraffin
13		30m	Paraffin
14		30m	Paraffin

COPY

SCHEDULE FOR CHANGING OF SOLUTION OF LAB-TEK TISSUE PROCESSOR

1. Solutions are changed on Wednesday (unless the load of surgicals is exceptionally heavy).
2. Discard 1st formalin, move 2nd up and put fresh formalin in 2nd place.
3. Discard 70% alcohol, 1st 95%, 1st 100% and move remaining containers up and put fresh alcohol in 2nd posltlon.
4. Discard 1st xylene move 2nd up and put fresh xylene in 2nd position.
5. every 2 weeks discard 1st paraffin and move 2 up, and 3 up, put fresh paraffin in 4th position.

REFERENCES:

Miles Laboratory

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L.HIST.11 Special Stain Techniques

COPY

PURPOSE:

To render the best possible outcome of slide stain and sectioning for the pathologist for diagnostic purposes.

Fresh, completely unfixed tissues or tissues that have been briefly fixed with formalin can be cut directly without embedding, on a cold microtome or cryostat. With frozen sections, the pathologist can often make a diagnosis in a few minutes rather than waiting the many hours necessary to prepare tissue by the routine paraffin method. Frozen sections are also used for study of fatty or lipoid material that would be dissolved out in the paraffin process, which employs alcohol and other fat solvents.

PROCEDURE:

Staining Frozen Sections:

1. Fix in Frozen Section Solution (RFS):
    a. 320mL Reagent Alcohol
    b. 80 ml 10% Formaldehyde
    c. 4 ml Glacial Acetic Acid
2. Rinse in distilled water.
3. Stain in Hematoxylin for I minute.
4. Rinse in tap water.
5. Rinse in distilled water.

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6. Blue in ammonia water.
7. Rinse in distilled water
8. Stain in eosin for 1 minute.
9. Dehydrate in 1 change of 95% alcohol.
10. Dehydrate in 4 changes of reagent alcohol
11. Clear in 3 changes of xylene.
12. Use Mounting Medium and coverslip

Preparation of Bone Sections

1. Because of its hard nature bone requires special treatment. Before bone or any calcified tissue can be processed and sectioned, it must have the lime salts removed. This process is called decalcification. The bone specimen must be cut into fairly small pieces first to allow penetration of the decalcifying solution. As soon as the small sections are obtained, the bone must be fixed to preserve and toughen the soft tissue and cellular structures attached to it. 10% formalin is sufficient fixative for bone sections. After fixation (3 to 24 hours), the tissue must be washed thoroughly to remove the excess fixative. It is then ready for decalcification.
2. Decalcification of the fixed, washed tissues should be carried out at room temperature in large jars with the decalcifying solution added generously.
3. The tissue may be checked to determine whether it is soft enough to cut by inserting a needle into it. If the needle enters the section easily, the bone is ready to be processed.
4. After tissues are decalcified, it is necessary that they be washed thoroughly in running water for 1 to 3 hours to remove the last traces of the decalcification solution.

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Decalcifying Solution (Leica/SurgiPath)

Decal I for Bone Marrows

- Formaldehyde
- Methanol
- Formic Acid

Decal II for all other Bone and Calcified tissue

- Hydrochloric Acid
- EDTA

Preparation of Bone Marrow Aspirates In Sections (See Full Bone Marrow Specimen Processing):

Bone marrow aspirates and biopsy cores are fixed in 10% formalin for at least 1 hour. After fixation the tissue is rinsed thoroughly in running water. If the specimen is soft enough it is then ready to be processed. The core is wrapped in lens paper and rinsed under tap water for 20 seconds before it is placed in the formalin.

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Cytology (Papanicolaou: Cell Block):

Papanicolaou slides are prepared using the Shandon Cytospin 4. Centrifuge the specimen at 1000 RPM for 5 Minutes. Using a pipet, take about 1mL of liquid and place in a glass centrifuge tube. Label 2 Cytospin slides with the Case Number and Patient's Last Name before placing the slides in the Cytosep Single Funnel. Aliquot one drop of liquid into each Cytosep and centrifuge at 1000 RPM for 5 minutes. Pap smears are fixed in 95% isopropyl alcohol. While some types of smears will be fixed in 15 minutes, a minimum of one hour will permit better penetration of the cells and the smear will adhere to the slide better.

Cell Block

1. It is possible to prepare pleural, ascetic, or other body fluids and to section them using the paraffin-embedding technique. The method has proven to be both simple and reliable. This procedure is often used for diagnosis when cancer is suspected. If a delay in processing is anticipated, refrigerate the material to prevent decomposition.
2. Centrifuge the specimen at 1000 rpm for 5 minutes. After the fluid is spun down and material is taken for cytospin slides, pour off the supernatant fluid, leaving the cell sediment in the bottom of the test tube. Add 4 drops of Histogel for every 1mL of sediment. Centrifuge at 1000 rpm for 5 minutes. If the sediment (bottom) does not fall out readily when the tube is inverted and tapped, remove with a wooden or metal applicator stick. Wrap the recovered sediment in fine lens paper and place in tissue capsule. The material is then processed by the Tissue Processor. The cell block is embedded and then sectioned on a rotary microtome.

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L.HIST.13 Policy For Retaining Tissue Obtained From Surgery

COPY

PURPOSE:

To Define the site of storage and method of disposal of wet tissue once reports have been issued.

POLICY:

- An appropriate space has been provided in the Laboratory and on Hospital grounds for the storage of tissue.
- On a daily basis, the tissue will be stored in the red containers or transported to the storage area and stored on the appropriate shelves.
- The tissue will be retained for a period of up to 31 days and the tissue will be disposed of at the end of that time.
- The tissue will be transported to the storage area by one of the histotechnicians or a designated person in the laboratory.
- The tissue will either be discarded by one of the histotechnicians or their designees. Any tissue which is felt to be necessary to retain more than the prescribed period will be stored in the main Histology laboratory on a designated shelf.

Surgical or Obstetric specimens, which have no orders must be disposed of according to their specific department policy and not sent to the laboratory for disposal

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L.HIST.14 Sending Pathology, Cytology, and Autopsy Material to Outside Institutions, Consultants, or Other Entities

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PURPOSE:

1. There will be occasions when a second pathologist's opinion is desired, special stains are needed, for when a patient is referred elsewhere for treatment and pathology/cytology material will be sent to an outside institution or consultant. There may also be occasions when slides or blocks may be subpoenaed by an attorney or other entity. In order to assure that representative and diagnostic material is retained by the laboratory as required by regulatory agencies, good medical practice, and good medical judgment and also to assure that outside institution, consultant or entity receives representative and diagnostic material, the following procedure must be followed. Further discussion may be found in the Laboratory Policy for sending pathology/cytology material to outside institutions, consultants or entities which is included in the Laboratory Policy Manual
2. In the interest of the best patient care, the laboratory will try to accommodate a physician's request to send pathology/cytology material to outside institutions or consultants, an to appropriately respond to subpoenas for slides or-blocks.
3. However, in order to comply with current regulations, good medical practice, and good medical-legal judgment, proper record keeping is essential and it is necessary that diagnostic material (preferably both microscopic slides and tissue blocks) be retained in the laboratory. It is also important that the institution, consultant, or entity to which the pathology/cytology material is sent be given representative and diagnostic material.

   In order to satisfy these demands, and in recognition of the practice of many outside institutions and consultants to retain microscopic slides sent to them for consultation, it is usually necessary to have a pathologist review all of the microscopic slides so that both the

laboratory and the outside institution, consultant, or other entity are assured of having representative and diagnostic material.

4. For the above reasons any reasons, any request to send pathology/cytology slides or blocks to an outside institution, consultant, or entity must be directed through the hospital pathologist. Because additional microscopic slides will usually have to be prepared, at least one working day and preferably two working days will be needed to accommodate any request to send requests to send out slides or blocks with less than this required notice will be honored as quickly as possible under the constraints discussed above.
5. At no time are microscopic slides or blocks to leave the laboratory without first being reviewed and approved for send out by the pathologist.
6. An accurate and complete log of all microscopic slides and blocks sent to any outside institution, consultant, or entity must be maintained in the laboratory. This log must include surgical pathology or cytology number on the slide(s) or block(s), the patient's name, the name and address of the institution, consultant, or entity to which the material is sent, the date the material is sent, and the date the material is sent, and the date the consultant's report and any returned slide(s) or block(s) returned. The detailed procedure for sending pathology/cytology material to outside institutions, consultants, or entities is found in the Laboratory Procedure Manual.

PROCEDURE:

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1. Any request to send microscopic slides or blocks out should be received by the laboratory at least one working day and preferably two working days in advance. Requests received without this much notice will be handled as quickly as possible so long as necessary laboratory retention of records, reports and mAterial is not compromised.
2. The histotechnologist, or transcriptionist will pull the patient's surgical pathology/cytology slides for the pathologist to review along with the signed release of records.
3. The pathologist will select the case(s) which are appropriate for send out and will advise the histotechnologist or transcriptionist to copy all pathology/cytology reports and to retrieve all slides/blocks from the case(s) selected for send out.
4. Representative and diagnostic material must be retained by the laboratory at all times. Because the outside institution or consultant will probably keep the slide(s) sent for consultation, it can be expected that additional sections will have to be prepared from the block(s).
5. With this is mind, the pathologist will review the slide(s) fro the case(s) selected for send out, and will ask the histotechnologist on the next regular working day to cut any additional section which will be needed so that at least one slide from each block is retained by the laboratory.
6. If a block is sent out, the laboratory should retain at least two slides prepared from this block in the event that one slide breaks or must later be sent elsewhere. When a block is sent out, the slides prepared from this block should have “SAVE” written in red on the slide label to serve as an alert that these slides are all that remains of this section of tissue.
7. AFTER the histotechnologist has prepared any additional slides, the pathologist will review the slide(s) and select the slide(s) which will be sent out and the slide(s) which will be retained by the laboratory.

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8. Copies of all pathology/cytology reports and the selected slides will be sent where requested and must be properly logged out.
9. In the event of an emergency or other special or unusual circumstance, the pathologist, and no one else, may authorize that the only slide(s) already available be sent out if the block(s) will be retained by the laboratory and if the pathologist has reviewed the slide(s) and the block(s) and is confident a representative and diagnostic slide can be prepared from the tissue in the block(s). A slide will be prepared from this block the next working day and this slide will be retained by the laboratory.
10. Cytology specimens present a special problem because there may not be a block. At least one representative and diagnostic smear must be retained by the laboratory whenever possible.
11. If, because of the most unusual circumstances, the laboratory is forced to send out all representative and diagnostic material, the institution, consultant, or entity to which this material is sent will be advised that the laboratory has sent them all of the available material and will be asked to return at least some representative or diagnostic material for the laboratory files. Only the pathologist can authorize sending out all representative and diagnostic material. If appropriate material is not returned follow-up letters and telephone calls will be made.
12. Any slide or block taken from the laboratory must be logged out of of the slide send-out area of the LIS for surgical pathology/cytology. This must include the surgical or cytology number on the slide(s) or block(s) sent, the patient's name, the entity to which the material is sent and the date the consultant's report and any returned slides or blocks are received as well as the number on the slide(s) or block(s) returned. This information must be entered into the LIS upon return of the slide/blocks.

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L.HIST.17 Calculus (Stone) Analysis

COPY

PURPOSE:

To ensure that all kidney stones will be analyzed and there will be appropriate treatment based on results of analysis.

POLICY:

Requisition Receipt

When a requisition comes in for any calculus (ureteral, kidney, bladder stones), give it to one of the histologists in the Pathology Department prior to entering it into the computer. The histologist will give it a surgical pathology accession number. The pathologist will dictate a gross description. The histologist will then give it back to the front office staff to be entered into the computer. Make sure the histologist wrote the surgical pathology accession number on the Routine requisition slip. Enter it into the computer as usual and deliver the slip and the specimen to the Chemistry Send-out area.

Results Receipt:

Calculi are sent to the Reference Laboratory for analysis. Therefore, the results will come back on a Reference Laboratory computer print out.

Make one copy of the entire report for our Monthly Send-out file.

Give the original to the Pathology Transcriptionist and she will distribute the reports to the chart and appropriate physicians, attached to the Surgical Pathology report.

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L.HIST.18 CT-Guided Biopsies and Fine Needle Aspirate (FNA)

COPY

PROCEDURE:

1. A specimen that was taken from the same source and same container, and then divided, shall be treated as a single specimen.
   EXAMPLE: If a fluid has been sent to us from one source, and we make smears, and then spin it down to make a cell block for processing, the specimen is a single specimen and not to be regarded as two separate specimens and given designations of (A) and (B).
2. If FNA slides are prepared at the time of collection and submitted with fluid/biopsy from the same source, the fluid/biopsy and the smears are two separate specimens and given the designations of (A) and (B).
3. If we receive a needle core biopsy that is suspended in saline, and if the pathologist thinks the saline might be needed for cytospin in the future, it will be placed in alcohol and preserved until needed, or until the report is signed out. If however, he/she feels the solution should be processed at the time it is received, it will be considered part of the biopsy specimen (in a single specimen).
4. Thyroid aspirates are always one specimen (fine needle aspirate).

HORMONE RECEPTOR ASSAYS - BREAST

Hormone receptor assays are useful in determining prognosis and treatment of breast carcinomas. Proper handling is essential to assure accurate results. The following procedure will be followed:

1. If the pathologist is available, the pathologist will handle the tissue immediately. IF the pathologist is not in-house, formalin will be placed on the tissue to allow it to start to fix immediately, and the pathologist will be notified.

2. The specimen will be examined at the cutting table and appropriate sections of the tumor will be embedded.
3. An appropriate block and representative slide of the lesion will be sent to our reference laboratory (Neogenomics, Quest, US Labs, etc.)
4. Once the results of the receptors are received from the Reference Lab, a copy of the results will be appended to an addendum report, which is distributed to all locations (chart room, clinics, etc.) and doctors associated with the specimen.
5. ASCO regulations concerning the amount of fixation necessary to obtain adequate ER/PR and HER/2 neu results, the time of the removal of the biopsy specimen or the core needle biopsies and the time the specimen is placed in fixative (cold ischemic time) is important and must be documented. The need for this information has been discussed with the surgeons and radiologists, both at Breast Conference and Tumor Board.
6. If the removal time for the breast tissue is not provided on the initial requisition, all attempts will be made to obtain this information from the surgeon/radiologist.
7. The ASCO guidelines indicate that any specimen whose transit time from a site will cause a specimen to exceed the recommended one hour cold ischemic time prior to gross examination by the pathologist should be immersed in a neutral buffered formalin with the time of the tumor removal and the time in fixation both be recorded.
8. If the breast biopsy or mastectomy occurs late in the day or at Santa Paula Hospital, then the surgeon should make at least one cut through the lesion to allow adequate fixation for subsequent marker studies.
9. if the pathologist was available during the time of the procedures, then the specimen can be sent fresh to Pathology to be processed by the pathologist on call.
10. The current recommendation for formalin fixation interval for ER/PR, HER/2 testing is 6 to 72 hours of fixation.

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L.HIST.19 Special Preparation for Electron Microscopy

COPY

PURPOSE:

Electron microscopy may be necessary to classify a poorly differentiated neoplasm. Electron microscopy is also useful in the evaluation of certain disorders such as glomerulonephritis. The following procedure should be followed when electron microscopy is anticipated.

POLICY:

1. Whenever possible, the laboratory will be notified in advance so that fresh fixative (2.5% glutaraldehyde) can be obtained from Ventura County Medical Center.
2. 2.5 % glutaraldehyde will be kept in the histology lab refrigerator.
3. The fresh tissue will be sectioned and a small amount of the selected tissue will be cut into 1mm cubes and several cubes will be placed in 2.5 % glutaraldehyde for electron microscopy. Some of the remaining tissue may be frozen for tumor markers and some of the remaining tissue may be fixed in formalin.
4. After the glutaraldehyde is added to one portion of the biopsy, it is sent out to a reference laboratory for further evaluation by electron microscopy.

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L.HIST.23 Formaldehyde and Vapor Concentration Monitoring

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POLICY:

1. Formaldehyde and VapOr Concentrations will be monitored in all areas where reagents are used to include surgical pathology gross dissection room, histology laboratory, autopsy room, etc.
2. The initial monitoring involved identifying all employees who may/will be exposed at or above action levels and at or above STE and actually determining the exposure of each patient that is identified. After the initial formalin monitoring procedure, further periodic formaldehyde monitoring will be performed if the initial monitoring equals to or exceeds 0.5 ppm's (8 hour time weighted exposure, and action level or 2.0 ppm's STEL.
3. Initial monitoring must be repeated at any time there is a change in procedure, equipment process, personnel and control measures that will result in a new or additional exposure to formaldehyde to any employee involved in the activity.
4. The laboratory may discontinue periodic formaldehyde if results from two (2) consecutive sampling periods taken at least seven (7) days apart show that the employee exposure is below the action level and the short term exposure limit and (1) no change has occurred in the production, equipment, processing, personnel or control measures that may result in new or additional exposure to formaldehyde, and (2) there have been no reports of conditions that may be associated with formaldehyde exposure.
5. If any person reporting signs or symptoms of respiratory or dermal conditions associated with formaldehyde exposure must be promptly monitored by the laboratory concerning the effects of the person's exposure.
6. The xylene limits will be monitored initially.

	8 hr Time-Weighted Exposure Limit	Action Level (8 hr Time-Weighted Exposure)	15 min Short-Term Average Exposure Limit (STEL)
Formaldehyde	0.75	0.5	2.0
Xylene	100		150

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L.HIST.24 Intra-Operative Frozen Sections

COPY

POLICY:

1. The tissue is brought from surgery to the Pathology Department and the pathologist on call for frozen sections is made aware that a frozen section has been requested.
2. The specimen is examined by the pathologist and appropriate sections are taken for frozen section. Slides are prepared with the patient's name and assigned case number and the sectioned tissue is placed on these slides.
3. Once the frozen section is examined microscopically, the pathologist will either call the Operating Room in which the surgery is being performed, or if it is a complicated case go the Operating Room and discuss the case directly with the surgeon.
4. The pathologist will talk directly with the surgeon and ask for identification of the patient and confirm the patient's identity.
5. Once the patient is identified, the diagnosis will be rendered to the surgeon.
6. A written report will be made at this time which contains the diagnosis rendered to the surgeon and the surgeon who received the diagnosis. This document will also document the time that the specimen was received in the Laboratory, the time that the diagnosis was rendered and the pathologist making the diagnosis.
7. The remaining diagnostic tissue or representative sections, if it is a large specimen, will be submitted to allow for a more detailed examination of the specimen.
8. The frozen section slide plus the additional slides will be made part of the permanent record as will a copy of the written consultation at the time of frozen section.
9. All intra-operative consultation reports are made a part of the final surgical pathology report.

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L.HIST.26 Special Handling of Highly Infectious Cytology and Surgical Pathology Specimens

COPY

PURPOSE:

Written instructions for handling highly infectious specimens for cytology should reduce the risk of transmission of these infections to laboratory personnel.

POLICY:

Universal blood/body fluid precautions will be followed in the handling of all tissue, blood and body fluid specimens. Gloves, plastic aprons, masks and goggles are available. Masks must be worn in the handling of all specimens suspected of harboring M. tuberculosis or other mycobacteria. All non-disposable instruments, containers and equipment (including the centrifuge and the cryostat) which come in contact with highly infectious specimens must be decontaminated according to the instructions in this manual (see “Cleaning of Surgical Pathology Grossing Area and Instruments) item 4.

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L.HIST.27 Biohazard and Contaminated Waste Disposal for Surgical, Cytology, Autopsy, Blood, Body Fluid, and all Other Material

COPY

PURPOSE:

To promote and maintain employee health and safety.

DESCRIPTION:

Hospital waste for which special precautions appear prudent include microbiology, pathology and all blood and body specimens which may be found in the entire laboratory.
The following categories will give specifics as to overall disposal procedures.

PROCEDURE I:

Non Infectious Waste:
Material not contaminated with blood or body secretions are to be placed in a large brown plastic trash bag in trash receptacles. The custodial service will remove, replace and discard appropriately.

PROCEDURE II:

Infectious or bio hazardous materials:
Needles, knife blades and other sharp objects: These are placed in puncture proof sharps containers. When the containers are full, they are securely closed and disposed of as infectious waste for pickup and safe disposal. The biohazard reclaiming company will discard and safely remove the material according to their protocol.

1. Bulk blood, body fluids, excretion, suctioned materials and secretions may be carefully, to avoid aerosols, are placed (in the containers received) into the red tissue buckets and

disposed of by the biohazard reclaiming company.

2. Glass is disposed of in puncture proof Sharps containers. When full or at timely intervals, it is given to the housekeeping department for disposal according to their stated protocol.
3. Tissue specimens or body parts and wet tissue used in pathology or remaining after processing are placed in plastic tissue storage barrels for placement in the lower storage area. The tissue is stored for at least one month. After an appropriate interval, the specimens are discarded, to be destroyed by incineration by a medical waste disposal company.
4. Bio hazardous materials such as formalin and xylene are carefully poured into a waste receptacle, labeled “BIOHAZARD”. This container is stored in a bio hazard cabinet located outside of the laboratory and is then collected for disposal by a commercial disposal company.

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L.HIST.28 Frozen Section Technique for Tissues Infected by the AIDS Virus

COPY

PURPOSE:

Frozen section technique for tissues infected by the AIDS virus and the decontamination of the cryostat. The AIDS virus is known to be inactivated by 0.5% sodium hypochlorite (:10 dilution of household bleach) (3,4), 95% ethanol (3,4,5,6), and 10% formalin (6). Sodium hypochlorite is the most effective decontaminant known for the virus, but it will also corrode metal. Therefore, 95% ethanol is favored for the inside of the cryostat. The AIDS virus does survive both freezing and drying (4,6), so decontamination is essential.

PROCEDURE(S):

1. Turn off refrigeration.
2. With protective clothing in place, remove the knife from microtome and dispose of in a red container marked for sharps biohazard materials.
3. If complete defrosting is desired, pour a small amount of 95% ethanol on the floor of the cryostat chamber where water will collect.
4. Wipe all exposed surfaces inside and outside the cryostat chamber with a towel or sponge that has been soaked in 95% ethanol.
5. Replace the microtome knife using a new disposable knife.
6. Turn on refrigeration for return to desired temperature.

Another decontamination technique, recommended before the ethanol sensitivity of the AIDS virus was known, consists of placing a large beaker of 40% formalin in the closed chamber and defrosting overnight. However, the efficacy of formalin vapor for this agent is not yet known. With the formalin

vapor method, the chamber still needs to be cleaned afterward and all movable parts must be re-oiled before the cryostat is used again.

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L.HIST.29 Handling Specimens from Patients: Blood and Body Fluid Precautions

COPY

PURPOSE:

To prevent infection of health care personnel collecting and processing blood and body fluids from potentially infectious patients.

Specimens from patients that are known to have or are suspected to have Hepatitis B, and Non A Non B Hepatitis, AIDS (acquired immune deficiency syndrome), ARC (AIDS related complex), and Jakob Creutzfeldt disease represent special laboratory hazards. All specimens from these patients or any patient that has been placed under “blood and body fluid precautions” must be labeled and handled in the following manner.

POLICY:

LABELING

1. All specimens from patients with any of the above conditions are to be labeled with preprinted labels stating “Blood/Body Fluid Precautions”. Urine, feces, body fluids, cultures, and pathology specimens are to be labeled in the same manner as blood specimens with the above sticker placed in a prominent position.
2. All laboratory requisition slips are to be labeled “Blood and Body Fluid Precautions” in the space provided for remarks.
3. Any specimen labeled “Blood and Body Fluid Precautions” that must be separated or aliquot in order to be tested must have the “Blood and Body Fluid Precautions” sticker placed on all aliquots.
4. Specimens sent to Reference Laboratories must also be labeled “Blood and Body Fluid

Precautions".

HANDLING

1. Gloves should be worn to avoid skin contact with blood, specimens containing blood, blood soiled items, body fluids, excretions, and secretions, as well as surfaces, materials, and objects exposed to them.
2. Laboratory coats, gowns, or uniforms should be worn while working with potentially infectious materials and should be discarded appropriately before leaving the laboratory. Disposable gowns or aprons are provided, to be worn when there is a possibility of being splashed with blood or body fluid. The gowns are to be discarded in the biohazard "red bags" when contaminated.
3. Masks and protective eyewear are to be worn if there is a possibility of being splashed with blood.
4. Wash hands thoroughly and immediately if they become contaminated with blood or body fluid, before and after drawing patients, upon completion of laboratory activities, removal of protective clothing, and before leaving the laboratory.
5. All blood and body fluid samples labeled "Blood and Body Fluid Precautions" must be stored in closed containers, i.e., recap the test tubes after use.
6. Needles and syringes are to be placed in Sharps Biohazard Container after use. Do not recap needles.
7. Use only mechanical pipetting devices; no mouth pipetting.
8. All procedures and manipulations of potentially infectious material should be performed carefully to avoid the creation of droplets and aerosols.
9. Laboratory work surfaces are to be decontaminated with a disinfectant following any spill and at the completion of work activities.
10. All potentially contaminated materials used in laboratory tests should be decontaminated, preferably by autoclaving, before disposal.

It is required that the above protocol be followed for all patients that have been placed under "Blood and Body Fluid Precautions". It is highly recommended that all samples be treated as if they originated from patients with "Blood and Body Fluid Precautions", as there is no way of determining which patients have been exposed to AIDS virus.

COPY

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L.HIST.30 Handling of Tissues Containing Radioactive Material (Sentinel Lymph Nodes, Breast Biopsies, Prostatic "Seeds")

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POLICY:

1. Tissue with low radioactivity potential (i.e., sentinel lymph nodes, breast biopsies) may be processed like any other tissues after being allowed to sit for 24 hours before being grossed.
2. The marker used for sentinel lymph nodes is 99mTcuCi which is injected (500 uCi) into tumor at the time of imaging. Surgery is performed 4 to 6 hours later. Since the ½ life is 6 hours, only a 2 to 10 uCi will reach the lymph node by the time of surgery.
3. If a prostate or other large organ is grossed, and radiation implants are found, the grossing will stop. The radiation physician will be contacted to come and take the implants to their treatment area where counts are taken on the remaining specimen until it is safe to gross the specimen.

REFERENCE(S):

Procedure for Laboratory Sentinel Lymph Node Biopsies for Melanoma and Breast Patients. American Medical Laboratories.2/01/01.

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L.HIST.31 Handling of Shared Specimens

COPY

PURPOSE:

To ensure proper specimen handling, when multiple tests are ordered on a single specimen.

PROCEDURE:

Tissue or fluid specimens received in the histology laboratory that are marked “shared specimen” should not be placed in any fixative.

1. Check in the computer under the patient’s medical record number to verify which department(s) the specimen is to be shared with such as hematology, chemistry, send-outs or microbiology. If microbiology is ordered, send the specimen immediately to the microbiology department and let them know it is a shared specimen.
2. If any specimen is received, in the histology laboratory without fixative, check the computer under the patient’s medical record number to verify if there are other orders even if the specimen is not labeled with a “shared specimen” label.
3. Specimens should never be left in histology, after hours, without preservative. See after hour protocol. The after hour protocol should only be followed after steps 1 and 2 (above) have been completed.
4. Ideally, a shared specimen should be received with a list of the ordered tests, a shared specimen label, and sent to the appropriate department first. The department, after completing their portion of the exam, should initial the list of ordered tests indication the specimen has been completed in their department, and then hand deliver it to histology. If the specimen is delivered to histology after hours, the after hour protocol should be observed.

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L.HIST.33 Criteria For Identifying Deaths Appropriate for Autopsy

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PROCEDURE:

1. Deaths, which come under the jurisdiction of the Medical Examiner, must be reported per Administrative Policy no. 100.030. Only after a potential Medical Examiner's case has been reported to the Medical Examiner and jurisdiction declined by the Medical Examiner, can the case be considered for a hospital autopsy.
2. An Autopsy may be indicated in the following circumstances:
    1. Any death in a person with no known underlying disease or condition which would readily explain the death and where an autopsy has a reasonable likelihood of identifying the cause of death.
    2. Any death in cases of unusual educational interest where the autopsy is not more appropriately performed in a university or research setting.
    3. **Examples of cases where an autopsy may be indicated include the following:**
        a. Identification (not just corroboration), of a hereditary or genetic condition where this information would be useful to the family of the deceased.
        b. Cases where an autopsy is likely to make a significant contribution to quality assessment.
3. The physician who requests an autopsy is responsible for communicating to the pathologist a relevant clinical history and should discuss the indications for the autopsy with the pathologist. The requesting physician should state what questions he/she expects the autopsy to resolve.
4. An autopsy represents a pathology consultation. After discussion with the referring physician, the pathologist will make the final determination of the extent of the autopsy. It is the practice

of the Pathology Department to perform directed (or limited) autopsies.

5. Because of the known risks of transmission of infectious disease, the presence of certain medical conditions in the deceased represents an absolute or relative contraindication for an autopsy at VCMC. If a relative contraindication is present, the pathologist, after discussion with the requesting physician, will decide whether the information, which might be gained from the autopsy, justifies the risk of disease transmission. If the pathologist chooses to do the autopsy, the pathologist will do everything to decrease the risk of disease transmission. These extra precautions may include having the body embalmed before the autopsy and performing a limited autopsy. Because of the increased risk of disease transmission, the autopsy will generally exclude opening of the cranium or examination of the spinal cord.
    1. **Medical conditions which represent an absolute contraindication for an autopsy at VCMC include, but are not limited to:**
        1. Jacob-Creutzfeld disease.
        2. Any unexplained encephalomyopathy that might be secondary to a slow virus infection.
        3. Anthrax.
    2. Medical conditions which represent a relative contraindication for an autopsy at VCMC include, but are not limited to:
        1. HIV or HTLV infection.
        2. Hepatitis B.
        3. Hepatitis C.
        4. Hepatitis non-A, non-B.
        5. Known or suspected disseminated Coccidioidomycosis.
        6. Known or suspected disseminated (miliary) tuberculosis.
6. Because of the intended educational value of an autopsy, the physician who requests an autopsy should attend the autopsy whenever scheduling allows.
7. After completion of the autopsy, the pathologist will promptly communicate relevant findings to the physicians involved in the care of the deceased and will complete the provisional anatomic diagnosis and the final autopsy report in accordance with Medical Staff Rules and Regulations

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Owner	Amanda Lo: Medical Director, SPH Lab
Policy Area	Laboratory Services - Histology
References	100.031 Processing a Death & Post-Mortem Exam

L.HIST.34 Hospital Death Procedure

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POLICY:

Handling Coroner/Medical Examiner's Cases

A. All deaths in the following categories are Coroner Medical Examiner's Cases and he is to be notified immediately by the physician in attendance, or notification will be made by the Admitting Department, at the request of the physician.

1. Known or suspected homicides, suicides and accidents.
2. Deaths involving criminal action or suspicion of a criminal act.
3. Poisonings and deaths related to substance abuse.
4. All deaths in jail or in police custody.
5. All deaths at state mental hospitals.
6. All deaths related to occupational diseases or hazards.
7. All deaths occurring outside health care facilities.
8. All deaths wherein the deceased has not been attended by a physician within the 20 days preceding death.
9. Deaths in which a physician is unable to reasonably state a cause of death (Unwillingness does not apply).
10. Deaths involving suspected contagious diseases constituting a public hazard.
11. Deaths of unidentified persons.

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12. Deaths occurring within 24 hours of admission to a hospital.*
13. Deaths suspected to be from Sudden Infant Death Syndrome.

Immediate reporting of the above listed deaths will assure compliance with the statutory provisions of California Government Code 27491 and Health and Safety Code 10250.

*Coroner policy to assure that minimally attended deaths are reviewed.

B. It is the duty of the Coroner Medical Examiner to notify the next of kin in all deaths coming under his jurisdiction.

C. Cases which are not bona fide Coroner Medical Examiner's cases shall not be made such simply because autopsy permission has been refused, nor shall authentic Coroner Medical Examiner's cases be withheld from the Coroner Medical Examiner's jurisdiction and autopsied by the Hospital Pathologist because permission for autopsy has been obtained. To do either of the above willfully is an offense punishable by imprisonment of up to five years and a $4,000 fine. (California Penal Code, Sec. 148).

D. Bodies of all patients dying in the hospital that come under Coroner's jurisdiction are not to be released to funeral homes at the request of friends or interested parties unless the release is approved by the Coroner Medical Examiner's Office. Only the next of kin can designate the desired funeral home. The body is to be released upon their request. Close relatives living in other areas who request release of body are to be referred to the Coroner Medical Examiner for clearance. In those cases that involve the Coroner Medical Examiner, the body may not leave the County until released by the Coroner Medical Examiner. This is to be adhered to even in those situations where relatives are at the hospital at the time of death.

E. Autopsy
    1. The family of the decedent should not be approached for permission for "academic autopsy prior to the clearance from the Coroner/Medical Examiner Office.
    2. Removal of tissue for scientific or transplant purposes should not be performed without prior approval of the Coroner/Medical Examiner.
    3. Dressings, IV needles, airways, tracheostomies or other diagnostic or therapeutic apparatus that are in the body at the time of death should not be disturbed or removed from the body prior to the arrival of the Coroner/Medical Examiner or his investigator or without his permission.

HANDLING PUBLIC ADMINISTRATOR'S CASES

A. The Public Administrator is responsible for the burial, estate and personal property of patients in the following situations:
    1. Any death in which there is no clearly defined next of kin, or in any case where next of kin are living out of the County. This notification is to be made by the Admitting Office, regardless of the financial situation. Further, in cases of this type, the body and/or personal effects are not to be released until so authorized by the Public Administrator.
    2. The following information is to be supplied to the Public Administrator's Office at the time the report is made:

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a. Full name of the decedent.
b. Last known address of decedent.
c. Name of next of kin, or if whereabouts is not know, name of close relative.
d. Address of next of kin or relative.
e. Name of any person we have contacted and any pertinent information.

3. Relatives are to be directed to the Mortuary for disposition of the body.
4. Medical Social Service is responsible for delivery to the Public Administrator all personal property entrusted to the Hospital for safekeeping, including money in the patient's Trust Fund and personal articles, other than clothing, received from the nursing units.
5. Nursing Service is responsible for delivering to the next of kin or Medical Social Service, when indicated as in Paragraph 4, all of the patient's clothing left at the bedside.
6. In all other cases, the disposition of the body and personal effects will be at the discretion of the next of kin.

Handling Routine Hospital Deaths (Not Potential Coroner/Medical Examiner's Cases)

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A. The nurse in charge of the unit where the death occurs will ascertain if the death requires Coroner Medical Examiner notification. Following this determination he/she should then notify the attending physician or the resident physician on the case, and Nursing Administration. The nurse is also responsible for determining the following:
    1. Whether or not the physician wishes to request an autopsy. If the death is subject to Medical Examiner's investigation, the physician may still request an autopsy be performed by either the Medical Examiner or the Hospital Pathologist and should obtain release accordingly.
    2. When the physician will notify the patient's family, or if he is not available, to which physician the responsibility of speaking to the family has been delegated.

B. When the above information has been obtained and the physician has pronounced the patient deceased, the nurse in charge will call the Admitting Department, notifying the time the patient was pronounced, the physician pronouncing, the autopsy status, and that the family has been notified.

C. When an autopsy is requested and permission obtained by the physician, the Nursing Office will immediately notify the Department of Pathology. During the hours the Pathology Department is closed, the laboratory technician in charge will be notified, and will follow through with notification to the Pathologist who will at that time decide on the approximate time of the autopsy examination and whether embalming may proceed prior to autopsy examination.

    Pathology will advise the Admitting Office at the time the body is to be released to the

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Mortuary.

D. The Pathology Department requires that a reasonable effort be made by the physician authorizing the autopsy examination to contact the pathologist on call and discuss with him/her the purpose of the autopsy prior to its implementation, and the physician will be notified of the time the autopsy will be performed.

E. Autopsy request is made by the physician to the next of kin. The signed request is delivered immediately to the Pathology Department or to the Laboratory Technician in charge during the hours the Pathology Department is closed. The original signed consent goes to the Admitting Office for inclusion into the patient's medical record when the final report is completed. Autopsy consent forms will be available to duplicate in all nursing areas and at the Admitting desk. The Pathology office will notify the Admitting Office and the mortuary when autopsy is completed. (See policy No.100.063 for Autopsy Phone Consents).

F. The Admitting Department will be responsible for determining from the family which mortuary is desired. The Admitting Department will notify the mortuary and inform them of the autopsy status of the patient.

UTILIZATION OF THE HOSPITAL MORGUE

A. Bodies of patients dying in the Hospital, over which there is a question pertaining to release, are to be retained in the Hospital Morgue until clarification is obtained.

B. DOA's and other non-Hospital deaths necessitating Coroner Medical Examiner's investigation may be retained in the Hospital Morgue when necessary. In these instances the responsibility for signing the body into the Morgue, identification, personal effects, etc., will be a function of the Coroner medical Examiner's Office. Hospital personnel will not be responsible for any part of this operation.

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GENERAL PROCEDURAL GUIDELINES

A. The attending or resident physicians should indicate in the progress notes why an autopsy was not obtained.

B. The physician may also indicate in the progress notes if he/she desires an autopsy. This will serve as an alert to Nursing and Medical Records staffs.

C. Those deaths that are of a questionable nature should be referred to the Hospital Pathologist for disposition.

POLICY STATEMENT REGARDING AUTOPSIES

The executive Committee of the Medical Staff, acting on the recommendation of the Medical records Committee, has approved and established the following Hospital policy:

All Hospital deaths are to be considered potential autopsy cases. When an autopsy is not obtained, a written note is to be placed on the progress sheet stating the reason. This note is to be made by the physician on the case or the physician who is responsible for signing the death certificate.

The Medical Records Department will be responsible for checking the chart of each deceased patient for the purpose of maintaining both the autopsy statistics and non autopsy statistics. This information is necessary in maintaining the approved Resident Training Program for the Hospital.

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FETAL DEATH ROUTINE STILLBIRTHS

Additional policies relating to fetal deaths and stillborns are located in Administrative Policy No. 100.028.

DEATH CERTIFICATES

Section 10204 of the Health and Safety Code of the State of California requires as follows:

“The physician shall within 15 hours after the death deposit the certificate at the place of death, or deliver it to the attending funeral director at his place of business or at the office of the physician.”

The policy of Ventura County Medical Center is as follows:

1. When a patient expires and there is no licensed physician available to sign the death certificate the Admitting Service will contact the Chief Resident or the Medical Director for signature.
2. This procedure applies only to those cases where there is a definite cause of death and no pending postmortem examination.

AUTOPSY

When an autopsy is performed, the provisional anatomic diagnosis will be recorded in the Medical Record usually within 24 hours, but always within 2 days. A complete autopsy protocol will be made as part of the permanent record within 30 days, unless the case is usually difficult requiring special studies and/or outside consultations.

A. Routine cases are to be considered cases where there are no unusual gross or histologic findings that require special stains or expert consultation.

B. Complicated cases are to be considered cases where there are unusual gross findings (i.e., congenital anomalies), where there is challenging histology, or where special stains (i.e., electron microscopy, immunofluorescence, etc.), are required to make the diagnosis.

COPY

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L.HIST.36 Fetal Deaths, Stillborn Infants, and Infant Deaths

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POLICY:

In response to the recent increase in cases of infant death requiring administrative action, the following policy has been adopted by Ventura County Medical Center.

It is the intent of this policy to distinguish between fetal deaths, stillborn infants and infant deaths and to establish the recommended guidelines to be followed for each.

THE FOLLOWING PROCEDURE IS FROM THE VENTURA COUNTY MEDICAL CENTER ADMINISTRATIVE POLICY MANUAL.

See Addendum: Fetal Deaths, Stillborn Infants and Infant Deaths, Administration Procedure No. 100.028

Forms Associated:

- Release of Body to the Undertaker - English and Spanish
- Cremation Authorization - English and Spanish

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Attachments

Cremation Authorization - English

Cremation Authorization - Spanish

Release of Body to Undertaker - English

Release of Body to Undertaker - Spanish

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L.HIST.37 Autopsy Protocol

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POLICY:

1. The requesting doctor, nurse, or Social Services worker brings the autopsy consent to the Laboratory. This is a two-page form, white is the original chart copy and yellow is the chart copy to keep with our files.
2. Inform the pathologist on duty that a consent for autopsy has been received. Telephone Medical Records Death Certificate desk (x3225) and notify them that an autopsy on *(patient name, chart #)* will be done. Also call Admitting (x6071) and tell them we are doing an autopsy on the patient and not to release the body until we call them to say the autopsy has been completed.
3. Locate the expired patient's chart by calling the Discharge Desk in Medical Records (x6008); if the chart is not there, call the floor where the patient expired and ask them if they still have the chart. If they do not have it, check with Admitting. Make photocopies from patient's chart of the following pertinent records: Recent Discharge Summary, Problem List, recent History and Physical, recent doctor's progress notes, and any other important reports (do not photocopy nurse's notes, medication records, etc.). Also, make a copy of the consent, to be given to the pathologist with the copies from the chart. The original (white and/or yellow copies) consent is to be kept with the pathology secretary in her folder.
4. A new autopsy number (YY-A-##) must be assigned to this autopsy and logged in the Autopsy LogBook. All necessary information needed to fill in the Logbook can be found in the photocopies of the patient's chart (hospital number, date died (found in progress notes), and requesting doctor name (found on either the autopsy consent or in the doctor's notes, most often it is the doctor pronouncing the death)).
5. Type in the above information on the Provisional Anatomic Diagnosis page (see sample).
6. Paper clip the following papers together, to be given to the pathologist:
    a. Provisional Anatomic Diagnosis page

b. All of the photocopies from the patient's chart

c. Copy of the consent

7. Make up two file folders – one folder is for the pathology secretary's file, which will contain the yellow copy of the autopsy consent and a copy of the Autopsy Provisional Diagnosis (when the pathologist has completed the autopsy and finished the dictation). The white copy of the consent is to be attached to the chart copy of the Provisional Diagnosis and taken to Medical Records. The other folder is for the pathologist, which will contain clipped papers as in #6 above. Clip the photocopy of the consent to the outside folder and give to the pathologist.
8. After the autopsy is completed, the pathologist should notify you that the autopsy is finished and you should then call Medical Records Death Certificate Desk (x3225) and tell them that the autopsy has been completed. Also call Admitting to tell them it has been completed.
9. The pathologist will then hand write the diagnoses on the Provisional Anatomic Diagnosis page or dictate the provisional diagnoses. (See instructions for entering autopsy in Meditech).
10. After completing the Provisional Anatomic Diagnosis Report, print a Proof report and have the pathologist edit and initial for the final copy.
11. Print final copies and distribute as follow:
12. Have pathologist sign yellow (chart) copy. Take this copy to Medical Records (with white copy of consent attached) as soon as possible so they can put this on the patient's chart. (This report is to be completed within 48 hours of the autopsy).
13. Copies to the physicians named on the report (if physician is a resident, discard his/her copy, give mail copies to in-house physicians or mail to private doctors).
14. One copy gray mail to Medical Staff Office, Attention BJ
15. One copy to pathologist's folder.
16. One copy to pathology secretary's folder.
17. Once the Provisional Diagnosis Report is completed and filed in the appropriate folders, give the folder back to the respective pathologist so that he/she can dictate the Gross Findings.
18. CAUTION!!! BE SURE THE PROVISIONAL DIAGNOSIS IS SIGNED OUT BEFORE YOU BEGIN THE GROSS FINDINGS. IF IT IS NOT SIGNED OUT, AND YOU HAVE TYPED IN THE GROSS FINDINGS SECTION, YOU WILL NOT BE ABLE TO PRINT THE PROVISIONAL DIAGNOSIS REPORT.
19. The pathologist will give you the folder with a tape of his/her dictation of the Gross Findings. Enter this in the computer. Print an Autopsy Proof Report (APR) and put in the pathologist's folder and give back to him/her.
20. The pathologist will give you the folder with a tape of dictation of the Microscopic Findings and probably Final Diagnosis. Enter this in the computer, print Autopsy Proof Report for his/her folder and give it back to him/her to make corrections or initial, if ready for final sign-out.
21. When the pathologist has completed the report and gives it back to you with his/her initials for final sign-out, you can make any corrections and then sign it out. You can
22. Distribute final reports as follows:

    a. Signed report (yellow copy) to Medical Records (if we have a white copy of the Autopsy consent, staple this to the back of the report).

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b. Copies to all physicians named on the report.
c. Copy to Medical Staff Office, Attention BJ
d. Copy to our file, stapled together in the following order: Autopsy report, Provisional Diagnosis, Autopsy consent.

23. Log final diagnosis in Autopsy Logbook in appropriate spaces and write in the date the final report was signed.
24. After final reports are completed and distributed appropriately, the file folders can be disassembled (place blank white label over previous name so it will be ready for future autopsies). Go through the photocopied materials to be sure there isn't anything important that needs to be kept with the autopsy report, or that the pathologist might want, and then dispose of the balance in the CONFIDENTIAL RECYCLE CONTAINER.

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L.HIST.39 Special Handling of Tissue in the Histology Lab of Autopsy, Surgical Tissue and Cytology Specimens in Which Creutzfeldt-Jakob Disease is Suspected

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PROCEDURE:

1. Universal precautions during autopsy procedures should be followed closely when doing an autopsy on patients on whom the diagnosis of Creutzfeldt-Jakob Disease is suspected.
2. The pathologist should consider taking these special precautions as well in cases of:
    a. Rapidly progressive dementia.
    b. Dementia with seizures, especially monoclonal seizures.
    c. Dementia associated with cerebellar or lower motor neuron signs.
3. The recommended method for handling these brains to reduce infectivity is to immerse the tissue blocks in 95% formic acid.
4. Aerosol formation must be avoided during removal of the brain.
5. If there is any suspicion of Creutzfeldt-Jakob disease, the autopsy should be limited to the brain.
6. Autopsy brain tissues should be fixed in formalin for 1–2 weeks before cutting.
7. Tissue blocks (representative regions of neocortex, basal ganglia, and cerebellum) should be taken and agitated in at least 50–100 mL of 95–100% formic acid for one hour and then returned to formalin for 2 days before embedding.
8. Alternatively, one may take the necessary diagnostic sections from the fresh brain, fix them in formalin for 2–7 days, treat with formic acid for one hour, fix again in formalin for 2 days, and then embed in paraffin. This method significantly reduces infectivity.
9. At the conclusion of the autopsy, the area of incision and other contaminated skin surfaces are

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washed with freshly opened undiluted commercial household bleach (sodium hypochlorite).

10. As sodium hypochlorite degenerates after several months, a newly opened container should be used for each autopsy.
11. After 10 minutes, the skin may be washed with water. All gowns, gloves, plastic sheets, and other disposable supplies should be placed in red or orange biohazard bags and incinerated. Alternatively, they may be autoclaved (132°C steam) and discarded.
12. Hard surfaces are decontaminated with freshly opened undiluted bleach or NaOH.
13. 1N NaOH is adequate unless there will be dilution by surface liquids, in which case 2N NaOH should be used.
14. Bleach and NaOH are equally effective, but NaOH is preferred for steel instruments and surfaces because it is less corrosive than bleach.
15. The disinfectant should remain in contact with the surface for at least 15 and preferably 60 minutes.
16. Autopsy instruments should have any visible blood removed, then decontaminated with undiluted bleach for 1–2N NaOH, as above.
17. Alternatively, they may be autoclaved for 1 hour at 132°C and 20 psi.

COPY

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3/2/2026

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Laboratory Service Dept	Erlinda Roxas: Director, Laboratory Services	3/26/2026
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L.HIST.40 Cleaning Autopsy/Pathology Grossing Area

COPY

PURPOSE:

The following procedure will be followed to assure a clean area for the gross examination and dissection of surgical tissues:

PROCEDURE:

1. The counter cutting board and sink will be rinsed with water when dirty and will be cleaned with 10% household bleach (stock solution of household bleach is 5.25% sodium hypochlorite) at least weekly.
2. After use, all small instruments (scissors, scalpel handles, tweezers, etc.) will be soaked overnight in a non-corrosive phenolic disinfectant such as Cidex. When not in use these tools can be kept in the non-corrosive disinfectant or can be rinsed in tap water and air-dried and stored on the counter, cutting board or in a designated drawer.
3. Large tools/equipment (such as the scale or hammer) will be cleaned after each use with a disinfectant such as 10% bleach or a phenolic disinfectant.
4. If any specimen is removed from a person with possible AIDS, Hepatitis, Herpes, Creutzfeldt-Jakob disease, mycobacterial infection, or any other infection which requires special precautions, the counter, cutting board and sink will be cleaned with 10% bleach or formic acid as described in the section on How to Handle Creutzfeldt-Jakob disease and other infectious agents.

REFERENCES:

- Chemical Disinfection of Creutzfeldt-Jakob Disease, NEJM: 1279-1282, 1982.
- Stability and Inactivation of HTLV-III/LAV Under Clinical & Laboratory Environments, JAMA 255: 1887-1891, 1986.

- Morbidity & Mortality Weekly Reports Vol 34 no. 45, Nov. 15, 1985.

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L.HIST.41 Specific Section Policies

COPY

PURPOSE:

To allow for minimal exposure to the Autopsy Surgeon of infection processes that could be obtained at autopsy.

POLICY:

The performance of anatomical pathology examinations (gross anatomy) can be extremely hazardous to the pathologist if the patient had any infection prior to the removal of tissue. Certain rules must be strictly adhered to if an accidentally acquired infection is to be prevented. All applicable to individuals working with tissues and a certain few are peculiar to the Pathology Department alone. These are as follows:

1. Care must be exerted when working with the instruments used in Pathology. Scalpels and dissecting instruments have sharp edges and sharp points, and if precautions are not observed in their use, a cut or puncture with the potential of causing an infection can occur.
2. Protective clothing (including gloves) should be used during every tissue examination. Such protective clothing should not be worn outside the laboratory.
3. Hands should be washed thoroughly using Phisohex after gloves are removed.
4. During tissue examinations, extreme care should be taken to avoid spilling tissue or fluid on the floor. If spillage does occur, housekeeping should be called immediately upon completion of the autopsy to thoroughly clean the floor using a disinfectant solution.
5. Following a tissue examination, instruments should be washed thoroughly with a disinfectant soap and allowed to air dry.
6. Bench top surfaces should be washed clean with Amphil after each tissue examination.

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Policy Area	Laboratory Services - Histology

L.HIST.45 Dissemination of Information when the Clinical History Submitted with a Specimen is Markedly Different from the Histologic Findings

COPY

POLICY:

A. In those cases where anatomic specimens are submitted for histologic evaluation and the anatomic findings are markedly different from the clinical findings, then the pathologist responsible for the case will contact the clinician that submitted the specimen to discuss the histologic findings.

B. Such diagnosis may include: (1) malignancy in an unexpected location or specimen (i.e. hernia sac, intervertebral disk material, tonsil, etc.), change of a frozen section diagnosis after review of permanent sections. Failure to identify POC in the tissue passed from uterus, etc.

C. The pathologist will document the physician contacted as well as the date and time of the conversation.

D. Several of the surgical pathology findings which would require prompt communication with the patient's physician are:

1. Neoplasms in unexpected locations.
2. Neoplasms causing paralysis/vena cava syndrome, etc.
3. Fat in endometrial curettage/GI biopsies.
4. Failure to identify POC in tissue from uterus/vagina.

E. If the doctor submitting the specimen can not be contacted, then the doctor on call for that service or the head of that service will be contacted concerning the discrepancy. The attempts to contact the appropriate doctors will be instituted as soon as the pathologist responsible for the case realizes that there is a discrepancy.

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L.HIST.46 Interdepartmental Consultations

COPY

PURPOSE:

Documentation of intradepartmental consultations in a manner such that the shared consultations are documented and, when appropriate, added to the patient's final surgical report, or maintained in pathology.

POLICY:

1. All difficult, controversial and unusual cases will be shown to other pathologists within the department.
2. If the case is shown to other pathologists and there is agreement, this can be documented in the patient's final report as determined by the pathologist assigned the case.
3. If there is disagreement in the diagnosis of the particular case, then the case will be sent out to a recognized consultant, and the consultant' impression will be the diagnosis rendered on the case.
4. In those cases where an outside consultant renders an opinion, a copy of the opinion will be distributed to the appropriate clinicians involved in the case and become part of the permanent pathology report.

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Owner	Amanda Lo: Medical Director, SPH Lab
Policy Area	Laboratory Services - Histology

L.HIST.48 Reflective Communication of Information Concerning Specimen tests and patient Care by the On-Call Physician

COPY

POLICY:

A. When there is a specimen test or patient care issue, which cannot be adequately addressed during the normal work day or when there may be an ongoing issue, the Pathologist taking care of the issue will communicate with the on-call Pathologist and other Pathologists who may be contacted about the specimen tests or patient care issues so that they will be able to address any questions from the clinicians.

B. As all the Pathologists carry pagers and/or cell phones, any questions which cannot be handled by the on-call Pathologist, can be referred to the Pathologist originally handling the issue if questions arise that the on-call or other Pathologists cannot adequately address.

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Owner	Amanda Lo: Medical Director, SPH Lab
Policy Area	Laboratory Services - Histology

L.HIST.49 Interdepartmental Consultations About Proficiency Testing

COPY

POLICY:

A. There will be no interdepartmental communication about the results of proficiency testing samples until after the deadline for submission of the data to the proficiency testing provider has passed.

B. Since there are two laboratories, if a pathologist is consulted by one of the Labs about the answers on the proficiency testing, that pathologist must remove himself from participation in the same proficiency testing at the other hospital.

C. If a pathologist is asked to comment on more than one of the same proficiency test, then that pathologist must refer the supervisor to one of the other pathologists to help with the answers to the proficiency testing.

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Owner	Amanda Lo: Medical Director, SPH Lab
Policy Area	Laboratory Services - Histology

L.HIST.50 Referral for Proficiency Testing Samples to Another Laboratory

COPY

POLICY:

A. There is a strict prohibition against referring proficiency testing samples to another laboratory. The laboratory may not refer a proficiency testing specimen to a laboratory with a CLIA number (even if the second laboratory is in the same health care system).

B. This is in strict compliance with CLIA-88 regulations preventing such referrals.

C. If a proficiency test is not confirmed in the laboratory then the result will not be recorded and it will be reported to the CAP that the proficiency testing is not performed.

D. There will be no exceptions to this policy.

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L.HIST.51 Tissue Sample Quality Control Including Corrective Action

COPY

POLICY:

A. If tissue sample has an embedding, processing, fixation, or staining problem, which may result in the inability for the pathologist to determine definitive diagnosis. The pathologist fills out the histology communication form stating the nature of the problem.

B. The communication log is reviewed by lead histologist at which time the lead histologist will enter the information on the Histology/Cytology Staining Quality Control Log (located in the histology laboratory).

1. The Histology/Cytology Staining Quality Control Log gives pertinent feedback from the pathologists to the histologist on matters concerning all stains daily. There is an area for the doctors comments as well as to which remedy the histologist is able to implement.
2. Before any patient samples are stained in the Sakura Automatic Tissue-Tek Stainer a control sample is run daily. The control slides are kept for 30 days.
3. A control slide is run in tandem for each batch of special stains and is routinely checked by the pathologist on call, and then logged into the Histology/Cytology Staining Quality Control Log.

C. If there is a problem with the quality of the automatic stainer or special stains the pathologist notifies the histologist immediately, corrective action is implemented, and the patient test is re-stained.

D. Histotechnologist feedback to Pathologist on the quality of gross tissue sections received for tissue processing. Quality issues include: inadequate fixation, thick sections, non-decalcified bone, and/or presence of surgical staples, all of which can cause poor quality sections or special studies.

1. Feedback: documentation is written in the Histology Correction Problem Log, and verbal feedback is given to the Pathologist of record, and if warranted documented on the Histology Communication form.

E. Specimen mislabel from the surgery department, clinics, or private doctor are documented electronically by way of Notifications Form, the grossing pathologist is informed, and the physician or surgeon is notified.

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Owner	Amanda Lo: Medical Director, SPH Lab
Policy Area	Laboratory Services - Histology

L.HIST.52 Quality of Formalin

PRINCIPLE:

To ensure the quality of formalin, a pH check is performed when a new lot is received. A pH of 7 is verified using pH test strips and documented on the attached below “Quality of Formalin” log.

COPY

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Attachments

Quality of Formalin Log.pdf

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Laboratory Service Dept	Erlinda Roxas: Director, Laboratory Services	3/26/2026

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Owner	Amanda Lo: Medical Director, SPH Lab
Policy Area	Laboratory Services - Histology

L.HIST.53 Cleaning Surgical Pathology Grossing Area and Instruments

COPY

POLICY:

The following procedure will be followed to assure a clean area for the gross examination and dissection of surgical tissues:

PROCEDURE:

A. The counter cutting board and sink will be rinsed with water when dirty and will be cleaned with 10% household bleach (stock solution of household bleach is 5.25% sodium hypochlorite) at least weekly.

B. After use, all small instruments (scissors, scalpel handles, tweezers, etc.) will be soaked overnight in a non-corrosive phenolic disinfectant such as Cidex. When not in use these tools can be kept in the non-corrosive disinfectant or can be rinsed in tap water and air dried and stored on the counter for cutting board or in a designated drawer.

C. Large tools/equipment (such as the scale or hammer) will be cleaned after each use with a disinfectant such as 10% bleach or a phenolic disinfectant.

D. If any specimen is removed from a person with possible AIDS, Hepatitis, Herpes, Jakob-Creutzfeldt disease, mycobacterial infection, or any other infection which requires special precautions, the counter, cutting board and sink will be cleaned with 10% bleach after the possibly infected tissue is handled and all instruments which came into contact with the possibly infected tissue must be soaked in 10% household bleach for at least one hour. After soaking the instruments in bleach, the instruments must be rinsed in tap water to minimize corrosion and will then be autoclaved. One hour of exposure to 0.5% sodium hypochlorite (10% bleach) should kill these organisms.

REFERENCES:

- Chemical Disinfection of Creutzfeldt-Jakob Disease, NEJM: 1279-1282, 1982.'
- Stability & Inactivation of HTLV-III/LAV Under Clinical & Laboratory Environments, JAMA 255: 1887-1891, 1986.
- Morbidity & Mortality Weekly Reports Vol. 34 no. 45, Nov 15, 1985.

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Laboratory Service Dept	Erlinda Roxas: Director, Laboratory Services	3/26/2026
Laboratory Service Dept	Amanda Lo: Medical Director, SPH Lab	3/18/2026

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Owner	Christian Press: Supervisor-LIS, Laboratory Services
Policy Area	Laboratory Services - Blood Bank

L.HIST.54 Decontamination of Cryostat

COPY

PURPOSE:

The AIDS virus is known to be inactivated by 0.5% sodium hypochlorite (1:10 dilution of household bleach (3,4)), 95% ethanol (3, 4, 5, 6), and 10% formalin (6). Sodium hypochlorite is the most effective decontaminant known for the virus, but it will also corrode metal. Therefore 95% ethanol is favored for the inside of the cryostat. The AIDS virus does survive both freezing and drying (4, 6), so decontamination is essential.

PROCEDURE:

1. Turn off refrigeration (for the older model cryostat only). The new Leica cryostat does not require defrosting since it has an automatic defrost feature, which prevents any ice build-up in the chamber.
2. With protective clothing in place, remove the knife from the microtome and dispose of it in the sharps container.
3. Wipe down all surfaces of the cryostat chamber with 100% alcohol paying special attention to cleaning the base of the chamber where tissue may collect. Then do a final wipe-down with the Sani-Cloth AF3 which is a bactericidal, tuberculocidal, and virucidal approved cleanser.
4. Wipe and dry all surfaces within the chamber.
5. Replace the knife with a clean microtome knife. All moveable parts must be re-oiled before the cryostat is used again.
6. Turn the refrigeration to the desired temperature.
7. The machine will be decontaminated every two weeks, or as necessary if the cryostat is felt to be contaminated by viral or fungal agents.

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Laboratory Service Dept	Erlinda Roxas: Director, Laboratory Services	2/24/2026
Laboratory Service Dept	Christian Press: Supervisor-LIS, Laboratory Services	2/11/2026

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L.HIST.55 Cleaning Flotation Bath

COPY

PURPOSE:

Written instructions for preventing cross-contamination of paraffin sections in the flotation bath.

PROCEDURE:

1. Skimming (blotting) of the water bath with a paper towel or Kim Wipe after every cut and between every block.
2. Periodic water changes (depending on the number of cases.)
3. Empty water bath daily and clean with Clear Rite or Xylene and Reagent Alcohol.

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Laboratory Service Dept	Amanda Lo: Medical Director, SPH Lab	3/18/2026

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Owner	Amanda Lo: Medical Director, SPH Lab
Policy Area	Laboratory Services - Histology

L.HIST.56 Disposal of Used Glass Slides and Paraffin Blocks

PROCEDURE:

COPY

1. Glass slides will be placed in the red and yellow containers and disposed of in the same manner as sharp objects.
2. Glass slides and paraffin blocks on surgical pathology cases will be retained in storage (Access) and in house and not be disposed of until allowed by CAP standards in case they are needed for future evaluation.
3. At such time as glass slides and paraffin blocks are to no longer be retained, the work will be contracted with a company that is licensed to perform such work.

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L.HIST.57 Storage Retrieval/Pickup

COPY

POLICY:

** THE ACCESS INFORMATION MANAGEMENT LOGBOOK IS KEPT IN THE FRONT OFFICE **

1. Recent (approximately 5 years) blocks and slides are stored on campus. They can be found either in the store room down the hall from the gift shop or in the hallway closets next to Histology.
2. Older cases are stored at Access Information Management.
3. The preferred way to obtain records is to complete a Customer Order Form and fax it to (805) 529-3099. This way you have a record of your request. You can also call Access (562) 404-0432 and tell them what you need by providing a detailed description of the item including patient name and accession number.
4. Access will advise you when to expect the item.
5. You or someone in the front office will have to sign the Document Retrieval Form and will be given a copy, which is to be filed in the York Storage Logbook under “Ordered/Received”.
6. You can also call Access for pick up of items to be returned to storage for re-filing or providing new records for storage.

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L.HIST.58 Cross-Contamination in Histology

COPY

PURPOSE:

Tissue fragments and cells can migrate and contaminate other specimens resulting in errors of diagnosis. The following recommendations are made to reduce the chances of cross-contamination i.e. “floaters”, during specimen processing, embedding, microtomy, and slide preparation. Instruments, equipment, and work stations, must be clean and maintained.

PROCEDURE(S):

A. Grossing/cutting station – clean i.e. wipe/rinse; instruments, tools and knife blade between each specimen the item is used for. Clean cutting board after each specimen. Use small perforation cassettes which will completely contain small specimens, or utilize nylon bags, wrapping paper, or sponges as necessary to contain the specimen.

B. Embedding station – wipe and clean forceps, equipment and instruments between cases is required. One cassette should be handled at a time.

C. Microtomy – one block should be handled at a time. Labeling of each slide should be made before tissue section is applied to the slide.

D. Flotation bath – require periodic water changes, depending on volume of cases, and blotting the water surface so that sections from one block are not inadvertently carried over to another case.

E. Staining – equipment must be clean and maintained. Stains need to be filtered and replaced as needed.

F. Cover slipping – equipment must be clean and maintained.

Histology/pathology tissue processing

A. The tissue specimens are received in the pathology lab and accessioned into the computer, after checking that the container is labelled with the appropriate name and specimen source, and that this information is consistent with the orders entered into the computer by the submitting physician.

B. The pathologist, using the information entered into the computer, checks that the specimen is correctly labeled and then proceeds to describe the specimen. In the case of a small specimen, such as a biopsy, the entire specimen is then placed into an appropriately labeled tissue cassette or multiple cassettes. This is generally done by using forceps.

C. Each cassette is then placed, together with the cassettes from other specimens, in a single basket in a container of formalin. At the end of the day, the basket containing the cassettes is placed in a tissue processor. The tissue is processed overnight, which involves sequentially dehydrating then rehydrating the specimens with different chemicals, which are pumped into a chamber under pressure. The end result, the following morning, is processed tissue which is then ready for embedding by a histotechnologist.

D. The histotechnologist opens the cassette, removes the tissue using forceps, orients the specimen and places the tissue in a metal form which is then filled with hot wax. This is placed back on the labeled cassette, which serves to retain the identity of the specimen.

E. The tissue is then cut using a microtome, which cuts extremely thin ribbons of the wax embedded tissue. These ribbons of tissue are then floated on a water bath. The technician uses the appropriately labeled glass slide to lift the tissue from the water.

F. The slides are further processed in order to melt the wax, and stain the tissue with a histological stain. A glass coverslip is placed on the slide and it is now ready for review by the pathologist.

COPY

Potential for errors and preventative actions

A. The specimen containers could be incorrectly labeled with the wrong patient name or site. The information is checked before entering the specimen into the computer.

B. The tissue could potentially be placed in the incorrect cassette. The cassette number is checked before tissue is placed in it.
There could potentially be carry over, on the forceps, of tissue from a prior specimen. The forceps need to be cleaned before use on a new specimen.

C. Tissue can be carried over from one cassette to another while the tissue is in the formalin bath during processing. Small specimens are placed in special biopsy cassettes, which have smaller perforations in the cassette. Friable tissue or tissue in small fragments may also be placed in a mesh bag or wrapped in tissue paper to prevent carry over of small tissue fragments to other cassettes.

D. There could potentially be carry over, on the forceps, of tissue from a prior specimen. The forceps need to be cleaned before use on a new specimen.

E. There could potentially be carry over of tissue from a prior specimen on the surface of the water bath. The water bath surface needs to be cleaned between each specimen. The tissue

could be placed on an incorrectly labeled glass slide. The information on the glass slide needs to be checked with that on the tissue cassette

All Revision Dates

3/2/2026

Approval Signatures

Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator, VCMC & SPH	3/27/2026
Laboratory Service Dept	Erlinda Roxas: Director, Laboratory Services	3/26/2026
Laboratory Service Dept	Amanda Lo: Medical Director, SPH Lab	3/18/2026

COPY

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Effective	3/27/2026		
Last Revised	3/2/2026		
Next Review	3/26/2028		

L.HIST.59 Cancer Protocols

COPY

PURPOSE:

Cancer Protocols are used to provide uniformity and increase accuracy of the diagnosis of malignancy in the pathology report.

PROCEDURE(S):

CAP Cancer Protocols are to be incorporated in Surgical Pathology reports of specimens for primary invasive malignancies, including DCIS of breast, with annual audits to ensure all required elements are included from the current CAP Cancer protocols edition.

The annual audit is made by the Hospital Cancer committee who will retain the records of the audit. If deficiencies are identified, the corrective action and results are to be documented.

All Revision Dates

3/2/2026

Approval Signatures

Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator, VCMC & SPH	3/27/2026

Laboratory Service Dept	Erlinda Roxas: Director, Laboratory Services	3/26/2026
Laboratory Service Dept	Amanda Lo: Medical Director, SPH Lab	3/18/2026

COPY

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L.HIST.60 Synoptic Reporting

COPY

PURPOSE:

To insure consistency and clarity of pathology reports of malignancy.

POLICY:

Required data elements must be in paired Synoptic format, ie Data Element: response.

Each data element is on a separate line, and include the following:

- Anatomic site, specimen, laterality, procedure
- Pathology Staging Tumor Node Metastasis (pTNM)
- Negative margins

Elements may be listed in any order, can be enhanced to increase visual clarity, and additional items can be added.

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COPY

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Effective	3/27/2026		
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L.HIST.62 Procedure for Reporting Gross Findings in the Surgical Pathology Reports

COPY

POLICY:

1. The dictation should start by including any information on the container in the first sentence, (i.e. the site of the specimen, the organ involved, etc.).
2. The gross report should include the type, number, dimensions and/or weight of the specimens, measurements and extent of the gross lesions involving the specimens. Once the specimen is sectioned and reviewed, the cassette should be numbered and recorded in a “Block Key” to allow for adequate determination of the extent lesion. The “Block Key” should include margins of resection, sections of tumor or lesion, quadrants (of breast) with evaluation, lymph nodes, etc.
3. Drawings and photographs may be used to document the gross findings and to augment the gross descriptions.

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Laboratory Service Dept	Amanda Lo: Medical Director, SPH Lab	3/18/2026

COPY

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VENTURA COUNTY HEALTH CARE AGENCY

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Owner	Amanda Lo: Medical Director, SPH Lab
Policy Area	Laboratory Services - Histology

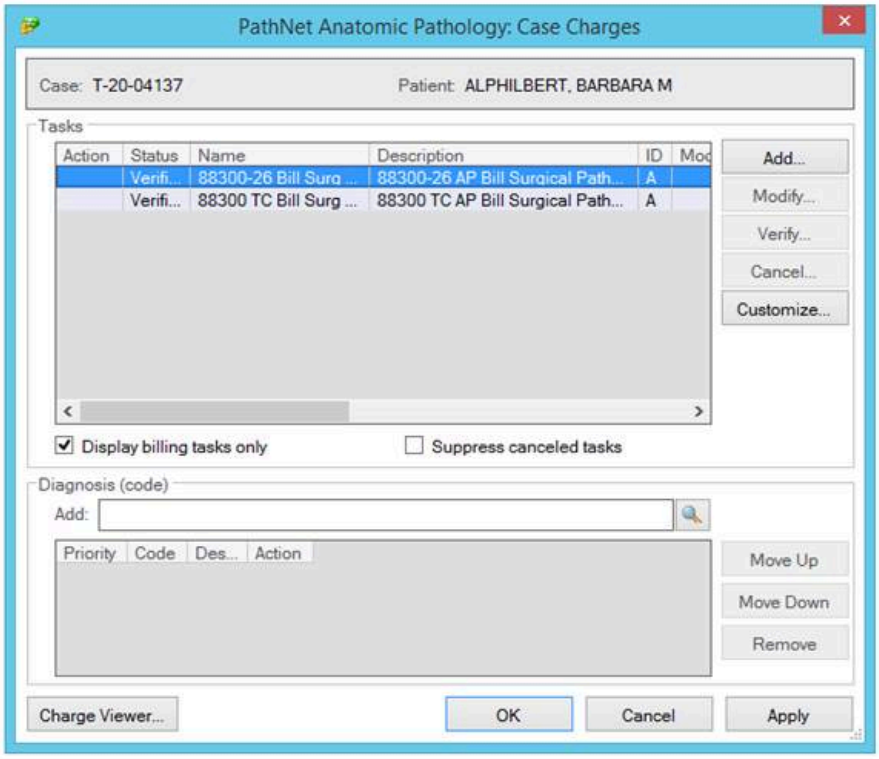
L.HIST.65 Manually Adding Charges to AP Reference Laboratory Testing

PURPOSE:

COPY

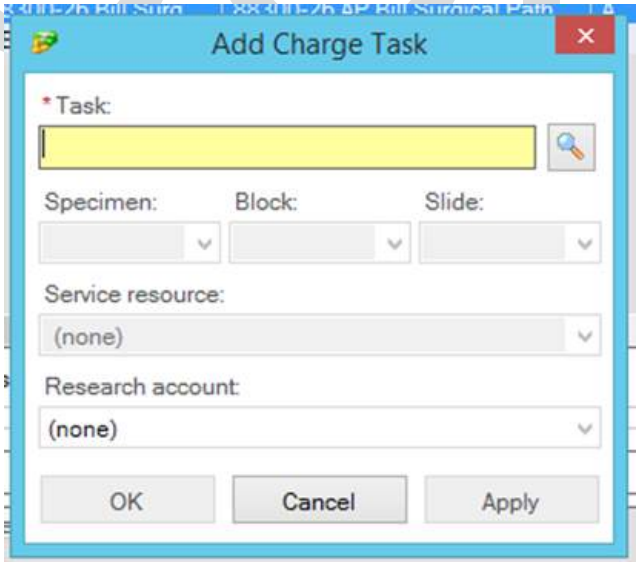
The purpose of this procedure is to properly charge the patient for Pathology Reference Laboratory tests that are not built in the Laboratory Information System (LIS)

1. Select from the AppBar - **Case Findings**
2. Type the Pathology accession number (T number such as T-XX-XXXXX).
3. Select Case Charges ICON
4. Select **ADD** from top right.

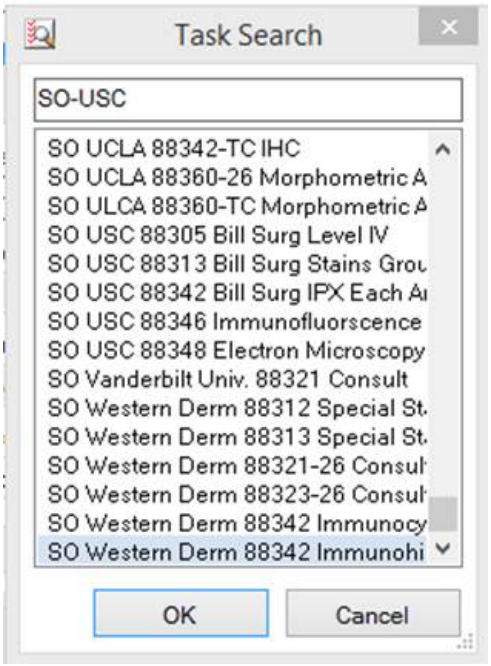


COPY

5. Type " **SO** – "abbreviation of the reference lab" such as **USC, UCLA, NEO, Clarient**, etc..... **Press Enter**.

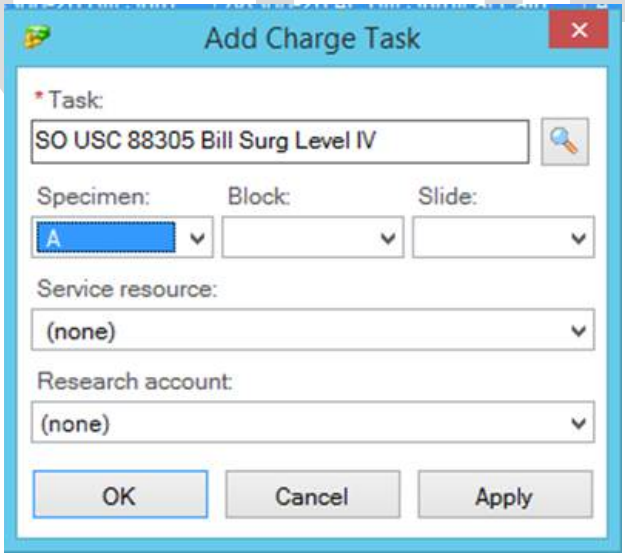


6. Select the appropriate send out test and click **OK**



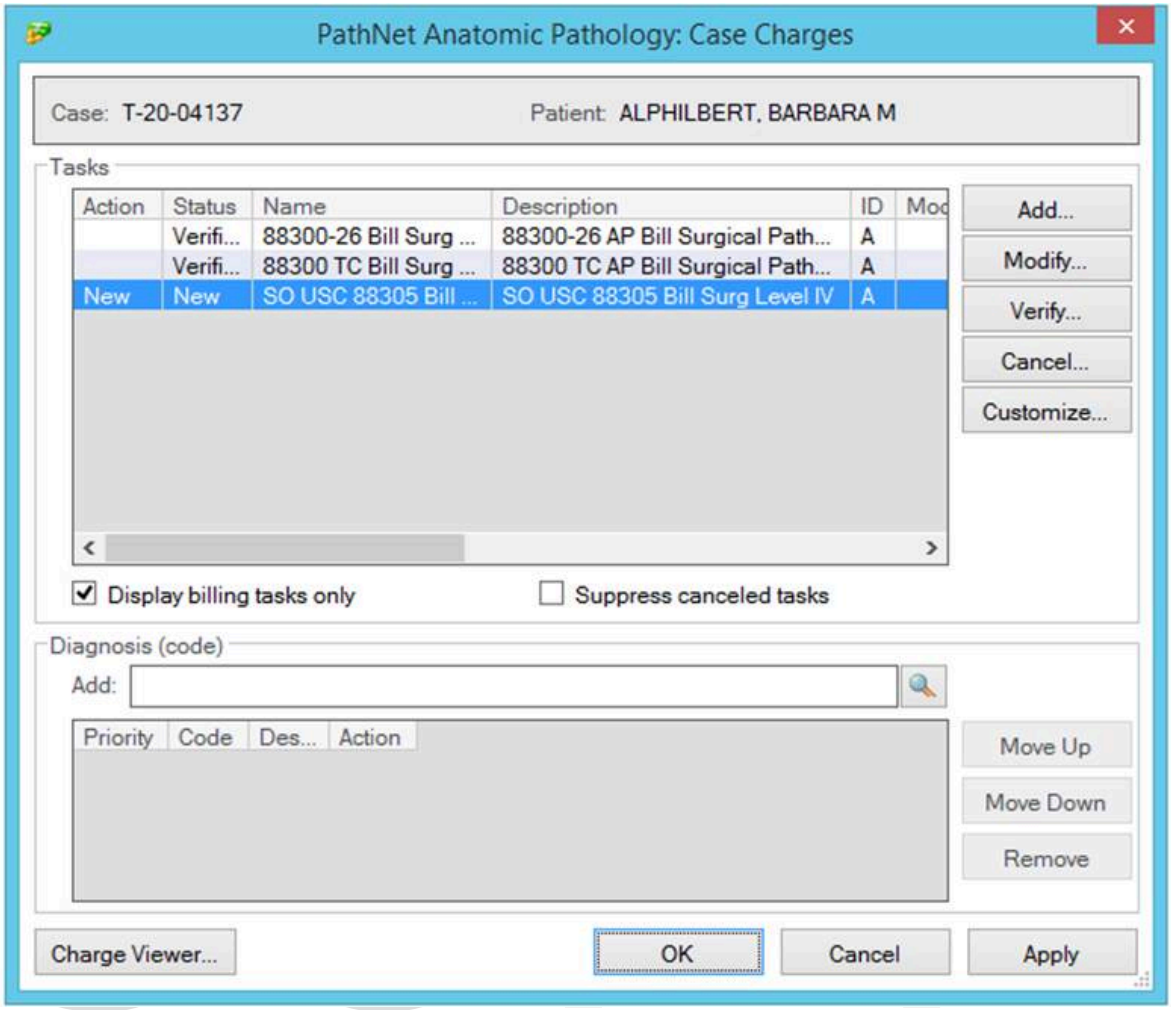
7. Select the appropriate Specimen using the drop-down option if there are multiple specimens. Click OK.

   This will add the test that was selected for billing. See below example for the added test.

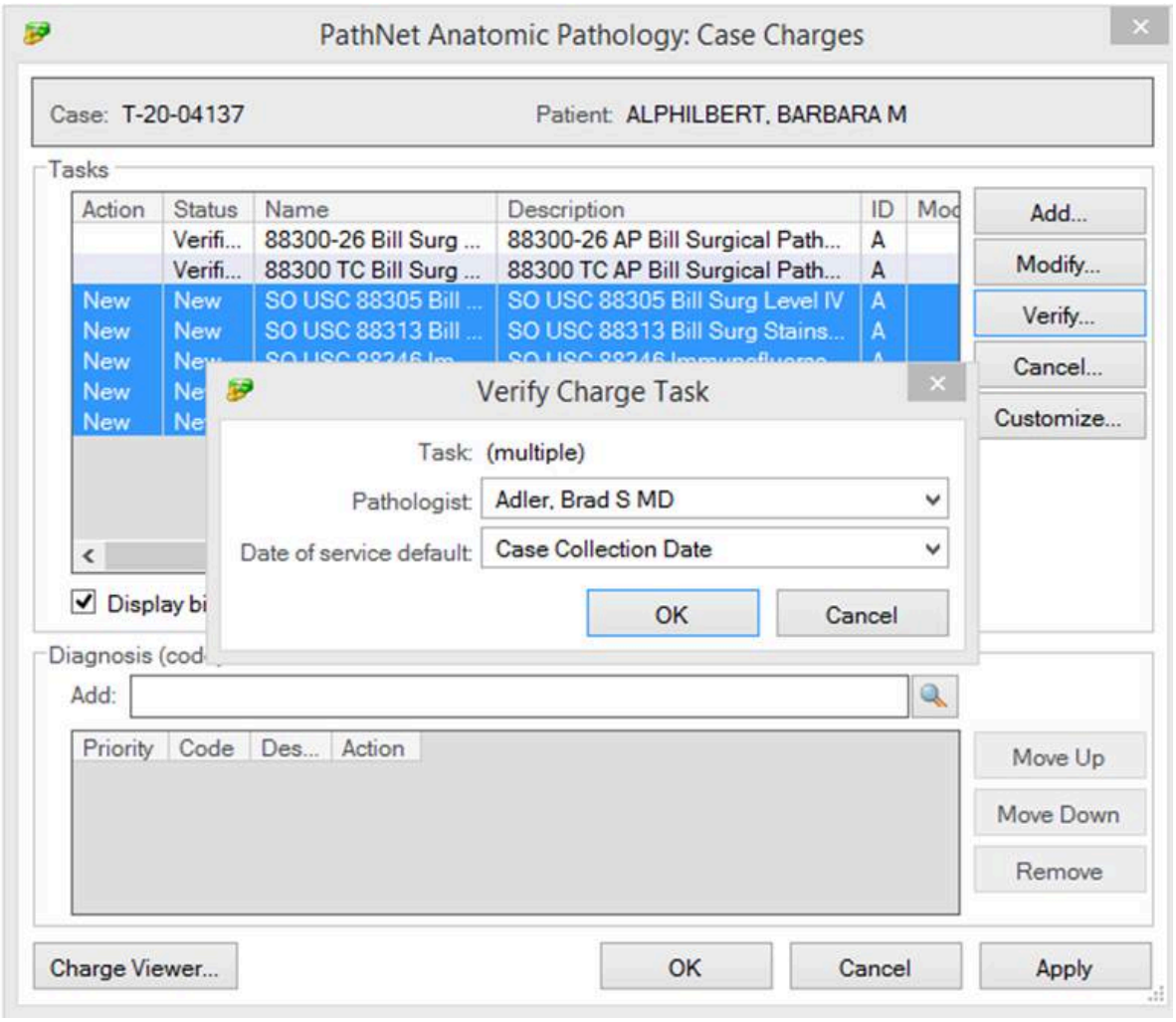


8. Repeat the process if other test codes are needed to add for billing.
9. If you cannot find a test code, then select Misc. 26 for consultation or TC for technical charge.
10. Highlight all the added test codes and press Verify at the top right.

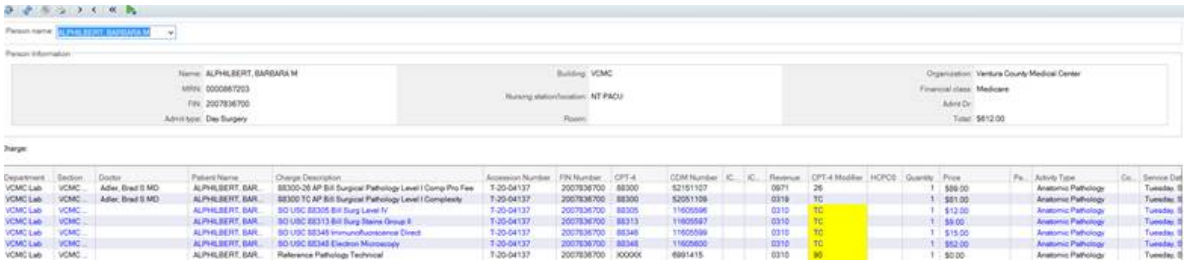
COPY



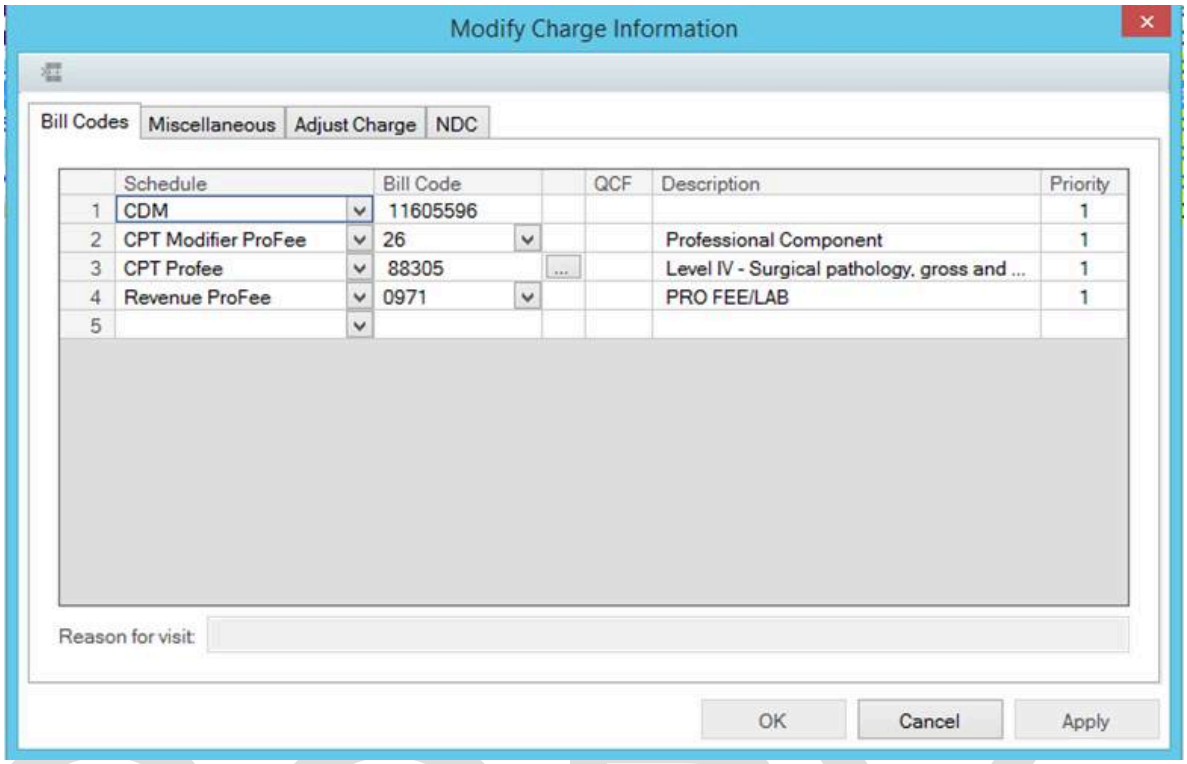
11. Press **Ok** at the bottom right.
12. Select the **Case Charges ICON** again.
13. Select **Charge Viewer** at the bottom left corner.



14. One can now see the entire **Charge Viewer**.



15. If the charges do not match as indicated on the invoice then select the test, right click and select "**Modify Charge Information**".



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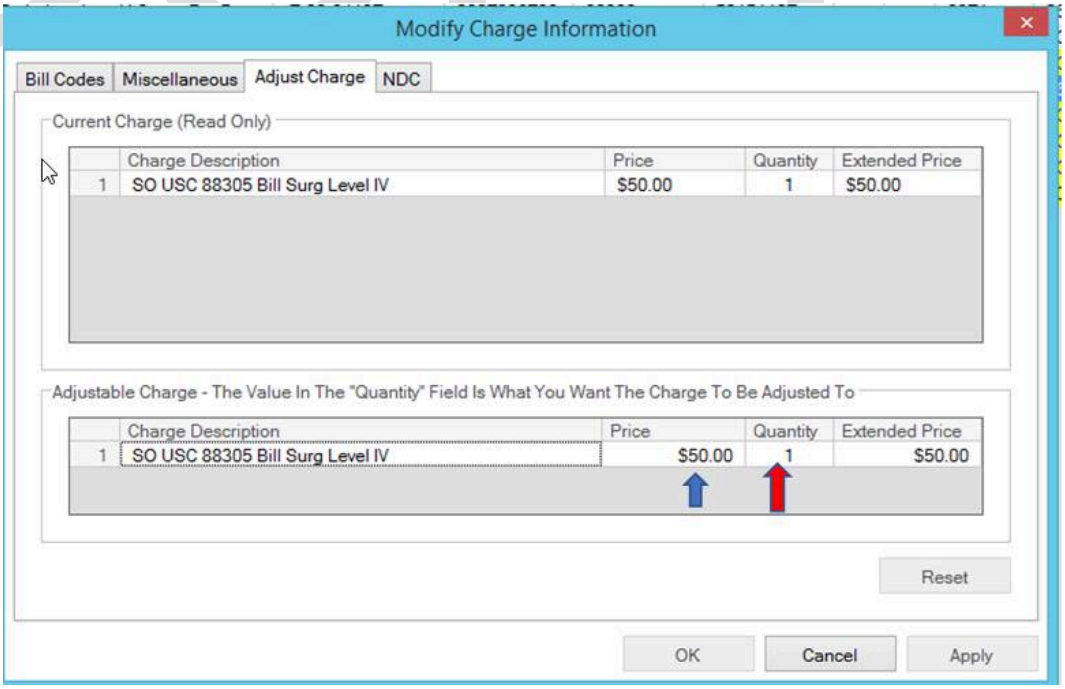
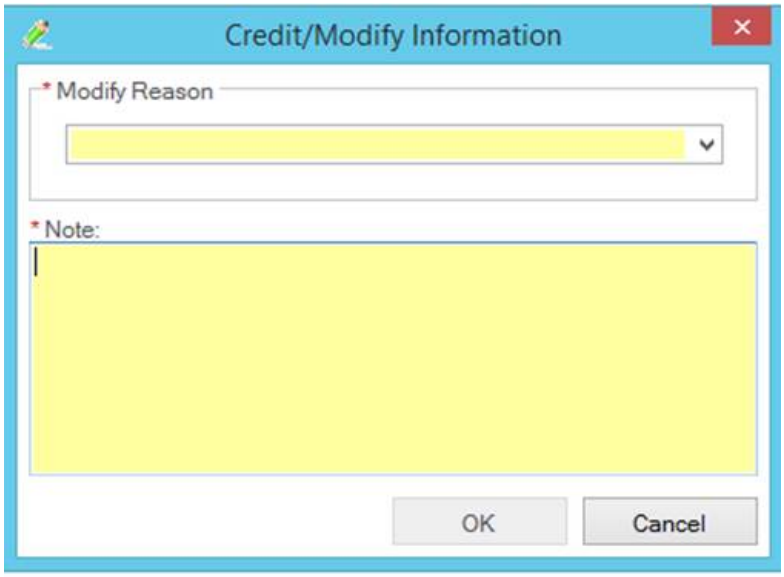
16. Select the **Adjust Charge** tab.
17. Select the price area in the Lower section and change the price (blue arrow).



18. Select **Modify Charge Information**.



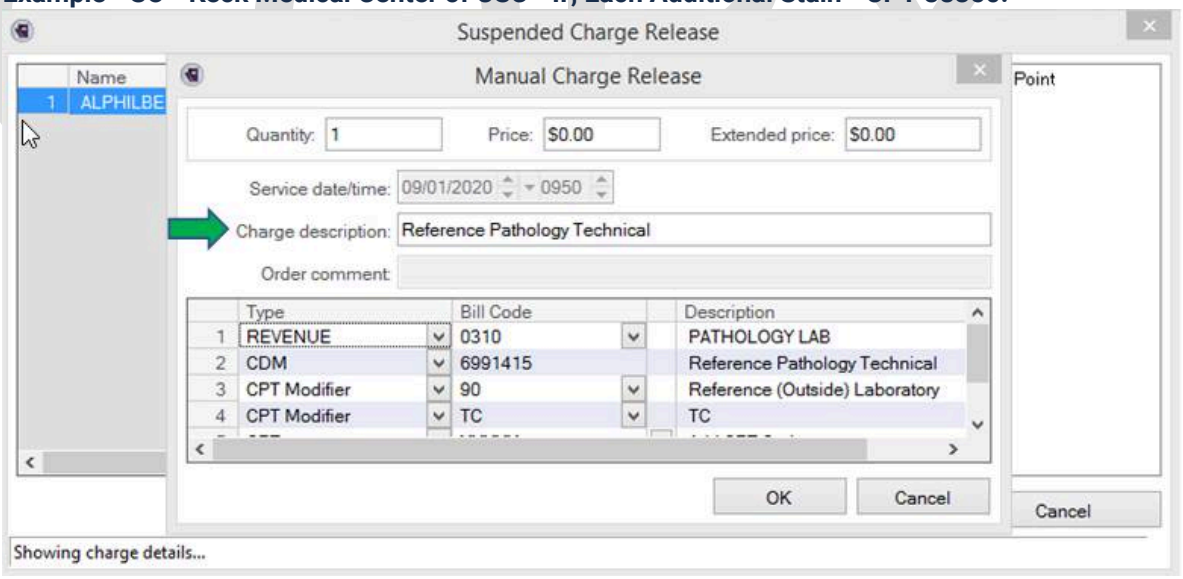
19. Using the drop-down selection for the **Modify Reason**: Select **Other**.
20. In the Note section please type "**Charge is as indicated on the invoice**".
21. Press **OK** or **Enter**.
22. If the Quantity is more than one, repeat the process from step 18 by selecting the Quantity Section (Red Arrow).
23. On Note section please type "Quantity as indicated on the invoice".
24. In some cases, one may have to change the price and Quantity. This can be done at the same time. In this situation under Note section please type "Charge and Quantity is as indicated on the invoice".
25. For test that is selected as MISC 26 or MISC TC, double click on the selected MISC test.
26. Double click on the row that is highlighted in pink.

COPY

27. Type the Quantity if it is more than 1, Type the price accordingly so the Extended Price is equal to the Charge on the invoice.

    Write the description of the reference test in the Charge description section (Green Arrow).

    Example - SO - Keck Medical Center of USC - IF, Each Additional Stain - CPT 88350.



28. Add the CPT code **88350** from the very last line.

29. Press on the square which has 3 dots.

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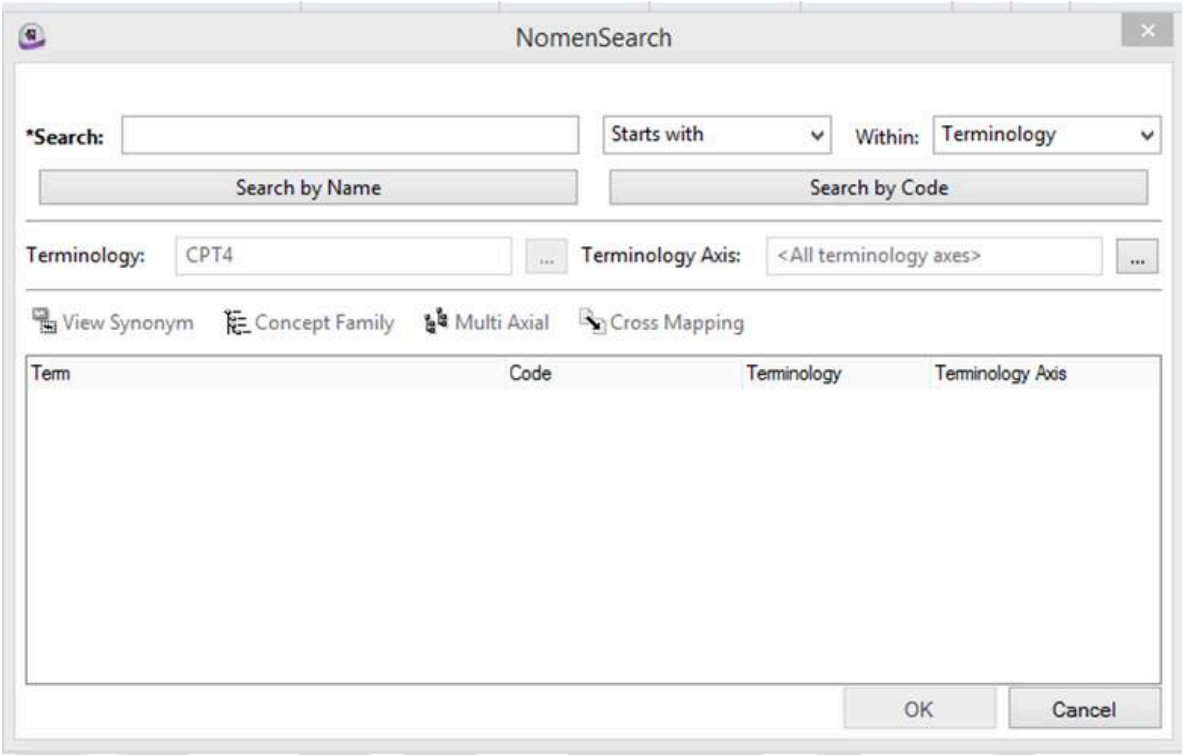

30. In the search section type in the CPT **88350** code from the invoice. And **press enter**
31. Highlight the CPT code and press OK twice
32. Select **Release All**

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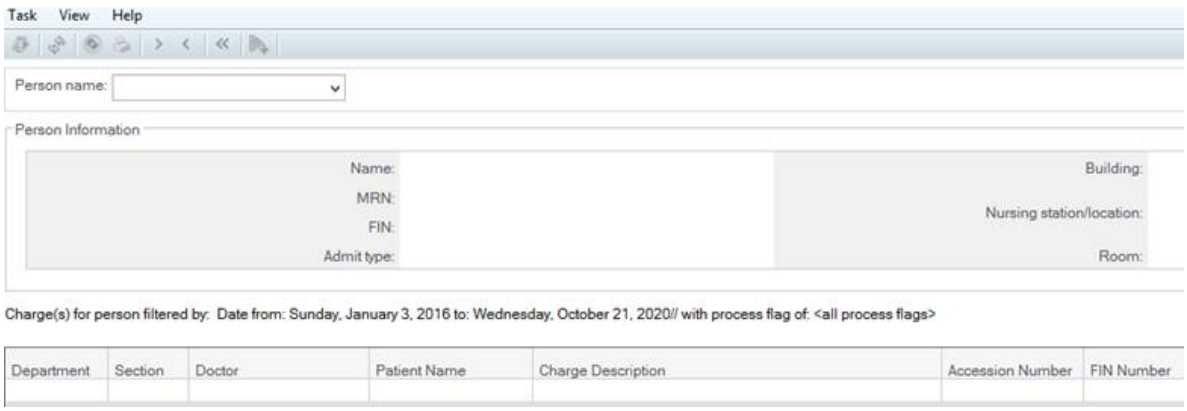
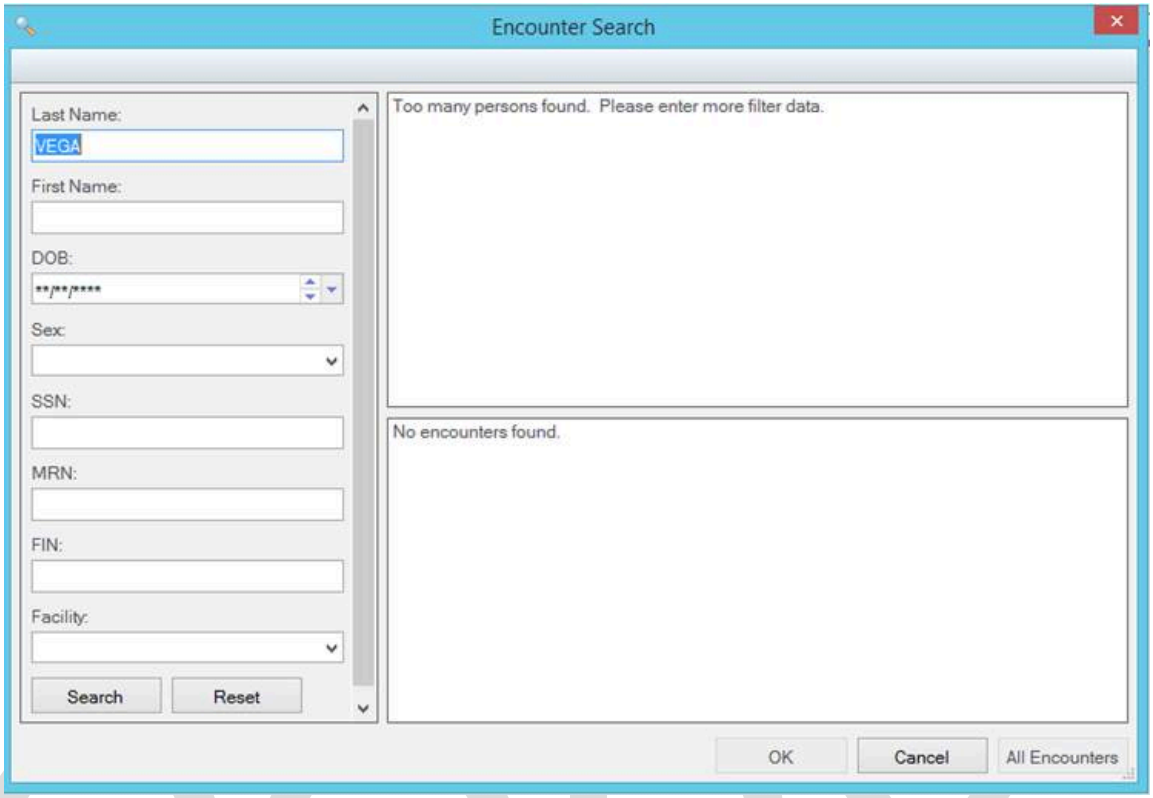
Submitting Charges For Reference Laboratory Testing

1. Select **Charge Viewer**
2. Type the **MRN** or patient's **Last Name** in the **Person Name** field. See below "blue arrow".



3. **Encounter Search** window opens. See below



4. Delete the name and type in the **MRN**.
5. Select the encounter for the date of service as indicated on the invoice. **Press OK twice**.
6. If there are other charges associated with the encounter, then all the posted charges will open. If there no charges posted then the screen will not show any charges.
7. Select the charge ion from top left.

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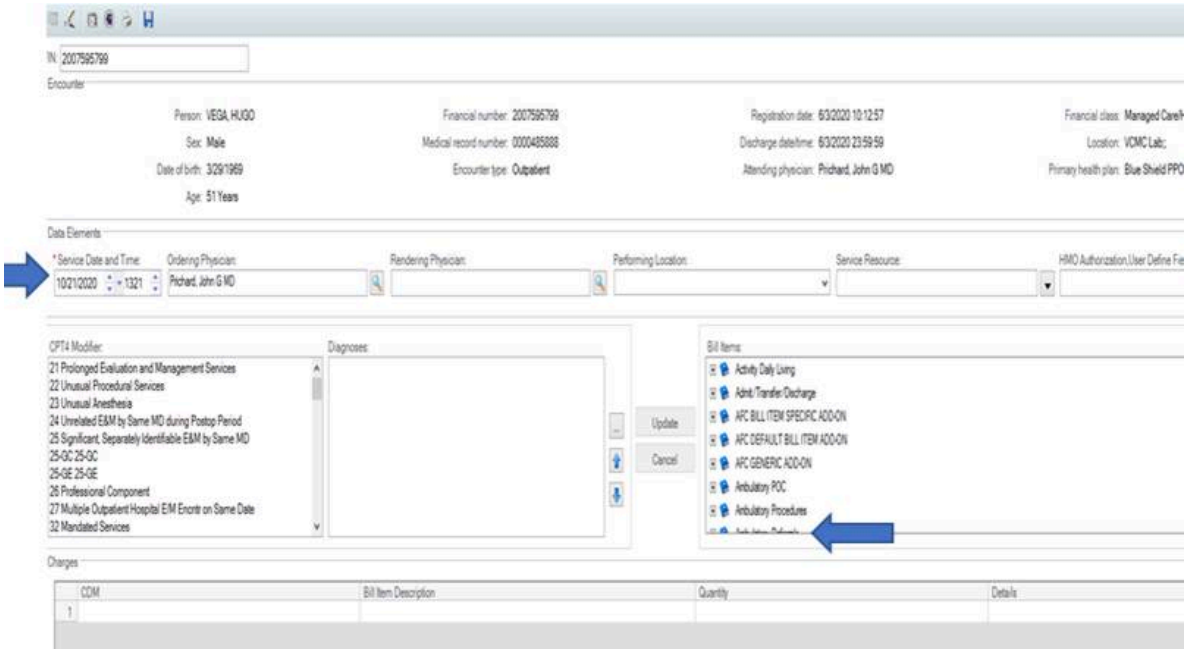

8. Change the data and time of the original date and time of the encounter.
9. Select Anatomic Pathology from right block “Blue Arrow”. Expand the Anatomic Pathology section. Select appropriate test and add the charge. If the test has more than one Quantity, make sure you change the quantity according to the invoice and then select. Add all the tests for the same encounter if more than 1 test at the same type and then submit the by selecting submit at the bottom right. The screen will go grey.
10. Close the screen by selecting “X” at the top right.
11. Select the double arrow at the top left. This will refresh the screen and you will then be able to see the submitted charge(s).

If the charges need to be modified or information about the test needs to be added, follow the instructions from step 16 to 33.

COPY

All Revision Dates

3/2/2026

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Step Description	Approver	Date

Hospital Administration	Jason Arimura: Associate Hospital Administrator, VCMC & SPH	3/27/2026
Laboratory Service Dept	Erlinda Roxas: Director, Laboratory Services	3/26/2026
Laboratory Service Dept	Amanda Lo: Medical Director, SPH Lab	3/18/2026

COPY

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L.HIST.67 Gram Stain for Bacteria in Tissue

COPY

PURPOSE:

Gram stain is used clinically to delineate two distinct groups of microorganisms. Those that retain primary dye (crystal violet), are called gram-positive. Those that lose the primary dye during a decolorization step are called gram-negative. The mechanisms whereby gram-positive organisms retain the primary stain are unknown, although the chemistry and structure of cell walls are most certainly involved.

Numerous modifications of the original Gram method have been described. The Sigma procedure is based on the work of Hucker and Conn utilizing a crystal violet-ammonium oxalate solution that aids in differentiation and is quite stable.

POLICY:

FIXATION:
Formalin preferred.

TECHNIQUE:
Paraffin sections at 4 to 6 microns.

QUALITY ASSURANCE:
Control slide with known gram-positive and gram-negative bacilli.

SOLUTIONS (Sigma Diagnostics Kit):
Crystal Violet Solution
Gram's Iodine Solution
Decolorizer Solution
Safranin O Solution
Tartrazine Solution

PROCEDURE:

1. Deparaffinize sections and hydrate to deionized water,
2. Place slides on staining rack and cover sections with Crystal Violet Solution for 1 minute.
3. Drain off Crystal Violet Solution and rinse thoroughly in deionized water.
4. Mordant in Gram's Iodine Solution for 5 minutes.
5. Rinse in deionized water and blot sections.
6. Differentiate in absolute alcohol or acetone.
7. Rinse in deionized water.
8. Cover slides with Safranin O Solution for 30-60 seconds.
9. Rinse in deionized water.
10. Cover sections with Tartrazine Solution for 5-10 seconds.
11. Blot off excess stain.
12. Rinse in 2 changes absolute alcohol.
13. Clear in xylene and mount.

COPY

RESULTS:

Gram-positive bacteria blue
Gram-negative bacteria red
Nuclei red
Other tissue elements yellow

REFERENCE(S):

- Gram C: Ueber die isoliete faarbung der schizomyceten in schmitt and trockenpraparaaten. Fortschr Med 2:185, 1884
- Hucker GM, Conn HG: Further studies on the methods of Gram staining. NY Agric Exp Stn Tech Bull No. 128, 1927
- Histopathological Technic and Practical Histochemistry, 3rd ed., RD Lillie, Editor, McGraw-Hill, New York, 1965, pp 565-567

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VENTURA COUNTY HEALTH CARE AGENCY

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Owner	Amanda Lo: Medical Director, SPH Lab
Policy Area	Laboratory Services - Histology

L.HIST.68 Kinyoun's Acid-Fast Stain (AFB)

COPY

POLICY:

FIXATION: 10% formalin preferred, others may be used.

SECTIONING: Paraffin sections at 4 microns.

SOLUTIONS: Volu-Sol kit, Kinyoun's

QUALITY ASSURANCE: Control--lung or other tissue with known acid-fast bacilli.

PROCEDURE:

1. Deparaffinize and hydrate to distilled water.
2. Ring tissue with Diamond point or wax pencil.
3. Place slides in a large Petri dish and flood with Kinyoun's Carbol Fuchsin solution at room temperature for 20 minutes.
4. Wash well in tap water.
5. Decolorize with acid alcohol until tissue is pale pink.
6. Wash in tap water.
7. Flood slide with Methylene blue.
8. Dehydrate with 2 changes of 95% alcohol, absolute alcohol, clear in 2 changes of xylol, and mount.

RESULTS:
Acid-fast bacteria -- bright red to fuschia
Background -- light blue

REFERENCE(S):

- Kinyoun, J.J.: Amer. J. Pub. Health, 5:867,1915

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3/2/2026

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Laboratory Service Dept	Amanda Lo: Medical Director, SPH Lab	3/18/2026

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Owner	Amanda Lo: Medical Director, SPH Lab
Policy Area	Laboratory Services - Histology

L.HIST.69 Grocott Methenamine Silver Nitrate (GMS) Stain

COPY

POLICY:

SOLUTIONS:

1. 10% aqueous chromic acid (chromium trioxide, CrO3).
2. 5% aqueous (silver nitrate, AgNO3).
3. 3% aqueous methenamine (hexamethylenetetramine, C6H12N4).
4. 5% aqueous borax (sodium borate, Na2B4O7 10H2O).
5. 1% aqueous (gold chloride, HAuCl4 3H2O).
6. 1% aqueous (sodium metabisulfate, Na2S2O5).
7. 2% aqueous (sodium thiosulfate, Na2S2O3 5H2O)
8. 0.290 light green solution.

METHENAMINE SILVER NITRATE SOLUTION (STOCK)

Silver nitrate, 5% solution..... 5.0 ml
Methenamine, 3% solution ..... 100.0 ml

METHENAMINE SILVER NITRATE SOLUTION (WORKING)

Methenamine silver nitrate solution (stock) ..... 25.0 ml
Distilled water ..... 25.0 ml
Borax, 5% solution ..... 2.0 ml

Make fresh.

PROCEDURE:

1. Deparaffinize sections and hydrate to distilled .
2. Place in 10% chromic acid for 10 minutes (do not discard).
3. Wash slides in tap water for a few seconds, to remove excess chromic acid.
4. Place in 1% sodium metabisulfate for 1 minute.
5. Rinse in tap water for 1 minute, then rinse in distilled H2O.
6. Place in freshly mixed working Methenamine Silver nitrate solution in water bath, at 58C to 68C for 20 minutes or more time until section turns “yellowish brown”.
7. Remove and rinse in distilled water.
8. Tone in 1% gold chloride, approximately 3 minutes (solution is reused 5 times).
9. Rinse in distilled water.
10. Place in 5% sodium thiosulfate solution for 3 minutes.
11. Wash thoroughly in tap water.
12. Slides ma y be counterstained with light green solution, for 2 minutes.
13. Deh ydrate in 95%alcohol, absolute alcohol, clear in xylene and coverslip.

COPY

RESULTS:

Fungi - sharply delineated in black.
Mucin - taupe to dark gray.
Inner parts of mycelia and hyphae - old rose.
Background - pale green.

REFERENCES:

- Arch Path Lab Med., Vol. 102, July, 1978. Charles T. Mahan, HT, George #. Slae, M.D.
- Grocott RG: A Stain for Fungi in Tissue Sections and Smears. Am. J. Clin Pathol. 25: 97a5 979, 1955
- Snmith JW, Hughes WT: A Rapid Staining Technique for the Identification of Pneumocystis carinii Cysts in Tissue Sections and Smears. J. Clin Pathol 16:383 384, 1963
- Bowling MC, Smith IM, Wescott SL: A Rapid Staining Procedure for Pneumocystis carinii. Am. J. Med. Technol. 39: 367 268, 1973.
- Lillie RD, Henson JPG, Burtner HCJ: Meta reduction Reactions of the Melanins: Silver and Ferric Ferricyanide Reduction by Various Reagents In Vitro. J. Histochem 5:311 324, 1957

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Owner	Amanda Lo: Medical Director, SPH Lab
Policy Area	Laboratory Services - Histology

L.HIST.70 Alcian Blue, pH 2.5

COPY

REAGENTS:

1. **3% Acetic Acid Solution**
   - Glacial acetic acid.....15.0 mL
   - Distilled water .....485.0 mL
   - **Stability**: Room Temperature. Refer to manufacturer label.
2. **1% Alcian Blue Solution (Buy from Poly Scientific)**
3. **Periodic Acid, 0.5%**
   1. Periodic Acid.....2.5 g
   2. Distilled water .....500 ml
   3. Stability: Room Temperature.
4. **Schiff's Reagent (Buy Sigma)**

PROCEDURE:

1. Deparaffinize and hydrate sections to distilled water.
2. Place slides in 3% acetic acid solution for 3 minutes.
3. Place slides in Alcian blue solution for 30 minutes.
4. Wash slides in running tap water for 2 minutes.
5. Place in periodic acid 5 minutes.
6. Rinse well.

7. Place slide in Schiff's for 10 minutes.
8. Place slide under hot water and rinse for 2 minutes.
9. Counterstain in the autostainer Program 7.
10. Mount slides.

RESULTS:

- **Weakly acidic sulfated mucosubstances, hyaluronic acid, and sialomucins** – dark blue
- **Background** – pink to red

REFERENCE:

- Histotechnology: A Self-Instructional Text, Freida L. Carson, HT, PhD, ASCP Press Chicago

All Revision Dates

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Approval Signatures

Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator, VCMC & SPH	3/27/2026
Laboratory Service Dept	Erlinda Roxas: Director, Laboratory Services	3/26/2026
Laboratory Service Dept	Amanda Lo: Medical Director, SPH Lab	3/18/2026

Status **Active** PolicyStat ID **20140636**

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Owner	Amanda Lo: Medical Director, SPH Lab
Policy Area	Laboratory Services - Histology

L.HIST.71 Periodic Acid-Schiff (PAS)

COPY

POLICY:

Test Schiff's Solution:

Pour a few drops of Schiff's solution into 10 cc of 40% formaldehyde. If solution turns reddish purple rapidly, it is good. If reaction is delayed and the resultant color is deep blue-purple, the solution is breaking down.

SOLUTIONS:

Sigma's – PAS Reagent 0.5% Periodic Acid Solution

Periodic acid crystals ..... 0.5 gm
Distilled water ..... 100.0 ml

0.2% Light Green Counterstain (stock)

Light green crystals ..... 0.2 gm
Distilled water ..... 100.0 ml
Glacial Acetic Acid ..... 10.2 ml

Light Green (working)

Light green, stock solution ..... 10.0 ml
Distilled water ..... 50.0 ml

OR Harris' Heematoxylin

NOTE: If PAS reaction with digestion is desired, place sections in Petri dish, with saliva covering tissue for 1 hour at room temperature. Wash in running water for 10 minutes, then distilled water before proceeding with stain.

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PROCEDURE:

1. Xylene.
2. Absolute alcohol.
3. Alcohol 95%.
4. If Zenker-fixed, remove mercury precipitate in iodine, wash in water and decolorize in hypo-solution.
5. Rinse in distilled water.
6. Periodic acid solution for 5 minutes (oxidizer).
7. Rinse in distilled water.
8. Place in Coleman's Feulgen or Schiff's leuco-fuchsin for 15 minutes.
9. Place in running tap water for 10 minutes for pink color to develop.
10. Stain in Harris' hematoxylin for 6 minutes, or light green counterstain for a few seconds. Light green is recommended for counterstaining sections in which fungi are to be demonstrated. Omit steps 11 through 15 if light green is used.
11. Rinse in tap water.
12. Differentiate in acid alcohol, 3 to 10 quick dips.
13. Wash in tap water.
14. Dip in ammonia water to blue sections.
15. Wash in running tap water 10 minutes.
16. Alcohol, 95%.
17. Absolute alcohol, 2 changes.
18. Xylene, 2 changes.
19. Mount.

COPY

RESULTS:

Glycogen, mucin, hyaluronic acid, reticulin, fibrin or thrombi, colloid droplets, hyalin of arteriosclerosis, hyalin deposits in glomeruli, granular cells in the renal arterioles were preserved, most basement membranes, colloid of pituitary stalks and thyroid, amyloid infiltration and other elements may show a positive reaction – rose to purplish red

Nuclei - blue
Fungi - red
Background – pale green (with light green counterstaining).

REFERENCE(S):

- MacManus, JFA: Stain Technology, 23:99, 1948 (AFIP Modification)

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L.HIST.72 Mayer's Mucicarmine Stain for Staining Mucins of Epithelial Origin

COPY

PRINCIPLE:

Tissue acid mucopolysaccharides may be demonstrated by a variety of techniques. Mayer's mucicarmine procedure as modified by Southgate achieves excellent contrast between red staining mucin and other cellular components. Aluminum, contained in the formulation, is believed to form a chelate complex with mucin, to which carmine attaches by dye-lake formation. The stain displays specificity towards mucins of epithelial origin, whereas mucins of fibroblastic origin stain poorly. Its major use may be in identification of primary tumor sites and distinguishing mucin-negative undifferentiated squamous cell lesions from mucin-positive adenocarcinomas. The procedure described by Sigma is similar to that of Southgate. A stable solution of tartrazine has been substituted for metanil yellow.

POLICY:

FIXATION: Any well-fixed paraffin sections cut 4-6 microns.

QUALITY ASSURANCE: Control slide – appendix.

SOLUTIONS: Mayer's Mucicarmine Stock Solution (Eng, Scientific, Inc.)

Carmine (certified, 10 g/L, aluminum hydroxide, 10 g/L and aluminum chloride, 5 g/L, in ethanol, 50% store in refrigerator (2-6 degrees C). Reagent labeled bears expiration date.

Tartrazine Solution: Tartrazine, 0.25% acetic acid, 0.25%. Store at room temperature (18-26 degrees C).

Or

- Metanil yellow ..... 0.25 gm
- Distilled water ..... 100.0 ml
- Glacial Acid ..... 0.25 ml
- Store at room temperature

Weigert's Iron Hematoxylin Solution, Part A and Part B

PROCEDURE:

1. Deparaffinize slides to deionized water.
2. Stain in working Weigert's hematoxylin solution for 7 minutes.
3. Wash in running tap water for 10 minutes.
4. Stain in mucicarmine solution overnight.
5. Rinse quickly and remove excess water before the next step by patting slides with filter paper.
6. Stain in Tartrazine yellow solution or Metanil yellow with on/off then quickly patting slides with filter paper.
7. Dehydrate with three changes of 95% alcohol and three changes of absolute alcohol.
8. Clear in Xylene and mount with synthetic resin.

COPY

RESULTS:

- **Nuclei** – Black
- **Nuclei** – deep rose to red
- **Capsule of Cryptococci** – deep rose to red
- **Other tissue elements** – blue or yellow

REFERENCES:

Handbook of Histopathological Techniques, Edited by DFA Culling, 2nd ed., Butterworth Inc., London 1963.

Theory and Practice of Histotechnology, Edited by DC Sheehan and BB Hrapchak, 2nd ed., Mosby, St. Luis (MO), 1980.

Histotechnology, A Self-Instructional Text, Freida L. Carson, ASCP pp. 123-125.

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COPY

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Policy Area	Laboratory Services - Histology

L.HIST.73 Stains for Pigments and Minerals: Iron Stain

COPY

PRINCIPLE:

The stain is based on the well known Prussian blue reaction in which ionic iron reacts with acid ferrocyanide producing a blue color.

POLICY:

FIXATION: Alcohol or 10% formalin.

TECHNIQUE: Any well prepared tissue section cut 5-6 microns and fixed in neutral buffered formalin is satisfactory for iron staining. Blood or bone marrow films are prepared in the usual fashion, air dried for at least 30 minutes and fixed in absolute methanol for 7 minutes.

SOLUTIONS (SIGMA Diagnostic Kits):

- Potassium ferrocyanide solution
- Hydrochloric acid solution.
- Eosin

PREPARATION:

Iron stain working solution is prepared by mixing equal volumes of Potassium Ferrocyanide solution and Hydrochloric Acid Solution. Use once and then discard.

PROCEDURE:

NOTE: Use chemically clean glassware and control slide.

1. Deparaffinize and hydrate tissue to deionized water.

2. Place slides in Iron Staining Solution for 10 minutes.
3. Rinse in deionized water.
4. Place slides in Eosin for 2 minutes.
5. Dehydrate through alcohol and xylene and mount.

RESULTS:

- Iron pigments: bright blue
- Nuclei: red
- Cytoplasm: light pink

REFERENCES:

- Theory and Practice of Histotechnology, 2nd ed. DC Sheehan, BB Hrapchak, Editors, CV Mosby, St. Luis (MO), 1980, p217
- Leong AS-Y Milios J: Rapid Immunoperoxidase Staining of Lymphocyte Antigens Using Microwave Irradiation. J Pathol 148:183,1986
- Brinn NT: Rapid Metallic Histologic Staining Using the Microwave Oven. J. Histotechnol 6:125, 1983
- Valle S: Special Stains in the Microwave Oven. J. Histotechnol 9:237, 1986
- Atlas of Cytochemistry and Immunochemistry of Hematologic Neoplasms. T Sun, C-Y Li, LT Yam, Editors, ASCP, Chicago (IL), 1985, p205

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L.HIST.75 Gomori's Method for Reticulum Fibers

COPY

POLICY:

FIXATION: 10% Buffered Formalin.

TECHNIC: Paraffin. Cut sections at 6 micrometers.

SOLUTIONS:

1. Ammoniacal Silver Nitrate Solution (Gomori's)
2. Potassium Permanganate 0.5% Aqueous
3. Potassium Meta-Bisulfite 2% Aqueous
4. Ferric Ammonium Sulfate 2% Aqueous
5. Formalin 20% Non-buffered
6. Sodium Thiosulfate 2% Aqueous
7. Gold Chloride 0.2% Aqueous

PROCEDURE:

1. Deparaffinize and hydrate water.
2. Oxidize in Potassium Permanganate 0.5% Aqueous for 8 minutes.
   Brown color
3. Wash in tap water for 2 minutes.
4. Place in Potassium Meta-Bisulfite 2% Aqueous for 1 minute.
   Turns Clear
5. Wash in tap water.

6. Place in Ferric Ammonium Sulfate 2% Aqueous for 1 minute.
7. Wash in distilled water.
8. Place in Ammoniacal Silver Nitrate Solution for 20 minutes.
   Light, Light Brown
9. Four changes of distilled water.
10. Mordant slide with Formalin 20% Non-buffered for 3 minutes (Sections should turn Dark Brown immediately. If this does not occur, one of your solutions is ineffective and entire procedure should be started again with fresh solutions and acid-cleaned glassware.)
11. Wash well in running water.
12. Dip 1 time in Gold Chloride 0.2% Aqueous.
13. Wash well in running water.
14. Place in Potassium Meta-Bisulfite 2% Aqueous for 1 minute.
15. Place in Sodium Thiosulfate 2% Aqueous for 1 minute.
16. Wash well in water.
17. Counterstain with Eosin or Light Green if desired.
18. Dehydrate in 95% Alcohol, Absolute Alcohol and clear in Xylene, 2 changes each.
19. Mount

RESULTS:

- Reticulum Fibers ..... Black
- Background ..... Gray

COPY

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Owner	Amanda Lo: Medical Director, SPH Lab
Policy Area	Laboratory Services - Histology

L.HIST.76 Monochromatic Blue Stain of Organism and Tissue

COPY

PURPOSE:

One of the differential dye solutions is Solution B, Thiazine Dye. It can be purchased separately as catalogue #10522. Used by itself, Thiazine Dye provides an even more rapid method for demonstrating Helicobacter pylori in tissue.

PROCEDURE:

1. Deparaffinize and hydrate sections. Drain slides.
2. Place slides in 1 change of Methanol, 10 minutes each.
3. Go directly from methanol into solution B (Thiazine) for 8 minutes, depending on your preference for intensity of staining. Usually somewhere mid-range is best.
4. Rinse quickly in distilled water only long enough to remove excess stain.
5. Dehydrate in 95% alcohol, 100% alcohol and clear with xylene. Coverslip.

RESULT:

Helicobacter stain dark blue against a blue background. This microorganism is recognized by its curved, spiral, wavy or gull-wing configurations under high dry magnification.

The times given in this procedure are suggestions only, derived from our own controlled conditions. Variations should be tried by individual users because of technique differences, section thickness or pathologists personal preferences. You may wish to judge the quality of the stain as much by the unknown section as the control. Our control has dense concentrations of organisms and can appear overly dark in a very short time.

- Helicobacter dark blue
- Collagen and muscle pale pink
- Cytoplasm varying lighter blue shades
- Nuclei blue to violet

REFERENCE(S):

- The Journal of Histotechnology,"A Rapid Stain for Campylobacter pylori in Gastrointestinal Tissue Sections," Skipper, Ray, Vol. 12, No. 4, Dec 1989.
- Laboratory Medicine, "A Modified Diff-Quick Stain for Helicobacter pylori in Gastrointestinal Biopsies," Vol. 25, No. 6, June 1994, Potvin, Carol.

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Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator, VCMC & SPH	3/27/2026
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Laboratory Service Dept	Amanda Lo: Medical Director, SPH Lab	3/18/2026

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Owner	Amanda Lo: Medical Director, SPH Lab
Policy Area	Laboratory Services - Cytology

L.CYT.23 Staining Non-Gyn Specimens to Avoid Cross-Contamination

COPY

PURPOSE:

The possibility of cross-contamination which might occur from highly cellular fluid sediment smears should be a serious consideration when staining several cases at one time. It is obvious that atypical or malignant cells floating from one patient's slide to another could result in a serious misdiagnosis.

If possible, specimens should be assessed for the potential for cross contamination. The clinical information should be taken into account. Concurrent cytological specimens from patients with known malignant tumors, e.g. ruptured tumor with concurrent washings, pleural fluid or ascites fluid in a patient with a lung carcinoma or an intraabdominal malignancy, should be considered high risk for cross contamination. Gross examination of the cytology specimen can also be helpful with very cellular smear or tissue fragments in the alcohol fixed material.

The following procedure should be followed to avoid this problem:

1. When making sediment smears, apply a few drops of concentrated cellular material and spread this evenly over the slides without excess layering of material.
2. Before staining, rinse each smear well with alcohol fixative from a wash bottle. It may be impractical to stain one case at a time; if so, place slides from different cases in separate staining racks.
3. If one staining rack is used, widely separate slides from different cases. Placing a blank slide on either side of each case may be helpful in containing cells which may detach.
4. When moving slides through the stains and rinses, avoid shaking or agitating the rack to reduce the possibility of loosening the cells from the smears. Highly cellular cases should be stained after the other cases and the staining fluids changed or filtered between each of the highly cellular cases.

5. A rapid stain, e.g., toluidine blue can be done on a wet specimen to detect highly cellular specimens.

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Laboratory Service Dept	Erlinda Roxas: Director, Laboratory Services	3/26/2026
Laboratory Service Dept	Amanda Lo: Medical Director, SPH Lab	3/18/2026

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Owner	Amanda Lo: Medical Director, SPH Lab
Policy Area	Laboratory Services - Histology

L.HIST.35 Processing a Death

POLICY:

The following policy will be observed for activity involving the morgue: *100.031 Processing a Death & Post-Mortem Exam (Autopsy)*.

COPY

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Laboratory Service Dept	Amanda Lo: Medical Director, SPH Lab	3/18/2026

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L.HIST.38 Autopsy Consent

COPY

POLICY:

The following is the protocol which will be followed in obtaining autopsy consent:

1. While all autopsies must be requested by a physician, it is a requirement that an autopsy consent be signed and witnessed by an employee of Ventura County Medical Center.
2. If the deceased's nearest legal relative lives some distance away and it is not possible to obtain an immediate written consent, then a phone conversation consent can be obtained.
3. If phone consent for an autopsy is obtained, a second party must listen to the conversation and witness that consent was given for the autopsy.
4. The physician asking for the autopsy and the person listening to the conversation must verify the consent was given by signing their names on the autopsy consent form.
5. If the person giving the consent comes to the hospital then that party should be asked to sign the consent.
6. There is a legal order of relative priority when obtaining autopsy consent.
    1. Spouse.
    2. An adult son or daughter.
    3. Either parent.
    4. An adult brother or sister.
    5. A guardian or conservator of the person deceased at the time of deceased's death.
7. An example of the legal order is that if a person (spouse) is married to the deceased, then he/she is the one who should decide if there should be an autopsy. If the spouse does not want an autopsy, but an adult son or daughter requests one, then the spouse's request should be honored.

8. If there are any questions, they should first be referred to the nursing supervisor or attending clinician. There is a pathologist on call who can answer any questions that cannot be answered by the nursing supervisor or clinician.

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L.HIST.43 Quality Assurance for Pathology and Non-Gynecological Cytology

COPY

PURPOSE:

Quality assurance for surgical pathology, cytology, and autopsies is important. The following quality assurance protocol for surgical pathology, non-gyn cytology, and autopsies has been implemented.

POLICY:

A. All difficult, controversial, or unusual cases will be shown to other pathologists or will be sent directly to a recognized authority for consultation.

B. Non-gynecological cytology findings should be correlated with histological and/or clinical findings. There should also be correlation with specialized studies such as immunohistochemistry, molecular studies, flow cytometry and outside consults.

   1. In many cases, especially those with a benign cytology diagnosis, there may be considerable delay between obtaining the cytology specimens and a later histological specimen or else obtaining significant clinical followup. In all histological cases, in which a previous cytology specimen was received, the cytology should be reviewed and any significant disparities should be reconciled and commented on in the current histology report. An amended report should be issued when the disparity would affect patient care. In cases in which additional clinical information should come to light at a later date, the cytology should also be reviewed.

C. All surgical pathology tissue diagnoses are made by a pathologist and a pathologist will sign the surgical pathology report. A pathologist will review all non-gynecological slides and sign the reports.

D. All frozen section diagnoses will be compared with the final diagnosis at the time the

pathology report is dictated and any significant discrepancies will be examined in writing in the pathology report.

E. A summary of the number of cases reviewed by in house pathologists, the number of cases sent to outside experts for consultation, the number of discrepancies in the diagnosis rendered by VCMC pathologist(s) and the consulting pathologists, and the number of frozen section diagnoses and the final diagnosis will be sent at least annually to the Medicine Committee and the Executive Committee.

F. Any cases with clinically significant discrepancies between the frozen section and the permanent section diagnosis, between the VCMC pathologist(s) and the consulting pathologists, and any corrections or changes in diagnosis due to diagnostic errors (missed cases) will be sent by the pathologist to the appropriate medical staff committee for review.

G. In addition to the above quality assurance protocols, the pathologic findings of each autopsy will be correlated with the clinical impressions and clinical findings. This will usually be done in a correlative note to the autopsy report. In addition, the correlation and autopsy findings may be part of a formal teaching conference or the autopsy findings may serve as the impetus for a more didactic teaching conference.

H. A copy of the final autopsy report will be sent to the medical staff quality assurance committee for incorporation into the hospital quality assurance program.

I. In cases where the pathology or cytopathology diagnoses are considered particularly significant or unexpected, the submitting clinician should be notified of the diagnosis. This should be documented in the pathology report. In cases where the submitting physician is not available such as the Emergency Room or a clinic, the message should be conveyed to the attending physician covering that area. In some cases, the message can be left with a nurse. In all cases, the name of the person who is notified should be noted in the pathology report.

COPY

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Owner	Amanda Lo: Medical Director, SPH Lab
Policy Area	Laboratory Services - Histology

L.HIST.47 Quality Management For Surgical Pathology and Autopsy

COPY

PURPOSE:

The laboratory Quality Management Program includes active surveillance of laboratory activities starting with specimen identification, preservation, and data entry, specimen processing and specimen reporting. The data from this surveillance is studied and used on an ongoing basis to correct any problems detected and used to improve the overall quality of patient care. The Quality Management Program encompasses the Performance Improvement Program, the Quality Improvement Program, the Competency Assessment Program and the Quality Assurance Program. The following indicators are monitored on an ongoing basis:

POLICY:

A. DATA ENTRY

1. The accurate transcription of the requisition slips into the computer, these are checked daily. A log is maintained of discrepancies. Corrective actions include issuing a corrected report, contacting the submitting physician or clinic and additional in-service training of individuals showing increased inaccuracies.

B. SPECIMEN PROCESSING

1. At this time, some surgical pathology and autopsy slides are sent to an outside consultant for consultation. A log is maintained of specimens sent out. This is reconciled when the slides are returned. Any missing slides are immediately tracked until they are received.
2. Any problems with the quality of the surgical pathology or autopsy slides are

addressed with the histologist.

3. The surgical pathology slides are accompanied by the daily log of staining quality. The reviewing pathologist initials the log. If corrective action is needed, it is discussed immediately with the technologist involved and resolved.

C. SLIDE INTERPRETATION AND REPORTING

1. All pathologists participate in mandatory proficiency testing for surgical pathology. Results are examined and corrective action will be taken if needed.
2. All pathologists participate in surgical and non-GYN inter-laboratory peer comparison programs (PIP and CAP non-GYN programs).
3. Ongoing quarterly quality assurance will continue. This includes: Comparisons of the frozen section diagnosis with the final diagnosis, interdepartmental consultations and outside consults. Thus the quarterly statistics will be examined and if disturbing trends are identified, appropriate action will be taken to correct the problem including issuing a corrected report and consultation with the clinician if clinically indicated.
4. Discrepancies between the frozen section diagnosis and the final diagnosis are addressed and reported in the quarterlyQuality Assurance Report. If discrepancies are present between frozen section interpretation and final diagnosis, these are addressed, if possible, as a comment on the biopsy. If the discrepancy is detected at a later date, an addendum report is issued if clinically significant.
5. Records of inter- and intradepartmental consultations will be maintained. Discrepancies will be resolved

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Policy Area	Laboratory Services - Histology

L.HIST.74 Masson's Trichrome Method for Connective Tissue

COPY

POLICY:

FIXATION: Bouin's or 10% buffered neutral formalin.

TECHNIQUE: Cut paraffin sections at 6 microns.

SOLUTIONS:

Bouin's Solution

Weigert's Iron Hematoxylin Solution

Biebrich Scarlet-Acid Fuchsin Solution

1. Biebrich Scarlet, aqueous, 1% ..... 90.0 ml
2. Acid fuchsin, aqueous, 1% ..... 10.0 ml
3. Glacial acetic acid ..... 1.0 ml

Phosphomolybdic-Phosphotungstic Acid Solution

1. Phosphomolybdic acid ..... 5.0 gm
2. Phosphotungstic acid ..... 5.0 gm
3. Distilled water ..... 200.0 ml

Aniline Blue Solution

1. Aniline blue ..... 2.5 gm
2. Glacial acetic acid ..... 2.0 ml

3. Distilled water ..... 100.0 ml

Light Green Solution
1% Glacial Acetic Acid Solution

1. Glacial acetic acid ..... 1.0 ml
2. Distilled water ..... 100.0 ml

QUALITY ASSURANCE:

Control section liver tumor, fibroid uterus, smooth muscle.

PROCEDURE:

1. Deparaffinize and hydrate to distilled water.
2. Mordant in Bouin's solution for 1 hour at 56 degrees C, or overnight at room temperature, if formalin fixed.
3. Cool and wash in running water until yellow color disappears.
4. Rinse in distilled water.
5. Weigert's iron hematoxylin solution for 10 minutes. Wash in running water 10 minutes.
6. Rinse in distilled water
7. Biebrich scarlet-acid fuchsin solution for 2 minutes. Save solution.
8. Rinse in distilled water.
9. Phosphomolybdic-phosphotungstic acid solution for 10 to 15 minutes before aniline blue solution. (Aqueous phosphotungstic acid 5% for 15 minutes before light green counterstain.) Discard Solution
10. Aniline blue solution for 5 minutes or light green solution for 1 minute (for central nervous system 15 to 29 minutes). Save solution.
11. Rinse in distilled water.
12. Glacial acetic solution for 3 to 5 minutes. Discard solution.
13. Dehydrate in 90% alcohol, absolute alcohol, and clear in xylene, 2 changes each.
14. Mount.

RESULTS:

- **Nuclei** - black
- **Cytoplasm, keratin, muscle fibers and intercellular fibers** - red
- **Collagen** - blue

NOTE: To insure proper mordanting, Bouin's solution should be preheated to 58-60 degrees C.

COPY

REFERENCE:

- AFIP Manual, 3rd edition.
- Masson, PJ: J. Techn. Methods 12:75-90, 1929, AFIP modification.

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Laboratory Service Dept	Amanda Lo: Medical Director, SPH Lab	3/18/2026

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Origination	3/3/2026	Owner	Gayle Haider: Supervisor-Quality Assurance, Laboratory Services
Last Approved	3/3/2026		
Effective	3/3/2026	Policy Area	Laboratory Services
Last Revised	3/3/2026		
Next Review	3/2/2028		

L.1.1 Statement Of Accountability

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VENTURA COUNTY MEDICAL CENTER
SANTA PAULA HOSPITAL

PROCEDURE: General Laboratory

SUBJECT: **ACCOUNTABILITY AND RESPONSIBILITY TO THE MEDICAL STAFF AND ADMINISTRATION**		POLICY NO: Admin 1.1
DEPARTMENT: Laboratory AFFECTS: LABORATORY	EFFECTIVE DATE: 12/06/2001	REVIEW DATES: 2/06,3/07,8/08,8/09,11/10,11/12 6/15, 1/22, 12/23
PREPARED BY: **Nancy Koenker** **(Reviewed by Gayle Haider)**		REVISION DATES: 11/16

The Pathology Department at Ventura County Medical Center includes the Clinical Laboratory and Anatomic Pathology. The services provided are Anatomic Pathology, Cytology, Blood Bank, Chemistry, Hematology, Coagulation, Urinalysis, Serology, Microbiology, Parasitology, and Molecular.

The Pathology Department, under the direction of the Laboratory Medical Director, shall be responsible for the daily operations of the department and shall report directly to administration and be accountable to the medical staff for meeting their needs and the needs of their patients. The functions performed, in order, to meet these needs shall include proper identification, collection, transportation, storage, processing and examination of clinical specimens and reporting of results.

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Pathology services shall also include consultation and active participation in prevention, diagnosis and management of patients. The service shall provide educational opportunities for medical and technical staff.

All Revision Dates

3/3/2026

Approval Signatures

Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator, VCMC & SPH	3/3/2026
Laboratory Services Department	Erlinda Roxas: Director, Laboratory Services	3/3/2026
Laboratory Services Department	Brad Adler, MD: Medical Director, Laboratory Services	11/14/2024
Laboratory Services Department	Gayle Haider: Supervisor-Quality Assurance, Laboratory Services	10/8/2024

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VENTURA COUNTY HEALTH CARE AGENCY

Origination	7/31/2003
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Last Revised	3/2/2026
Next Review	3/1/2028
Owner	Evan Gamad: CLS III
Policy Area	Laboratory Services

L.101 Amplified Gc/Chlamydia (Genital Swab and Urine)

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PRINCIPLE:

Chlamydia is one of the most common sexually transmitted diseases for men and women in all age groups. Although there often is pain and fluid discharge, a person can be infected without symptoms. Sources may include the urethra, cervix, eye, throat, rectum, and nasal wash (newborns).

Gonorrhea is a sexually transmitted disease of men and women. Gonorrhea can affect the urethra in men and the cervix in women, as well as the eye, throat, and rectum.

The GEN-Probe ***APTIMA*** method is a Target Amplified Nucleic Acid Probe for the presence of both Chlamydia trachomatis and Neisseria gonorrhea in men and women for **genital and urine specimens only.** Probe Tec vials cannot be processed by VCMC or Santa Paula Hospital.

PROCEDURE:

Swab collection for female endocervical specimens:

Specimen collection is performed by nursing staff or physicians.

Each collection kit contains a white transport tube, a white swab, and a blue swab.

The white swab is used for cleaning only. It is not acceptable for testing. The inoculated ***APTIMA*** vial should only contain the blue swab.

Swab collection for male urethral swab specimens:

Specimen collection is performed by nursing staff or physicians.

The patient should not have urinated for at last one hour prior to specimen collection.

Each collection kit contains a white transport tube, a white swab, and a blue swab. It is not necessary to use the white swab.

The inoculated ***APTIMA*** vial should only contain the blue swab.

Specimen Transport and Storage for Genital Swab Specimens:

After collection, transport and store the swab in the swab transport tube at 2-30 degrees C until tested. Specimens must be assayed with the *APTIMA* Assay for CT and/or GC within 60 days of collection. If longer storage is needed, freeze at -20 to -70 degrees C for up to 90 days after collection.

Collection for Male and Female Urine Specimens:

Patients should not have urinated for at least one hour prior to specimen collection.

Patient should provide first-catch urine (approximately 20-30 ml of initial urine stream into a urine collection cup free of any preservatives. The specimen should not be a clean catch collection.

Each collection kit contains a yellow transport tube and a disposable pipette.

Two ml of urine should be transferred into the *APTIMA* urine collection tube using the disposable pipette provided within one hour of collection. The correct volume of urine has been added when the fluid level is between the black fill lines on the label on the transport tube. The urine transport tube should be re-capped tightly.

Specimen Transport and Storage for Urine Specimens:

After collection, transport and store the processed urine in the *APTIMA* transport tube at 2-30 degrees C until tested. Specimens must be assayed with the *APTIMA* Assay for CT and/or GC within 30 days of collection. If longer storage is needed, freeze at -20 to -70 degrees C for up to 90 days after collection.

Processing Specimens from non-genital or urine sources:

If the source of a specimen is the eye, throat, nasal wash or rectum, the *APTIMA* vials cannot be used.

Instead order a Chlamydia culture to Public Health Laboratory.Test code is GC/Chlamyd Probe.

The swab used must be a copan swab placed in a UTM vial.

A nasal wash must be added to a UTM vial.

The specimen then must be transported refrigerated at 2-8 degrees C.

A Gonorrhea Culture is collected on a BBL Culture Swab Plus, a collection and transport device with a rayon tipped swab.

It must not be refrigerated. It should be kept at room temperature. The GC culture is performed at Public Health Laboratory

The chart on the following page may help summarize the different specimen requirements.

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CHLAMYDIA / GC TESTING SUMMARY

SOURCE	NAME OF TEST	VIAL	ORDER IN COMPUTER
Genital Male, Female	Chlam/GC-Amplified	Aptima-White with blue swabs	GC/Chlamyd Probe
Urine	Chlam/GC-Amplified	Aptima-Yellow Urine in Cup	GC/Chlamyd Probe
Eye	Chlamydia Culture	UTM with copan swab (Pertussis kit ok)	C Chlamydia
Eye	Gonorrhea Culture	Culture Swab Plus	C Gonorrhea
NP Wash (Newborn)	Chlamydia Culture	NP Wash in UTM	C Chlamydia

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Note: Do not send ProbeTec vials to VCMC or Santa Paula Hospital

REFERENCE

GEN-Probe APTIMA Manufacturer Instruction for Use.

All Revision Dates

3/2/2026

Approval Signatures

Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator, VCMC & SPH	3/2/2026

Laboratory Services Department	M. Anwar Molani: Medical Director, Laboratory Services	3/1/2026
Laboratory Services Department	Evan Gamad: CLS III	2/28/2026
Laboratory Services Department	Erlinda Roxas: Director, Laboratory Services	2/28/2026

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Status **Active** PolicyStat ID **19981489**

Origination	3/2/2026	Owner	Linda Conboy: Supervisor-Microbiology, Laboratory Services
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Effective	3/2/2026		
Last Revised	3/2/2026		
Next Review	3/1/2028		

L.MIC 7.09 STERILE BODY FLUIDS SUBMITTED IN BACTALERT BLOOD CULTURE BOTTLES

COPY

PRINCIPLE

The Virtuo Blood Detection System is used to detect the presence of microorganisms in blood of patients suspected of having bacteremia and fungemia. The System and supporting media provide a complete system for microbial detection and growth requirements.
The media provides optimal nutritional requirements for organisms commonly found in blood infections, while the instrument provides the environmental conditions needed for growth. Inoculated bottles are placed into the instrument where they are continuously monitored for the detection of microbial growth. No other manipulations of the bottle are required until the instrument determines the bottle positive or until the maximum test time has been reached as final negative. Positive samples must then be processed for identification and susceptibility via microbiological methods.

The Virtuo Blood Detection System utilizes a colorimetric sensor and reflected light to monitor the presence and production of carbon dioxide CO2 that is dissolved in the culture medium. If microorganisms are present in the sample, CO2 is produced as the organisms metabolize the substrate in the culture medium. When growth of the microorganisms produces CO2, the gas-permeable, liquid emulsion sensor installed in the bottom of each culture bottle changes from a blue green to yellow color. Positive bottles are determined by one of three software algorithms and are indicated as a yellow sensor and high reflectance units. Negative bottles result from darker sensors and low reflectance units. Bottles are read every ten minutes and processed through software algorithms to measure changes in reflected light.

MEDIA

1. Standard Aerobic Medium

a. (Color-coded Green) Pancreatic digest of casein, papaic digest of soybean meal, SPS, (0.355%) w/v), pyridoxine HCl, and other complex amino acid and carbohydrate substrates in purified water. Bottles are prepared with an atmosphere of CO2 in oxygen under vacuum. 40 ml of media in bottle.

1. Standard Anaerobic medium

a. (Color-coded Orange) Pancreatic digest of casein, papaic digest of soybean meal, SP (0.035% w/v) menadione, hemin, reducing agents, and other complex amino acid and carbohydrate substrates in purified water. Bottles are prepared with an atmosphere of CO2 in nitrogen under vacuum. 40 ml of media in bottle.

1. Sensor

a. A Colorimetric carbon dioxide sensor attached internally to the bottom of each bottle.

1. Prior to use, the BacT/Alert culture bottles should be examined for evidence of damage or deterioration (discoloration). The media should be clear, but there may be a trace of precipitate due to the anticoagulant SPS. Do not use a bottle, which contains media exhibiting turbidity or excess gas pressure; these are signs of possible contamination.
2. Inoculate one standard aerobic and one standard anaerobic medium for each culture.

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NOTE: For specialized patients (e.g., pediatric patients that do not have an abdominal abnormality), anaerobic cultures may not be indicated. However, always inoculate at least two bottles for adults. Always include anaerobic cultures for febrile neutropenic patients and patients with diabetes or wound infection.

Theory of Operation

a. The Virtuo Blood Detection System incubates, agitates, and with solid state reflectometers, continuously monitors the status of each culture bottle for microbial growth.

b. The system utilizes a colorimetric sensor and reflects light to determine the amount of carbon dioxide that is dissolved in the culture medium.

c. If microorganisms are present in the test sample, CO2 is produced as the organisms metabolize the substrates in the culture medium. When growth of the microorganisms produces CO2, the color of the sensor in the bottom of each culture bottle changes from green to lighter green or yellow.

d. Cells are scanned with data points graphed every 10 minutes. Positive reading is triggered by one of three algorithms.

1. Acceleration: A sustained acceleration in the rate of CO2 production.
2. Rate: An unusually high rate of CO2 production.
3. Initial: An unusually high Co2 lever detected soon after a bottle is loaded.

a. A Light Emitting Diode (LED) projects light onto the sensor. The light reflected is measured by a photodetector. As more CO2 is generated, more light is reflected. This information is transmitted to a computer where it is compared to the initial CO2 level in the bottle. If

bacterial CO2 has been produced, the sample is determined positive by one of the above algorithms. If, after a specified number of days, the CO2 level does not change significantly, the sample is determined negative.

b. The liquid emulsion sensor is impermeable to most ions, including hydrogen ions, and to components of media and whole as well as degraded blood. It is freely permeable to CO2. CO2 diffuses across the membrane, dissolves in the water contained in the sensor, and generates hydrogen ions:

   $CO2 + H2O <> H2CO3 <> H^+ + HCO3$

c. Free hydrogen ions interact with the sensor. As CO2 is produced, the concentration of hydrogen ions increases, the pH falls causing the sensor to become lighter in color. The result is an increase of red light reflected to the photodiode.

ACCEPTABLE SPECIMENS

- Pleural fluid/thoracentesis fluid/empyema fluid
- Peritoneal fluid/ascites fluid/paracentesis fluid
- Pericardial fluid
- Cul-de-centesis fluid

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LOADING BOTTLES INTO VIRTUO

A. Place bottles on the loading belt. Bottles will be detected by the instrument sensors and will be moved into the carousel at the entry point.

B. The instrument automation will evaluate the sample for volume and will take an image of bottle and specimen identification.

C. The loader arm located inside of the instrument will place the bottle in an available cell and testing will commence.

PATIENT DATA ENTRY INTO LIS

A. Body Fluid bottles will be detected by the system to be a non-blood culture and placed on an orphan list. This list will be reviewed daily and when body fluid is noted, the instrument will be accessed, and the accession number modified to include a BF at the forefront of the accession number.

B. The microbiologist will manually enter the bottle information into the workcard. Using the F3 key, a free text will be added to note whether one or two bottles were collected. These will be designated BTAx1 or BTAx2.

C. A preliminary report will be generated on day 1 that will read, "No growth to date. Culture held for 5 days.

FINALIZING BODY FLUIDS FROM VIRTUO

A. At the end of 5 days, the body fluid, identified by BF preceding the accession number, will

appear on the Report Negative List. At this time, a final can be issued in the LIS that states, "No growth at 5 days."

B. The instrument will unload the bottle and discard into the waste bin. There is no need to manually remove the bottle.

All Revision Dates

3/2/2026

Approval Signatures

Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator, VCMC & SPH	3/2/2026
Policy Owner	Linda Conboy: Supervisor-Microbiology, Laboratory Services	3/1/2026
Policy Owner	M. Anwar Molani: Medical Director, Laboratory Services	2/25/2026
Policy Owner	Erlinda Roxas: Director, Laboratory Services	2/25/2026

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Next Review	3/1/2028

Owner	Linda Conboy: Supervisor-Microbiology, Laboratory Services
Policy Area	Laboratory Services - Microbiology

L.MIC.2.1 Biofire RP2.1

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PURPOSE:

The BioFire RP2.1 is a multiplexed nucleic acid test intended for the simultaneous qualitative detection and differentiation of nucleic acids from multiple viral and bacterial respiratory organisms, including nucleic acids from Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2), in nasopharyngeal swabs (NPS) obtained from individuals suspected of COVID-19 by their healthcare provider. Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform high complexity or moderate complexity tests.

The BioFire RP2.1 is intended for the detection and differentiation of nucleic acid from SARS-CoV-2 and the following organism types and subtypes identified using the BioFire RP2.1 (EUA)

SARS-CoV-2 RNA and nucleic acids from the respiratory viral and bacterial organisms identified by this test are generally detectable in nasopharyngeal swabs (NPS) during the acute phase of infection. The detection and identification of specific viral and bacterial nucleic acids from individuals exhibiting signs and/or symptoms of respiratory infection is indicative of the presence of the identified microorganism and aids in the diagnosis of respiratory infection if used in conjunction with other clinical and epidemiological information. The results of this test should not be used as the sole basis for diagnosis, treatment, or other patient management decisions. Positive results are indicative of the presence of the identified organisms, but do not rule out co-infection with other pathogens. The agent(s) detected by the BioFire RP2.1 Panel (EUA) may not be the definitive cause of the disease.

Laboratories within the United States and its territories are required to report all SARS-CoV-2 positive results to the appropriate public health authorities.

Viruses	Bacteria

• Adenovirus Coronavirus 229E Coronavirus HKU1 Coronavirus NL63 Coronavirus OC43 • Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Human Metapneumovirus • Human Rhinovirus/Enterovirus Influenza A, including subtypes • H1, H3 and H1-2009 • Influenza B Parainfluenza Virus 1 • Parainfluenza Virus 2 • Parainfluenza Virus 3 • Parainfluenza Virus 4 Respiratory Syncytial Virus	*Bordetella parapertussis* *Bordetella pertussis* *Chlamydia pneumoniae* *Mycoplasma pneumoniae*

Negative results in the setting of a respiratory illness may be due to infection with pathogens not detected by this test, or lower respiratory tract infection that may not be detected by an NPS specimen. Negative results do not preclude SARS-Co-V-2 infection and should not be used as the sole basis for treatment or other patient management decisions.

Negative SARS-CoV-2 results must be combined with clinical observations, patient history, and epidemiological information. Negative results for other organisms identified by the test may require additional laboratory testing (e.g., bacterial, and viral culture, immunofluorescence, and radiography) when evaluating a patient with possible respiratory tract infection.

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PRINCIPLE:

The BioFire RP2.1 Panel (EUA) pouch is a closed system disposable that stores all the necessary reagents for sample preparation, reverse transcription, polymerase chain reaction (PCR), and detection in order to isolate, amplify, and detect nucleic acid from multiple respiratory pathogens within a single NPS specimen. After sample collection, the user injects hydration solution and sample combined with sample buffer into the pouch, places the pouch into a BioFire® FilmArray® System instrument module, and starts a run. The entire run process takes about 45 minutes. Additional detail can be found in the appropriate BioFire® System Operator's Manual.

During a run, the BioFire System:

- Lyses the sample by agitation (bead beading) in addition to chemical lysis mediated by the Sample Buffer.
- Extracts and purifies all nucleic acids from the sample using magnetic bead technology.
- Performs nested multiplex PCR by:
    - First performing reverse transcription, followed by a multiplexed first stage PCR reaction (PCR1).
    - Then performing multiple simultaneous second-stage PCR reactions
    - Uses endpoint melting curve data to detect target-specific amplicons and analyses the data to

generate a result for each analyte on the panel

Reagent Storage, Handling, and Stability

Store the test kit, including reagent pouches and buffers, at room temperature (15°-25°C). **DO NOT REFRIGERATE.**

Avoid storage of any materials near heating or cooling vents or in direct sunlight.

All kit components should be stored and used together. Do not use components from one kit with those of another kit. Discard any extra components from the kit after all the pouches have been consumed.

Do not remove pouches from their packaging until a sample is ready to be tested. Once the pouch packaging has been opened, the pouch should be loaded as soon as possible (within approximately 30 minutes).

Once a pouch has been loaded, the test run should be started as soon as possible (within approximately 60 minutes). Do not expose a loaded pouch to temperatures above 40°C (104°F) prior to testing.

Sample Requirements:

The following table describes the requirements for specimen collection, preparation, and handling that will help ensure accurate test result

1.

Specimen Type	**Nasopharyngeal Swab** (NPS) collected according to standard technique and immediately placed in in up to 3 mL of transport media
Minimum Sample Volume	0.3 mL (300 µL)
Transport and Storage	Specimens should be processed and tested with the BioFire RP2.1 Panel (EUA) as soon as possible. **If storage is required, specimens can be held:** • At room temperature for up to 4 hours (15-25 °C) • Refrigerated for up to 3 days (2-8 °C) • Frozen (≤-15 °C or ≤-70°C) (for up to 30 days)

Frozen storage for up to 30 days was evaluated for this sample type. However, longer frozen storage ma y be acceptable.

1. **NOTE: NPS specimens should not be centrifuged before testing.**
2. ***NOTE: Bleach can damage organisms/nucleic acids within the specimen, potentially causing false negative results. Contact between bleach and specimens during collection, disinfection, and testing procedures should be avoided.***

Materials:

Materials Provided	Materials Required But Not Provided

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Each kit contains sufficient reagents to test 30 samples (30-test kit; 423738): • Individually packaged BioFire RP2.1 Panel (EUA) pouches • Single-use (1.0 mL) BioFire® FilmArray® Sample Buffer ampoules • Single-use pre-filled (1.5 mL)BioFire® FilmArray® Hydration Injection Vials (blue) • Single-use BioFire® FilmArray® Sample Injection Vials (red) • Individually-packaged Transfer Pipettes	BioFire® System including: • BioFire® FilmArray® 2.0 or BioFire® FilmArray® Torch and accompanying software • BioFire® FilmArray® Pouch Loading Station • 10% bleach solution or a similar disinfectant

PROCEDURE:

1. Specimens should be processed in the Molecular Hood away from other specimens.
2. The specimen must be handled to minimize aerosolization.
3. Specimens should be handled individually to prevent cross contamination during processing
4. Gloves must be worn and frequently changed during the processing especially when transitioning from molecular hood to testing area.
5. Biological hood will be cleaned with 70% ethanol or equivalent and allow to set for 5 minutes prior to wiping each time a specimen is processed to prevent cross contamination

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Prepare Pouch

Thoroughly clean the work area and the Pouch Loading Station with freshly prepared 10% bleach (or suitable disinfectant) followed by a water rinse.

1. Remove the pouch from its vacuum-sealed package by tearing or cutting the notched outer packaging and opening the protective canister.

   NOTE: The pouch may still be used even if the vacuum seal of the pouch is not intact. Attempt to hydrate the pouch using the steps in the Hydrate Pouch section. If hydration is successful, continue with the run. If hydration fails, discard the pouch and use a new pouch to test the sample

2. Check the expiration date on the pouch. Do not use expired pouches. Insert the pouch into the Pouch Loading Station, aligning the red and blue labels on the pouch with the red and blue arrows on the Pouch Loading Station.
3. Place a red-capped Sample Injection Vial into the red well of the Pouch Loading Station.
4. Place a blue-capped Hydration Injection Vial into the blue well of the Pouch Loading Station.

Hydrate Pouch

1. Unscrew the Hydration Injection Vial from the blue cap.

2. Remove the Hydration Injection Vial, leaving the blue cap in the Pouch Loading Station.
3. Insert the Hydration Injection Vial's cannula tip into the pouch hydration port located directly below the blue arrow of the Pouch Loading Station.
4. Forcefully push down in a firm and quick motion to puncture seal until a faint "pop" is heard and there is an ease in resistance. Wait as the correct volume of Hydration Solution is pulled into the pouch by vacuum.
5. If the hydration solution is not automatically drawn into the pouch, repeat Step 2 to verify that the seal of the pouch hydration port was broken. If hydration solution is again not drawn into the pouch, discard the current pouch, retrieve a new pouch, and repeat from *Step 1: Prepare Pouch*.
6. Verify that the pouch has been hydrated.
7. Flip the barcode label down and check to see that fluid has entered the reagent wells (located at the base of the rigid plastic part of the pouch). Small air bubbles may be seen.
8. If the pouch fails to hydrate (dry reagents appear as white pellets),repeat Step 2 to verify that the seal of the pouch hydration port was broken. If hydration solution is still not drawn into the pouch, discard the current pouch, retrieve a new pouch, and repeat from *Step 1: Prepare Pouch*.

Prepare Sample Mix:

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1. Add Sample Buffer to the Sample Injection Vial.
2. Hold the Sample Buffer ampoule with the tip facing up.
3. NOTE: Avoid touching the ampoule tip during handling, as this may introduce contamination.
4. Firmly pinch at textured plastic tab on the side of the ampoule until the seal snaps.
5. Invert the ampoule over the red-capped Sample Injection Vial and dispense Sample Buffer using a slow, forceful squeeze followed by a second squeeze.
6. NOTE: Avoid squeezing the ampoule additional times. This will generate foaming, which should be avoided
7. **WARNING: The Sample Buffer is harmful if swallowed and can cause serious eye damage and skin irritation.**
8. Thoroughly mix the NPS specimen by vortex or inversion.
9. Use the transfer pipette provided in the test kit to draw specimen to the third line (approximately 0.3 mL) of the transfer pipette.
10. Add the specimen to the Sample Buffer in the Sample Injection Vial.
11. Tightly close the lid of the Sample Injection Vial and discard the transfer pipette in a biohazard waste container.
12. NOTE: DO NOT use the Transfer Pipette to mix the sample once it is loaded into **the Sample Injection Vial.**
13. Remove the Sample Injection Vial from the Pouch Loading Station and invert the vial at least 3 times to mix.
14. Return the Sample Injection Vial to the red well of the Pouch Loading Station.

Load Sample Mix:

1. Slowly twist to unscrew the Sample Injection Vial from the red cap and wait for 5 seconds with the vial

resting in the cap.
NOTE: Waiting 5 seconds decreases the risk of dripping and contamination from the sample.

2. Lift the Sample Injection Vial, leaving red cap in the well of the Pouch Loading Station, and insert the Sample Injection Vial cannula tip into the pouch sample port located directly below the red arrow of the Pouch Loading Station.
3. Forcefully push down in a firm and quick motion to puncture seal (a faint “pop” is heard) and sample is pulled into the pouch by vacuum.
4. Verify that the sample has been loaded.
5. Flip the barcode label down and check to see that fluid has entered the reagent well next to the sample loading port.
6. If the pouch fails to pull sample from the Sample Injection Vial, the pouch should be discarded. Retrieve a new pouch and repeat from *Step 1: Prepare Pouch*.
7. Discard the Sample Injection Vial and the Hydration Injection Vial in appropriate biohazard sharps container.
8. Record the Sample ID in the provided area on the pouch label (or affix a barcoded Sample ID) and remove the pouch from the Pouch Loading Station.

Run Pouch:

The BioFire® FilmArray® Software includes step-by-step on-screen instructions that guide the operator through performing a run. Brief instructions for BioFire® 2.0 and BioFire® Torch Systems are given below. Refer to the appropriate BioFire System Operator’s Manual for more detailed instructions.

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BioFire 2.0:

1. Ensure that the BioFire Torch system is powered on.
2. Select an available Module on the touch screen or scan the barcode on the pouch using the barcode scanner.
3. Pouch identification (Lot Number and Serial Number), Pouch Type and Protocol information will b e automatically entered when the barcode is scanned. If it is not possible to scan the barcode, the pouch Lot Number, Serial Number, Pouch Type and Protocol can be manually entered from the information provided on the pouch label into the appropriate fields. To reduce data entry errors, it is strongly recommended that the pouch information be entered by scanning the barcode.
4. NOTE: When selecting a Pouch Type manually, ensure that the Pouch Type matches the label on the BioFire RP2.1 Panel (EUA) pouch.
5. Enter the Sample ID. The Sample ID can be entered manually or scanned in by using the barcode scanner when a barcoded Sample ID is used.
6. Insert the pouch into the available Module.
7. Ensure that the pouch fitment label is lying flat on top of pouch and not folded over. As the pouch is inserted, the module will grab onto the pouch and pull it into the chamber.
8. If necessary, select and/or confirm the appropriate protocol for your sample type from the Protocol drop down list. The BioFire RP2.1 Panel (EUA) has a single protocol available in the drop-down list.
9. Enter operator username and password, then select Next.
10. NOTE: Color of the username is red until the username is recognized by the software.
11. Review the entered run information on the screen. If correct, select Start Run.
12. Once the run has started, the screen displays a list of the steps being performed by the module and the

number of minutes remaining in the run.

13. NOTE: The bead-beater apparatus can be heard as a high-pitched noise during the first minute of operation.
14. At the end of the run, remove the partially ejected pouch, then immediately discard it in a b iohazard waste container.
15. The run file is automatically saved in the BioFire® Software database, and the test report can be viewed, printed, and/or saved as a PDF file.

Interpretation:

When PCR2 is complete, the BioFire® System instrument performs a high-resolution DNA melting analysis on the PCR products and measures the fluorescence signal generated in each well (for more information see appropriate BioFire Operator's System Manual). The BioFire® Software then performs several analyses and assigns a final assay result. The steps in the analyses are described below.

Analysis of melt curves. The BioFire Software evaluates the DNA melt curve for each well of the PCR2 array to determine if a PCR product was present in that well. If the melt profile indicates the presence of a PCR product, then the analysis software calculates the melting temperature (Tm) of the curve and compares it against the expected Tm range for the assay. If the software determines that the Tm falls inside the assay-specific Tm range, the melt curve is called positive. If the software determines that the melt curve is not in the appropriate Tm range, the melt curve is called negative.

Analysis of replicates. Once melt curves have been identified, the software evaluates the three replicates for each assay to determine the assay result. For an assay to be called positive, at least two of the three associated melt curves must be called positive, and the Tm for at least two of the three positive melt curves must be similar (within 1°C). Assays that do not meet these criteria are called negative.

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Organism Interpretation: For most organisms detected by the BioFire RP2.1 Panel (EUA), the organism is reported as Detected if a single corresponding assay is positive. For example, Human Metapneumovirus will have a test report result of Human Metapneumovirus Detected if the hMPV assay is positive (at least two of the three hMPV assay wells on the array have similar positive melt peaks with Tm values that are within the assay-specific Tm range). The test results for SARS-CoV-2, Adenovirus, and Influenza A depend on the interpretation of results from more than one assay. Interpretation and actions for these three multi-assay results are provided below.

SARS-CoV-2:

The BioFire RP2.1 Panel (EUA) pouch contains two different assays for the detection of the SARS-CoV-2. The target of each assay is shown in Table 1 below. The BioFire Software interprets each assay independently and if either one or both of the assays is positive, the test report will show Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) as Detected. If both assays are negative, the test report result will be Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Not Detected.

Table 1. Gene Targets for SARS-CoV-2 Assays on the BioFire RP2.1 Panel (EUA)

Assay Name	Gene Target
SARSCoV2-1	Spike protein (S) gene
SARSCoV2-2	Membrane protein (M) gene

Adenovirus:

The BioFire RP2.1 Panel (EUA) pouch contains five different assays (Adeno2, Adeno3, Adeno6, Adeno7.1, and Adeno8) for the detection of Adenovirus. The BioFire Software interprets each of these assays independently (as described above) and the results are combined as a final test result for the virus. If one or any combination of assays is positive, the test report result will be Adenovirus Detected. If all assays are negative, the test report result will be Adenovirus Not Detected.

Influenza A:

The assays in the BioFire RP2.1 Panel (EUA) are designed to both detect Influenza A and to differentiate commonly occurring hemagglutinin subtypes. To accomplish this, the BioFire RP2.1 Panel (EUA) uses two Influenza A assays, (FluA-pan-1 and FluA-pan-2) and three subtyping assays directed at the hemagglutinin gene (FluA-H1-2, FluA-H1-2009, and FluA-H3). Each of the individual assays is interpreted independently (as described above) and the test result reported for Influenza A is based on the combined results of the five assays as outlined in Table 2. Specimens with an Equivocal result or multiple Influenza A subtypes detected should be retested once.

Table 2. Possible Assay Results for Influenza A and the Corresponding Interpretation

Assay Result	FluA-pan Assays (n=2)	FluA-H1-2	FluA-H1-2009	FluA-H3	Action
Influenza A Not Detected	Negative	Negative	Negative	Negative	None
Influenza A H1	**≥1 positive**	**Positive**	Negative	Negative	
Influenza A H3	**≥1 positive**	Negative	Negative	**Positive**	
Influenza A H1-2009	**≥1 positive**	Any result	**Positive**	Negative	
Influenza A H1 Influenza A H3	**≥1 positive**	**Positive**	Negative	**Positive**	Multiple infections are possible but rare a, retest to confirm result b
Influenza A H1-2009 Influenza A H3	**≥1 positive**	Any result	**Positive**	**Positive**	
Influenza A (no subtype detected)	**2 positive**	Negative	Negative	Negative	Retest (see below)
Influenza A Equivocal	**1 positive**	Negative	Negative	Negative	Retest once (see Result Summary section below for further instruction).
Influenza A H1 Equivocal	Negative	**Positive**	Negative	Negative	
Influenza A H3 Equivocal	Negative	Negative	Negative	**Positive**	
Influenza A H1-2009 Equivocal	Negative	Any result	**Positive**	Negative	

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The BioFire RP2.1 Panel (EUA) can simultaneously detect multiple influenza viruses contained in multivalent vaccines (see Limitations).

Repeated multiple positives should be further confirmed by other FDA-cleared Influenza subtyping tests.

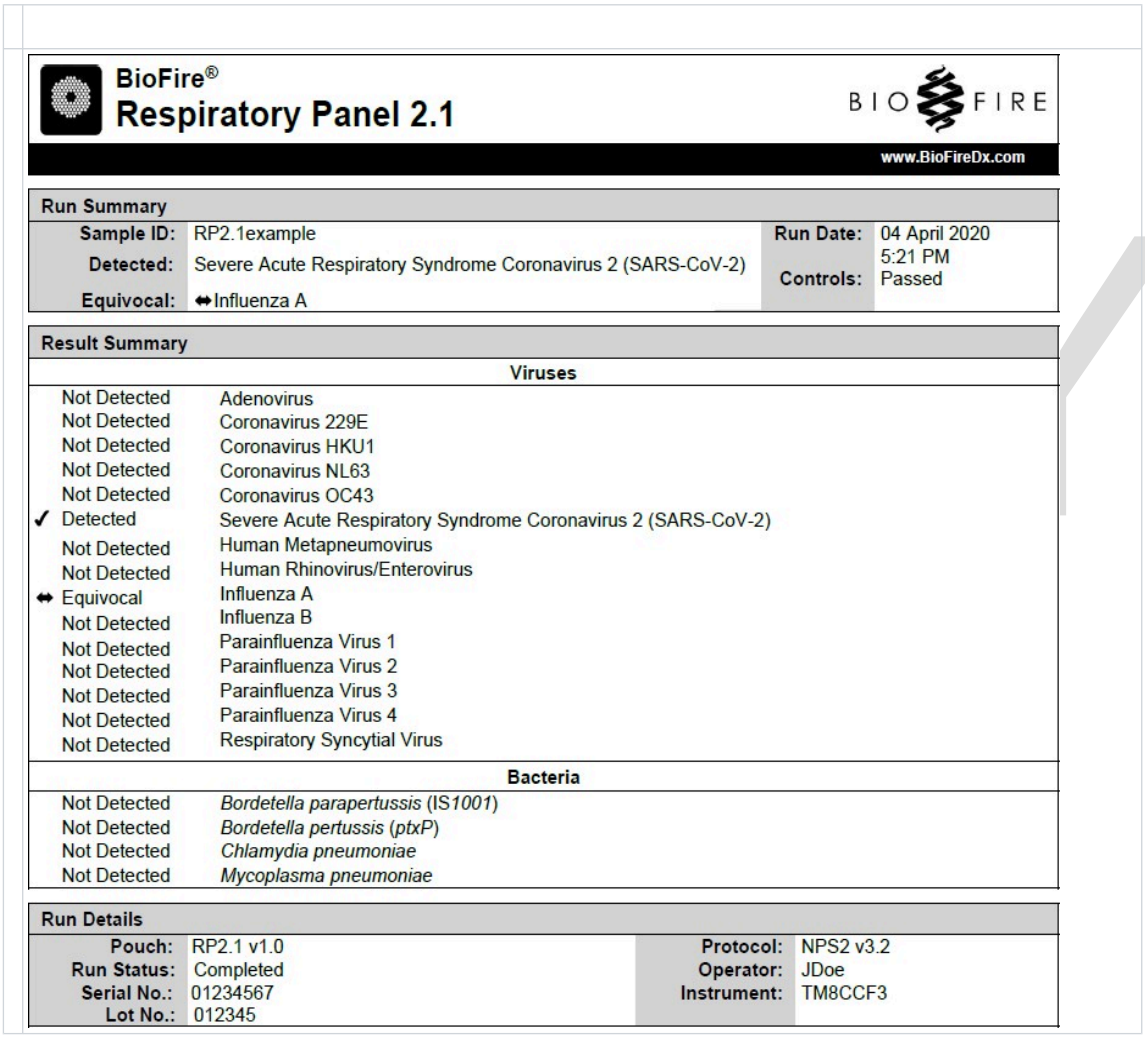
Influenza A (no subtype detected):

If both of the FluA-pan assays are positive, but none of the hemagglutinin subtyping assays are positive, then the interpretation is Influenza A (no subtype detected). This result could occur when the titer of the virus in the

specimen is low and not detected by the subtyping assays. This result could also indicate the presence of a novel Influenza A strain. In both cases, the sample in question should be retested. If the retest provides a different result, test the sample a third time to ensure the accuracy of the result. If the retest provides the same result, then the function of the BioFire RP2.1 Panel (EUA) pouches should be verified by testing with appropriate external control materials (known positive samples for Influenza A H1, Influenza A H3, and Influenza A H1-2009), and a negative control should also be run to test for PCR- product contamination. If the BioFire RP2.1 Panel (EUA) accurately identifies the external and negative controls, contact the appropriate public health authorities for confirmatory testing.

BioFire RP2.1 Panel (EUA) Test Report:

The BioFire RP2.1 Panel (EUA) test report is automatically displayed upon completion of a run and can be printed or saved as a PDF file. Each report contains a Run Summary, a Result Summary, and a Run Details section.



BioFire®
Respiratory Panel 2.1

BIOFIRE
www.BioFireDx.com

Run Summary

Sample ID:	RP2.1example	**Run Date:**	04 April 2020 5:21 PM
Detected:	Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2)	**Controls:**	Passed
Equivocal:	⬌Influenza A		

Result Summary

	Viruses
Not Detected	Adenovirus
Not Detected	Coronavirus 229E
Not Detected	Coronavirus HKU1
Not Detected	Coronavirus NL63
Not Detected	Coronavirus OC43
✓ Detected	Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2)
Not Detected	Human Metapneumovirus
Not Detected	Human Rhinovirus/Enterovirus
⬌ Equivocal	Influenza A
Not Detected	Influenza B
Not Detected	Parainfluenza Virus 1
Not Detected	Parainfluenza Virus 2
Not Detected	Parainfluenza Virus 3
Not Detected	Parainfluenza Virus 4
Not Detected	Respiratory Syncytial Virus
	Bacteria
Not Detected	*Bordetella parapertussis* (IS*1001*)
Not Detected	*Bordetella pertussis* (*ptxP*)
Not Detected	*Chlamydia pneumoniae*
Not Detected	*Mycoplasma pneumoniae*

Run Details

Pouch:	RP2.1 v1.0	**Protocol:**	NPS2 v3.2
Run Status:	Completed	**Operator:**	JDoe
Serial No.:	01234567	**Instrument:**	TM8CCF3
Lot No.:	012345		

Run Summary:

The Run Summary section of the test report provides the Sample ID, time and date of the run, control results and an overall summary of the test results. Any organism with a Detected result will be listed in the corresponding field of the summary. If all of the organism assays were negative, then 'None' will be displayed

in the Detected field. Controls are listed as Passed, Failed, or Invalid. Table 3. Interpretation of Controls Field on the BioFire RP2.1 Panel (EUA) Test Report 3 provides additional information for each of the possible control field results.

Table 3. Interpretation of Controls Field on the BioFire RP2.1 Panel (EUA) Test Report

Control Result	Explanation	Action
Passed	The run was successfully completed AND Both pouch controls were successful.	None Report the results provided on the test report
Failed	The run was successfully completed BUT At least one of the pouch controls (RNA Process Control and/or PCR2 Control) failed.	Repeat the test using a new pouch. If the error persists, contact Technical Support for further instruction.
Invalid	The controls are invalid because the run did not complete. (Typically, this indicates a software or hardware error).	Note any error codes displayed during the run and the Run Status field in the Run Details section of the report. Refer to the appropriate BioFire® System Operator's Manual or contact Technical Support for further instruction. Once the error is resolved, repeat the test, or repeat the test using another instrument.

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Results Summary:

The Result Summary section of the test report lists the result for each target tested by the panel. Possible results for each organism are Detected, Not Detected, or Invalid (Equivocal is also a possible result for Influenza A and its subtypes). Table 4 provides an explanation for each interpretation and any follow-up necessary to obtain a final result.

Table 4. Reporting of Results and Required Actions

Result	Explanation	Action
Detecteda	The run was successfully completed AND The pouch controls were successful (Passed) AND The assay(s) for the organism were POSITIVE (i.e., met the requirements for a positive result described in the Assay Interpretation section above)	Report results.

Not Detected	The run was successfully completed AND The pouch controls were successful (Passed) AND The assay(s) for the organism were NEGATIVE (i.e., did not meet the requirements for a positive result described in the Assay Interpretation section above)	Report results.
Equivocal	The run was successfully completed AND The pouch controls were successful (Passed) AND The combination of positive and negative assay results for Influenza A were inconclusive (see Table 2. Possible Assay Results for Influenza A and the Corresponding Interpretation2)	Retest the original specimen. If If the result of the retest is again 'Equivocal', the final result should be considered 'Detected'.
Invalid	The pouch controls were not successful (Failed) OR The run was not successful (Run Status displayed as: Aborted, Incomplete, Instrument Error or Software Error)	See Table 3. Interpretation of Controls Field on the BioFire RP2.1 Panel (EUA) Test Report, Interpretation of Control Field on the BioFire Test Report for instruction.

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If four or more organisms are detected in a specimen, retesting is recommended to confirm the polymicrobial result.

Run Details:

The **Run Details** section provides additional information about the run including: pouch information (type, lot number, and serial number), Run Status (Completed, Incomplete, Aborted, Instrument Error, or Software Error), the protocol that was used to perform the test, the identity of the operator that performed the test, and the instrument used to perform the test.

Change Summary:

It is possible to edit the Sample ID once a run has completed. If this information has been changed, an additional section called **Change Summary** will be added to the test report. This Change Summary section lists the field that was changed, the original entry, the revised entry, the operator that made the change, and the date that the change was made. Sample ID is the only field of the report that can be changed.

Change Summary				
Field	**Changed To**	**Changed From**	**Operator**	**Date**
[1]Sample ID	New Example Id	Old Example Id	Anonymous	06 Apr 2020

REFERENCE:

- BioFire® Respiratory Panel 2.1 (RP2.1) Instructions for Use, for Emergency Use Only (BFR0000-8303-01) BioFire Diagnostics, LLC.

All Revision Dates

3/2/2026

Approval Signatures

Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator, VCMC & SPH	3/2/2026
Policy Owner	Linda Conboy: Supervisor-Microbiology, Laboratory Services	3/1/2026
Policy Owner	M. Anwar Molani: Medical Director, Laboratory Services	2/28/2026
Policy Owner	Erlinda Roxas: Director, Laboratory Services	2/28/2026

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Status **Active** PolicyStat ID **20004077**

VENTURA COUNTY HEALTH CARE AGENCY

Origination	1/1/2000
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Effective	1/1/2000
Last Revised	3/2/2026
Next Review	3/1/2028
Owner	Evan Gamad: CLS III
Policy Area	Laboratory Services

L.102 Cortisol and Cortisol Stimulation Test

COPY

PRINCIPLE:

Cortisol is an adrenocorticol steroid hormone. In the diurnal rhythm of normal individuals, peak levels are seen in the morning (0600) with the lowest levels late in the evening (2200). Abnormal changes in cortisol levels may be due to hypothalamic, pituitary, or adrenal malfunction. If undiagnosed and untreated, these disorders can lead to severe metabolic imbalance, which may be life threatening. The Cortisol Stimulation Test uses serum cortisol levels to evaluate adrenal cortical insufficiency. Administration of ACTH (adrenocorticotropic hormone) to normal subjects rapidly increases serum cortisol. Patients with adrenal cortical insufficiency conditions have subnormal responses.

PROCEDURE:

Cortisols are run at Ventura Count Medical Center Laboratory M-F on the day shift. The plasma from a lithium heparin tube or serum may be used.

Cortisol Stimulation Test:

- A blood baseline cortisol is drawn before the administration of synthetic ACTH in the form of Cosyntropin or Cortrysyn by a physician. Then a cortisol is drawn at 30 minutes and/or 60 minutes post administration at the discretion of the physician. Questions about protocol or dosage should be referred to the pharmacy. This test is primarily performed on in-patients.
- CORT-STIM is the mnemonic to order the test. The report will contain all the specimen results on a one page format.
- Specimens should be clearly labeled with the times and "fasting, 30 minute, or 60 minute" designations. If possible, one phlebotomist should be responsible for the collection of all the specimens since the timing of the draw is critical.

REFERENCE

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3/2/2026

Approval Signatures

Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator, VCMC & SPH	3/2/2026
Laboratory Services Department	M. Anwar Molani: Medical Director, Laboratory Services	3/1/2026
Laboratory Services Department	Evan Gamad: CLS III	2/28/2026
Laboratory Services Department	Erlinda Roxas: Director, Laboratory Services	2/28/2026

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VENTURA COUNTY HEALTH CARE AGENCY

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Last Revised	3/2/2026
Next Review	3/1/2028
Owner	Evan Gamad: CLS III
Policy Area	Laboratory Services

L.103 Cortisol and ACTH Stimulation Test

COPY

PRINCIPLE

Cortisol is an adrenocorticol steroid hormone. In the diurnal rhythm of normal individuals, peak levels are seen in the morning (0600) with the lowest levels late in the evening (2200).

Abnormal changes in cortisol levels may be due to hypothalamic, pituitary, or adrenal malfunction. If undiagnosed and untreated, these disorders can lead to sever metabolic imbalance, which may be life threatening.

The ACTH Stimulation Test uses serum cortisol levels to evaluate adrenal cortical insufficiency. Administration of ACTH (adrenocorticotropic hormone) to normal subjects rapidly increases serum cortisol. Patients with adrenal cortical insufficiency conditions have subnormal responses.

PROCEDURE:

Cortisols are run at VCMC M-F on the day shift. The plasma from a lithium heparin tube or serum may be used.

ACTH Stimulation Test:

- A blood baseline cortisol is drawn before the administration of synthetic ACTH in the form of Cosyntropin or Cortrysyn by a physician. Then a cortisol is drawn at 30 minutes and/or 60 minutes post administration at the discretion of the physician. Questions about protocol or dosage should be referred to the pharmacy. This is primarily an in-patient send out test.
- CORT-ACTH is the mnemonic to order the test. The report will contain all the specimen results on a one page format.
- Specimens should be clearly labeled with the times and "fasting, 30 minute, or 60 minute"

designations. If possible, one phlebotomist should be responsible for the collection of all the specimens since the timing of the draw is critical.

- At the physician's discretion, an ACTH may also be run at the timed intervals. ACTH is test code #211 and is performed at QUEST laboratories.
- The specimen requirement is frozen plasma from a Lavender (EDTA) tube that is separated from the cells ASAP or within 2 hours of collection.

REFERENCE

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3/2/2026

Approval Signatures

Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator, VCMC & SPH	3/2/2026
Laboratory Services Department	M. Anwar Molani: Medical Director, Laboratory Services	3/1/2026
Laboratory Services Department	Evan Gamad: CLS III	2/28/2026
Laboratory Services Department	Erlinda Roxas: Director, Laboratory Services	2/28/2026

Status **Active** PolicyStat ID **20004081**

Origination	7/30/2010	Owner	Evan Gamad: CLS III
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Effective	7/30/2010		
Last Revised	3/2/2026		
Next Review	3/1/2028		

L.104 Cystic Fibrosis

COPY

PRINCIPLE

Cystic Fibrosis (CF) is caused by a defective gene which causes the body to produce abnormally thick and sticky fluid, called mucus. This mucus builds up in the breathing passages of the lungs and in the pancreas, the organ that helps to break down and absorb food.

This collection of sticky mucous results in life-threatening lung infections and serious digestion problems. The disease may also affect the sweat glands and a man's reproductive system.

Millions of Americans carry the defective CF gene without symptoms. In order to have Cystic Fibrosis, a person must inherit two defective CF genes, one from each parent.

PROCEDURE

Sweat chloride analysis provides laboratory confirmation of the clinical diagnosis of cystic fibrosis. Patients with cystic fibrosis have a normal sweat rate with an increased concentration of sweat chloride. The test is performed by a CLS and requires an appointment. Patients requesting the test should be referred to the Chemistry Department for scheduling.

The two most common genetic tests are QUEST: Cystic Fibrosis (CFTR) 32 Mutations with Reflex to Sequencing, and Cystic Fibrosis (CFTR) 32 Mutations for routine obstetric screening. Use Quest website for the test code.

The specimen required is 3 ml of EDTA whole blood transported refrigerated. The stability refrigerated is 1 week. A patient history form is required that can be printed from the QUEST website.

REFERENCE

L.CHEM.3.14 Sweat Chloride Test

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Hospital Administration	Jason Arimura: Associate Hospital Administrator, VCMC & SPH	3/2/2026
Laboratory Services Department	M. Anwar Molani: Medical Director, Laboratory Services	3/1/2026
Laboratory Services Department	Evan Gamad: CLS III	2/28/2026
Laboratory Services Department	Erlinda Roxas: Director, Laboratory Services	2/28/2026

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VENTURA COUNTY HEALTH CARE AGENCY

Origination	8/22/2003	Owner	Evan Gamad: CLS III
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Effective	8/22/2003		
Last Revised	2/27/2026		
Next Review	2/27/2028		

L.105 Fetal Fibronectin

COPY

PRINCIPLE:

The Rapid fFN is a qualitative test for the detection of fetal fibronectin. Detection of fFN in cervicovaginal secretions is associated with preterm delivery in symptomatic pregnant women between 24 to 34 weeks and in asymptomatic pregnant women between 22-30 weeks.

RELATED POLICY:

OB.36 Fetal Fibronectin Specimen Collection for Enzyme Immunoassay

PROCEDURE:

The specimen should be obtained by nursing staff or a physician using the Adeza Biomedical Collection Kit that is available directly at no charge from the Adeza Biomedical Corporation at 1-800-442-9892. The kit may also be ordered by Fax at 1-508-229-2860. The specimen consists of a swab in the Adeza vial.

Specimens should be obtained prior to digital examination and manipulation of the cervix. Patients with suspected or known placental abruption, placenta previa, or moderate or gross vaginal bleeding should not be tested for fFN.

Specimen Storage and Transport:

- The specimen is stable at room temperature for 8 hours. Specimens that are not tested within eight hours of collection must be stored refrigerated at 2-8 degrees C and assayed within three days of collection to avoid degradation of fetal fibronectin. The test is performed at VCMC laboratory.
- Specimens should be transported at 2-8 degrees C. Exposure of the specimen to heat for even short periods of time can be detrimental.

Unacceptable Specimens:

- Specimens collected in or by any sample device other than the Adeza Biomedical Specimen Collection Kit. Specimens with insufficient volume for testing. Specimens received >three days after the sampling date.
- Specimens received at temperatures >25 degrees C.

The suitability of the specimen will be determined by the clinical laboratory scientist that is performing the test.

If the specimen is received without an order, please call the department or clinic where the collection occurred for orders. The specimen should be stored in the refrigerator at 2-8 degrees C.

REFERENCE:

All Revision Dates

2/27/2026

COPY

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Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator, VCMC & SPH	2/27/2026
Laboratory Services Department	M. Anwar Molani: Medical Director, Laboratory Services	2/26/2026
Laboratory Services Department	Evan Gamad: CLS III	2/26/2026
Laboratory Services Department	Erlinda Roxas: Director, Laboratory Services	2/26/2026

Status **Active** PolicyStat ID **20004094**

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Effective	3/2/2026		
Last Revised	3/2/2026		
Next Review	3/1/2028		

L.106 HIV Testing

COPY

PRINCIPLE

The human immunodeficiency virus (HIV) causes acquired immunodeficiency syndrome (AIDS), a chronic, life-threatening condition, by damaging the immune system. HIV interferes with the body's ability to fight off viruses, bacteria, and fungi that cause disease and increases susceptibility to certain types of cancers and infections that the body would normally resist, like pneumonia and meningitis.

The tests associated with the treatment of HIV have become very complex. It is imperative that the specimens are processed correctly. If the wrong tube is used, or if the specimen is sent in the wrong state, the specimen must be rejected because the integrity of the test is compromised.

PROCEDURE

HIV ^{1}/2: Initial Screening for HIV

Ordered as HIV 1-2 Ab/Ag EIA in Laboratory Information System, this test is an Elisa method performed by Public Health. The specimen requirement is serum, heparinized plasma, or EDTA plasma, refrigerated. If positive, a confirmation test is reflexed.

HIV STAT

Ordered as HIV STAT in Laboratory Information System, the OraQuick Advance Rapid HIV-1/2 Antibody Test is a qualitative immunoassay to detect antibodies to HIV ^{1}/2 in whole blood performed at VCMC. This test is primarily ordered on the source of an exposure to blood borne pathogens and infectious agents. However,

it is also available when physicians need the results STAT.

HIV 1 RNA Quantitative Real-Time PCR

Ordered as HIV-1 RNA-QUEST(or QUEST-HIV-1 RNA) in the Laboratory Information System, this test detects a range from 1.7-7.0 log copies /ml (48-10,000,000 copies /ml). The specimen requirement is 3.0 ml

EDTA plasma, separated from the cells and frozen within 4 hours. For more information, reference the QUEST Laboratory Directory

HIV-1 Genotyping

Ordered as HIV-1 Geno-QUEST (or QUEST-HIV-1 Geno) in the Laboratory Information System, this test predicts HIV-1 resistance to protease and reverse transcriptase inhibitor anti-viral drugs. The specimen requirement is 5.0 nil of EDTA plasma, separated from the cells and frozen in a polypropylene tube at -20 degrees C ASAP. For more information, reference the QUEST Laboratory Directory.

Trofile: HIV Co-receptor Tropism Assay

Ordered as a miscellaneous sendout SO in the Laboratory Information System, this test is intended for use only in patients with documented HIV-1 infection with a viral load >1000 copies/ ml. The specimen requirement is at least 3 ml /EDTA plasma, separated from the cells and frozen at -20 degrees C immediately. For more information, Quest forwards test to Monogram. (The Monogram customer service line 1-877-436-6243.)

T Cell Subsets:

Ordered as Lym Subset 4- QUEST (or QUEST-Lym Subset 4) in the Laboratory Information System, this test is used to monitor CD4 (Helper T cells) and CD8 (Suppressor T-cells) in the treatment of HIV positive patients. The specimen requirement is 5.0 ml EDTA whole blood. It is ***critical* that** the specimen is ambient. Only Hemogard tubes are acceptable, and specimens must be analyzed within 48 hours. The test is performed daily. For more information, reference the QUEST Laboratory Directory.

COPY

REFERENCE

All Revision Dates

3/2/2026

Approval Signatures

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Hospital Administration	Jason Arimura: Associate Hospital Administrator, VCMC & SPH	3/2/2026
Laboratory Services Department	M. Anwar Molani: Medical Director, Laboratory Services	3/1/2026
Laboratory Services Department	Evan Gamad: CLS III	2/28/2026
Laboratory Services Department	Erlinda Roxas: Director, Laboratory Services	2/28/2026

COPY

Status **Active** PolicyStat ID **20004099**

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Last Approved	3/2/2026	Policy Area	Laboratory Services
Effective	9/22/2003		
Last Revised	3/2/2026		
Next Review	3/1/2028		

L.107 Rapid HIV-1/2 Antibody Test in Whole Blood OraQuick® AdvanceTM Rapid HIV-1/2 Antibody Test

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INTENDED USE

The OraQuick® *Advance* Rapid HIV-1/2 Antibody Test is a single-use, qualitative immunoassay to detect antibodies to Human Immunodeficiency Virus Type 1 (HIV-1) and Type 2 (HIV-2) in oral fluid, fingerstick whole blood and venipuncture whole blood. The OraQuick® *Advance* Rapid HIV-1/2 Antibody Test is intended for use as a point-of-care test to aid in the diagnosis of infection with HIV-1 and HIV-2.

CLINICAL SIGNIFICANCE

Acquired Immune Deficiency Syndrome (AIDS), AIDS related complex (ARC) and pre-AIDS are thought to be caused by the Human Immunodeficiency Virus (HIV). The first AIDS-related virus, HIV-1 (also known as HTLV-III, LAV-1 and ARV) has been isolated from patients with AIDS and from healthy persons at high risk for AIDS. Genetic analysis of HIV-1 isolates has documented the existence of subtypes. To date, eight HIV-1 subtypes (A through H), designated as Group M, have been identified world-wide in addition to the highly divergent HIV-1 isolates from AIDS patients in Cameroon, designated as Group 0. A closely related but distinct second type of pathogenic human immunodeficiency retrovirus, designated HIV-2 has been isolated from West African patients with AIDS. HIV-2 has been shown to share a number of conserved sequences with HIV-1, but serological cross-reactivity between HIV-1 and HIV-2 has been shown to be highly variable from sample to sample.

HIV is known to be transmitted by sexual contact, by exposure to blood (including sharing contaminated needles and syringes) or by contaminated blood products, or it may be transmitted from an infected mother to her fetus during the prenatal period. Individuals infected with HIV

produce antibodies against the HIV viral proteins. Testing for the, presence of antibodies to HIV in bodily fluids (e.g., blood, oral fluid, and urine) is an accurate aid in the diagnosis of HIV infection. However, the implications of seropositivity must be considered in a clinical context. For example, in neonates, the presence of antibodies to HIV is indicative of exposure to HIV, but not necessarily of HIV infection, due to the acquisition of maternal antibodies that may persist for up to eighteen months. Conversely, absence of antibody to HIV cannot be taken as absolute proof that an individual is free of HIV infection or incapable of transmitting the virus. An antibody response to a recent exposure may take several months to reach detectable levels. HIV has been isolated from asymptomatic, seronegative individuals presumably before seroconversion following exposure.

The standard laboratory HIV testing algorithm used in the United States consists of screening with an enzyme immunoassay (EA) and confirmation of repeatedly reactive EIAs using a Western blot test. Results are typically reported within 48 hours to 2 weeks, making these standard screening and supplemental tests inadequate to meet the need for rapid HIV diagnosis. The OraQuick® *Advance* Rapid HIV-1/2 Antibody Test is a point-of-care test to aid in the diagnosis of infection with HIV-1 and HIV-2

PRINCIPLE

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The OraQuick® *Advance* Rapid HIV-1/2 Antibody Test is a manually performed, visually read, 20 minute immunoassay for the qualitative detection of antibodies to HIV-1 and HIV-2. in human whole blood obtained from a finger puncture or a venipuncture. The OraQuick® *Advance* Rapid HIV-1/2 Antibody Test is comprised of a single-use test device and a single-use vial containing a pre-measured amount of a buffered developer solution. Each component is sealed in separate compartments of a single pouch to form the test. The OraQuick® *Advance* rapid test utilizes a proprietary lateral flow immunoassay procedure. The device plastic housing holds an assay test strip comprised of several materials that provide the matrix for the immunochromatography of the specimen and the platform for indication of the test results.

The assay test strip, which can be viewed through the test device result window, contains synthetic peptides representing the HIV envelope region and a goat anti-human IgG procedural control immobilized onto a nitrocellulose membrane of the Test. (T) zone and the Control (C) zone, respectively.

A fingerstick whole blood or venipuncture whole blood is collected and transferred into the vial of developer solution, followed by the insertion of the test device. The developer solution facilitiates the flow of the specimen into the device and onto the test strip. As the diluted specimen flows through the device, it rehydrates the protein-A gold calorimetric reagent contained in the device. As the specimen continues to migrate up the strip, it encounters the T zone. If the specimen contains antibodies that react with the antigens immobilized on the nitrocellulose membrane, a reddish-purple line will appear, qualitatively indicating the presence of antibodies to HIV-1 and/or HIV-2 in the specimen. The intensity of the line color is not directly proportional to the amount of antibody present in the specimen.

Further up the assay strip, the sample will encounter the C zone. This built-in procedural control

serves to demonstrate that a specimen was added to the vial and that the fluid has migrated adequately through the test device. A reddish-purple line will appear in the C zone during the performance of all valid tests, whether or not the sample is positive or negative for antibodies to HIV-2 and/or HIV-2.

The test results are interpreted after 20 minutes but not more than 40 minutes after the introduction of the test device into the developer solution containing the test specimen. No precision pipeting, predilutions, or specialized instrumentation are required to perform the the OraQuick® *Advancer™* Rapid HIV-1/2 Antibody Test.

SPECIMEN

Whole blood specimens may be collected either by fingerstick or by venipuncture. Using standard phlebotomy procedures, collect a whole blood sample using a tube containing any of the following anticoagulants: EDTA (lavender tip), sodium heparin (green top), or sodium citrate (light blue top). Other anticoagulants have not been tested and may give an incorrect result. If the specimens are not tested at the time of collection, the whole blood may be stored at 2°- 30°C (35°-86°F) for up to 5 days.

COPY

All Revision Dates

3/2/2026

Approval Signatures

Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator, VCMC & SPH	3/2/2026
Laboratory Services Department	Evan Gamad: CLS III	2/28/2026
Laboratory Services Department	M. Anwar Molani: Medical Director, Laboratory Services	2/28/2026
Laboratory Services Department	Erlinda Roxas: Director, Laboratory Services	2/28/2026

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Effective	11/22/2002		
Last Revised	2/26/2026		
Next Review	2/26/2028		

L.109 Neonatal UA and Neonatal Urine Glucose

POLICY

COPY

Neonatal ICU has asked the lab to perform a limited urinalysis on some of their tiniest babies. The Neonatal UA (NUA) includes glucose, protein and specific gravity. The Neonatal Urine Glucose (NUGLU) may be ordered as a separate test.

These specimens will be collected by putting a cotton ball in the baby's diaper, then the cotton ball will be submitted in a syringe. This method of collection is acceptable for the Neonatal UA and Neonatal Urine Glucose only.

To run the UA, depress the syringe plunger to express the urine into a Kova tube. Perform test according to "ROUTINE URINALYSIS" procedure.

There will be reflex testing of UA Microscopic for positive protein results, and no Clinitest will be performed. The reflex microscopic testing will performed only if there is enough urine sample. If a routine UA is needed on a baby, the specimen will be collected by bagging the baby, and a UA Chemical or Complete UA will be ordered on the baby.

REFERENCES

All Revision Dates

2/26/2026

Approval Signatures

Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator, VCMC & SPH	2/26/2026
Laboratory Services Department	Evan Gamad: CLS III	2/26/2026
Laboratory Services Department	M. Anwar Molani: Medical Director, Laboratory Services	2/26/2026
Laboratory Services Department	Erlinda Roxas: Director, Laboratory Services	2/26/2026

COPY

Status **Active** PolicyStat ID **20004103**

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L.111 Bordetella Pertussis by PCR

COPY

PRINCIPLE:

Rapid Bordetella pertussis by PCR provides a rapid and sensitive method for the diagnosis of B. pertussis. The sensitivity of the test is 93% in comparison to the former reference method of direct culture and direct fluorescent antibody testing, whose respective sensitivities are 15% and 52%.

PROCEDURE:

1. The Send Out Department at Ventura County Medical Center Laboratory will provide a kit for specimen collection that includes basic instructions, a nasopharyngeal swab, and a vial of Universal Transport Media (UTM).
2. The test name in Laboratory Information System to order the test is *Bordetella Pertussis by PCR*. The test is performed Sunday to Saturday at QUEST Laboratory.

COLLECTION (Nasopharyngeal Swab Method)

Note:

The specimen cannot be collected on a calcium-alginate swab because of PCR inhibition. For other specimen alternatives, refer to the QUEST Laboratory.

Since Pertussis may sequester in one nostril only, it is very important to use the swab to sample both nostrils.

1. Patient's head should be inclined at 70 degrees from vertical for proper specimen

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recovery.

2. Insert swab into one nostril and rotate over surface of nasopharynx and allow it to remain for 4 seconds.
3. Withdraw the swab and immediately insert into the other nostril, repeating the process in step 2.
4. Withdraw the swab from the second nostril and place immediately into the UTM tube. Make sure the cap is securely tightened.
5. Label the tube properly, enter the source, and send specimen refrigerated to VCMC for processing.

REFERENCES

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2/27/2026

COPY

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Hospital Administration	Jason Arimura: Associate Hospital Administrator, VCMC & SPH	2/27/2026
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L.113 Processing Induced Sputum for PCP

PROCEDURE

COPY

The Respiratory Therapy Department will collect induced sputum for the methenamine silver stain for Pneumocystis carinii (PCP). Histology will not accept sputum for this procedure that is not induced. The specimen should be accompanied with a pathology request form. Usually this test is performed on three specimens on separate days, depending on clinical findings. However, several specimens may be collected in one day.

The Histology Department will process these specimens Monday through Friday 6am — 2pm. On weekends and holidays from 6am — 2 pm, the microbiology aid on duty will be responsible for preserving the specimen until slides are made by Histology. Preservation should be done immediately.

To prepare the sputum for the silver stain for PCP, the microbiology aid should put up to 5cc of the sputum in a small jar containing the Saccomanno Fluid in the hood. These jars can be found in the cabinet in histology to the left of the tissue cutting area. The inoculated container should be shaken to thoroughly mix the specimen with the fixative. The specimen should be left at room temperature with the order in the histology department. The specimen may remain in the fixative for several hours or days until slides may be prepared for staining.

Occasionally an induced specimen will have orders for AFB culture and smear as well as a silver stain for PCP. The specimen should be brought to the lab with an order in the computer for AFCS and with a pathology request form. If there are also orders for a routine culture, the specimen should be plated by the microbiology aid first. Then the microbiology aid should put part of the sputum specimen in the Saccomanno Fluid while the remainder should be sent to Public Health for AFB testing.

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Sputum in the Saccomanno Fluid cannot be used for AFB and should not be sent to Public Health. As much specimen as possible should be sent to Public Health since specimens less than 5 cc must be reported out as "Scant," and this may affect the clinical significance of the test results.

When handling any sputum specimens, make sure that the cap is securely tightened to avoid spilling into the interior of the protective bag.

Organism_	# Required.	Method	How to Order	Continents
Fungal	1*	Spontaneous. Induce if patient unable to produce specimen without assistance,	"Sputum for fungal culture."	If a KOIJ prep is needed, this will require a separate order but it can be performed on the *some* specimen.
Bacterial	1	Spontaneous. Induced only if pt cannot produce adequate specimen spontaneously.	"Sputum for bacterial culture & grain stain" *or* "Resp. Therapy: induce sputum for bacterial culture & Gram stain"	If stat Grain stain result needed, review with technologist yourself.
P. carimi	3**	Ultras° II icated hypertonic saline. Two on first day and one next AM.	"Sputum for PCP per protocol."	Slides are prepared and stained with CMS, *not* cultured. Time consuming test that should not be done unless patient being treated for PCP. Specimens are usually scant and non purulent.

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Acid Fast Bacilli (TB)	3	Usually induced with Albuterol and saline. If cavity present, a spontaneous sample may be adequate. Obtain I q early AM x 3.	"Sputum for AFB per protocol."	Many patients with TB do not have purulent sputum. If you wish to make your own smear, do so with proper cautions but still SU bruit for formal analysis.

* One can order, on a single sample, "bacterial, fungal, and AFB culture". It would still be necessary to order Iwo additional sputum samples for AFB to complete the evaluation for TB. Hence, 3 samples would be sufficient to complete an evaluation for possible bacterial, fungal, or TB pneumonia.

** If *P. carinii* organisms are identified on an initial smear, subsequent specimens need not be submitted.

REFERENCES

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Hospital Administration	Jason Arimura: Associate Hospital Administrator, VCMC & SPH	2/27/2026
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L.114 Stool Collection and Handling

COPY

PRINCIPLE:

Diagnosis of parasitic disease is confirmed by recovery and identification of helminth eggs and larvae, or protozoan trophozoites and cysts in the stool. The Para-Pak vials provide a standardized procedure for the routine collection, transportation, and preservation of stool specimens for intestinal parasites.

Diagnosis of intestinal disease of bacterial origin is confirmed by isolation and identification of the causative organisms by culture. The Para-Pak Enteric Plus vial provides a standardized procedure for the routine collection, transportation, and preservation of stool specimens for the culture of bacterial enteric pathogens.

PROCEDURE:

1. If the physician has ordered Ova & Parasites X3, the specimens **must** be collected on three separate days. Each specimen **must** be labeled with the patient name, date of birth, date of collection, and time of collection. A stool culture is normally ordered once, and may be collected with any one of the Ova & Parasite specimen collected.
    a. The containers in the kit contain solutions that are poisonous. Do not drink. Keep them out of the reach of children.
2. The stool should be passed into a clean, dry container. To collect the specimen, use a bed pan, or place a large piece of saran wrap across the toilet, or use a white speci-pan that fits into the toilet.
3. Open the vial containing the liquid. Using the collection spoon built into the lid of the vial, place small scoopfuls of stool from areas which appear bloody, slimy or watery into

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the tube until the contents rise to the red line. If the stool is hard, try to sample small amounts from each end and the middle.

4. Mix the contents of the vial with the spoon, then twist the cap **tightly** closed and shake the vials vigorously until the contents are well mixed. Keep the vial at room temperature.
5. If one of the vial has no liquid in it, fill it to the red line, but do not mix or shake. Keep this vial refrigerated.
6. When labeling the specimen, check the box on the label which looks most like the specimen when collected.
7. Wash your hands thoroughly. If any liquid from the vials gets on your skin or in your eyes, flush with plenty of running water. If irritation develops, consult a physician.
8. Return the vials to your physician or laboratory as soon as possible.

NOTES:

a. **Antidote if swallowed:** Dilute by drinking 2-4 glasses of water. Immediately contact an emergency facility, poison information center, or a physician to receive medical attention. Save the reagent vial. Label information will be helpful for determining appropriate medical treatment.
b. If the order is for Stool Culture, submit specimen in a sterile container during the acute stage of infection (usually 5 to 7 days), because pathogens decrease in number with time.
c. Fecal sample: Patient should pass stool into a clean dry container

COPY

REFERENCE

Directions taken from Meridian Bioscience, Incc. Package Insert. 01/04, 01/07.

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2/27/2026

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Laboratory Services Department	M. Anwar Molani: Medical Director, Laboratory Services	2/26/2026
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L.115 Specimen Collection: Urine

COPY

PRINCIPLE

The physical and chemical properties of urine are important indicators of health. The kidneys are responsible for maintaining homeostasis, including the regulation of body fluids, acid-base balance, electrolyte balance and the excretion of waste products.

The analysis of urine is used to detect and assess a wide range of disorders, including urinary tract infection, kidney disorders, and diabetes.

PROCEDURE

MATERIALS FOR COLLECTION:

The Vacutainer Brand Urine Collection and Transport Kit are used for collection, storage, and transport of urine specimens for Urinalysis, Chemistry and Microbiology. The kit includes a collection cup, a yellow top tube, and a grey top tube and towelettes.

The collection specimen cup is a sterile screw-cap cup graduated to indicate volume up to 120 ml of urine with or without an integral sampling device. Stable for 24 hours when stored at 4°C - 35° C.

The grey top tube for urine culture is a 6 x 75 mm evacuated tube which draws 5 ml of urine with lyophilized (freeze-dried) maintenance formula (C&S preservative: Boric Acid, Sodium Borate, Sodium Formate) to maintain the urine bacterial population for up to 48 hours from time of collection at room temperature (18-30°C) or refrigerated at 2-8°C.The maintenance formula will not inactivate antibiotics. Failure to add urine to the minimum mark on the grey tube label could result in a reduction of micro-organisms over a 24 hour period.

The yellow top tube for urinalysis and urine chemistries (including urine pregnancy) is a

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16 x 100 mm plastic conical tube with no preservative evacuated to draw 12 ml of urine. This specimen is stable for up to 24 hours from time of collection when refrigerated at 2-8°C.

The towelettes are 2 — 6 x 4 1/2" folded towelettes saturated with 2% Castile Soap. They are used to cleanse the area of collection prior to collection.

BEFORE COLLECTION:

1. Remove tubes from packaging and place in a protected location.
2. Give cup and towelettes to patient for mid-stream urine collection following instructions in "Patient Instructions," **Patient needs to be alerted to the presence of a needle under the label that must not be removed by the patient.**

AFTER COLLECTION:

1. Place cup upright on flat surface. Container may be tipped at an angle if volume of urine is limited.
2. Label all containers.
3. Peel back label on top of cup to expose integral sampling device (needle).
4. Place grey top tube in holder portion with stopper down and push tube over puncture point to pierce stopper.
5. Hold in position until urine stops flowing into tube.
6. Remove tube from device and shake grey top tube vigorously to mix contents.
7. Repeat with yellow top tube.
8. Replace label over needle hole and reseal. Specimen top should be treated as a contaminated sharp and discarded in a biohazard container.
9. Indicate collection time and Collection ID (Cerner ID #).
10. Refrigerate containers

For short samples (5mL to 15mL):

1. If Urine Culture is ordered, fill grey top tube first. Remove stopper of grey top tube and pour urine into tube to min. mark, replace stopper and shake tube vigorously.
2. Pour the remaining sample in a yellow top tube.

INFANT/ CHILD INSTRUCTIONS:

1. Place the U Bag Single Specimen urine collection bag on patient before blood draw. (The process of collecting blood often stimulates urination.)
2. Remove bag when full.

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PATIENT INSTRUCTIONS:

You have been asked to provide a urine specimen for our laboratory. It is important that this specimen be as clean as possible. Read instructions on bag for collection of clean voided, midstream urine specimen carefully before you start.

1. Unscrew cap of the urine specimen cup. Place cap on counter with 'straw' facing upward. **To AVOID CONTAMINATION, DO NOT TOUCH INSIDE OF CUP, CAP OR STRAW**
2. Cleanse yourself with towelettes as follows:
    a. Female - Separate the labia. Wipe inner labial folds front to back in a single motion with first towelette. Wipe down through center of labial folds with second towelette. Keep the labia separated and urinate a small amount into toilet. Proceed to step 3
    b. Male - Wipe head of penis in a single motion with first towelette. Repeat with second towelette. If not circumcised, hold foreskin back before cleansing. Urinate a small amount into toilet. Proceed to step 3
3. Place cup under urine stream and continue to urinate into cup and collect specimen.
4. Finish voiding into toilet.
5. Replace cap on cup. Tighten cap securely. **Do NOT REMOVE LABEL FROM CAP.**
6. Place cup on counter in wire basket.

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PACIENTE:

A usted le han pedido una muestra de su orina para nuestro laboratorio. Es muy importante que est muestra o especimen sea lo mas limpia possible. **Lea** las instrucciones ciudadosamente antes de empezar.

1. Desenrosque la tapa del recipiente. Ponga la tapa a un lado conel tubito apuntando hacia arriba ... **PARA EVITAR CONTAMINACION, NO TOQUE EL INTERIOR DEL RECIPIENTE, LA TAPA 0 EL TUBITO.**
2. Limpiese con las toallitas de la siguiente manera:
    a. iMuier - Separe los labios de la vulva. Limpie los pliegues de los labios interiores del frente hacialatras con un solo movimiento, con la primera toallita. Limpie todo el centro de los pliegues labiales con la segunda toallita. Mantenga los labios separados y orine una pequena cantidad en el inodoro. Proceda al paso 3.
    b. Hombre - Limpiese la cabeza del pene con un solo movimiento, on la primera toallita. Repitalo con la segunda toallita. Si usted no esta circuncidado, levante el prepucio antes de limpiarse. Orine una pequena contidad en el inodoro o la cuna. Proceda al paso 3.

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3. Coloque el receipiente en el fiujo de orina y orine en el receipiente para colectar el especimen.
4. Termine do orniar en el inodoro.
5. Pongale la tapa at recipiente. Asegureses de que la tapa este bien cerrada. **No QUITE LA ETIQUETA DE LA TAPA.**
6. Pongan la tacieta en la mesa.

REFERENCE

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Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator, VCMC & SPH	3/2/2026
Laboratory Services Department	M. Anwar Molani: Medical Director, Laboratory Services	3/1/2026
Laboratory Services Department	Evan Gamad: CLS III	2/28/2026
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VENTURA COUNTY HEALTH CARE AGENCY

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Owner	Evan Gamad: CLS III
Policy Area	Laboratory Services

L.116 24 Hour Urine Collection

COPY

PRINCIPLE

The 24 hour urine specimen is useful when it is important to know what amount of analyte is excreted during a 24 hour period. It provides more accurate quantitative results than a random specimen because some analytes are not excreted equally throughout the 24 hours.

PROCEDURE

COLLECTION INSTRUCTIONS FOR A 24 HOUR URINE

Most 24- hour specimens can be collected in a clean, nonmetal container without preservatives if the specimen is refrigerated during the collection and is transported to the laboratory in a timely manner. The 24 Hour Urine Handling Requirements chart following is a summary of specific instructions for the most common tests.

The laboratory has the proper containers available. The containers have labels to record collection dates and times. The volume will be measured when the urine specimen is returned to the lab.

Certain urine tests also require a blood specimen to be drawn within a certain time frame. The creatinine clearance requires that the patient be drawn within a 24 hour window before or after the collection.

Patient Instructions:

1. The patient should follow the physician's directions regarding food, drink, or medications before and during collection. Normal fluid intake is recommended.

2. Empty bladder completely on awakening in the morning and discard this urine.
3. Record the date and time as the "Start" of the collection.
4. All urine passed during the rest of the day and night for the next 24 hours must be poured into the container. Do not collect the urine directly into the container. Urine should be collected in another clean container and then carefully poured into the 24 hour container. There is a "speci-pan" available that fits onto the toilet for simplifying collection.
5. Collect the final portion the next morning at the same time that the collection began. This is the "Finish."
6. The patient name, date and times of start and finish are critical so that the specimen can be processed.
7. Deliver the specimen to the physician's office, drawing station, or hospital laboratory as soon as possible.

REFERENCE

Special Specimen Collection and Handling, www.quest.com

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Laboratory Services Department	M. Anwar Molani: Medical Director, Laboratory Services	3/1/2026
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Owner	Gayle Haider: Supervisor-Quality Assurance, Laboratory Services
Policy Area	Laboratory Services

L.60 Laboratory Chemical Hygiene Plan

COPY

POLICY:

The Laboratory is committed to providing a safe working environment and believes employees have a right to know about health hazards associated with their work so that employees can make knowledgeable decisions about any personal risks of employment, The Laboratory Chemical Hygiene Plan includes policies, procedures, and provides an outline of responsibilities designed to develop an awareness of potentially hazardous chemicals in the workplace and to train employees in appropriate, safe working conditions.

It is important that employers assume responsibility for laboratory safety. All employees will have access to pertinent safety information through their supervisory staff. The people who work in any given area are best able to detect potential hazards in either the facility or in work procedures. When safety concerns arise, employees are encouraged to contact their supervisor immediately.

PROCEDURE:

A training program has been designed for the benefit and protection of all Laboratory employees. Necessary information will be available to inform the employee how best to handle hazardous chemicals and how to make use of the new law.

Copies of the Chemical Hygiene Plan are located in the following areas:

1. Blood Gas Laboratory Safety Manual hardcopy (located in the Respiratory Care Department)
2. The Clinical Laboratory Quality Assurance Supervisor's office.
3. Electronic copies are located on most all data workstations with other Healthcare Agency (HCA) and Hospital Procedures.

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4. The Chemical Hygiene Plan will be updated as new hazards are introduced, old hazards deleted or procedures/instrumentation changed.

RESPONSIBILITIES:

A. The Laboratory Medical Director provides overall direction and approves all procedures for the Chemical Hygiene Plan.

B. The Respiratory Department Manager is the designated Chemical Hygiene Officer. Other staff members will be appointed as tasks arise. The following sections identify the responsibilities Ventura County Medical Center/Santa Paula Hospital (VCMC/SPH) Blood Gas Laboratory staff have in regard to the Chemical Hygiene Plan.

C. Chemical Hygiene Officer/ Committee

1. The Chemical Hygiene Committee (CHC) is composed of Respiratory staff who are familiar with the current procedures used and their associated hazards.
    a. Work with administrators and other employee to develop and implement appropriate chemical hygiene policies and practices.
    b. Review the Chemical Hygiene Plan and update where necessary.
    c. Seek ways to improve the Chemical Hygiene Program.
    d. Review each existing and new Laboratory procedures for safe work practice.
    e. See the appropriate audits are maintained.
    f. Ensure that facilities and training for use of any material being ordered are adequate.
    g. Ensure that chemical compatibility is maintained for the storage of chemicals.
    h. Know the current legal requirements concerning regulated substances.
    i. Determine the required levels of protective apparel and equipment.
    j. Certify the performance of protective equipment.
    k. Assure that each new employee receives appropriate training and information and that review sessions are held in accordance with the schedule listed in "Employee Information and Training".
    l. Provide regular, formal chemical hygiene and housekeeping inspections including routine inspections of emergency equipment.

D. Respiratory Care Department Manager (Chemical Hygiene Officer):

1. Ensures that workers know and follow the chemical hygiene rules, and that protective equipment is available and in working order, and that appropriate training has been provided.
2. Knows the current legal requirements concerning regulated substances.
3. Determines the required levels of protective apparel and equipment.
4. Ensures that facilities and training for use of any material being ordered are

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adequate.

5. Provides regular chemical hygiene and housekeeping inspections including routine inspections of emergency equipment.

E. Laboratory Employees

1. All Laboratory employees are responsible for compliance with the provisions of the Chemical Hygiene Plan.
    a. Plan and conduct each operation in accordance with the Laboratory's chemical hygiene procedures.
    b. Develop good personal hygiene habits.
    c. Use appropriate safeguards for using any chemicals, including personal protective equipment.
    d. Know the location and proper use of emergency equipment.
    e. Know the location of the Safety Data Sheet (SDS) and other safety information. Know that you can all for a "fax-back" using information located on every phone.
    f. Use appropriate procedures for emergencies, including evacuation routes, spill cleanup procedures and proper waste disposal.

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STANDARD OPERATING POLICIES/PROCEDURES

A. Because few laboratory chemical are without hazards, general precautions for handling all laboratory chemicals should be adopted to include minimizing exposure and assuming that any mixture of hazardous chemicals is more toxic than the most toxic component.

B. General Rules:

1. Do not smell or taste chemicals.
2. Inspect gloves before use.
3. Do not eat, drink, smoke, or apply cosmetics or lip balm in the working area of the laboratory. Wash hands before conducting these activities.
4. Food, beverages, dishes and utensils should be stored or consumed only in designated areas.
5. Wash areas of exposed skin thoroughly before leaving the laboratory.
6. Avoid practical jokes or other behavior that might confuse, startle or distract another worker.
7. Confine long hair and loose clothing.
8. Wear shoes at all times in the Laboratory, but do not wear sandals, perforated shoes, open toe, sneakers or any shoe made of canvas.
9. Ensure that appropriate eye protection, where necessary, is worn by all persons, including visitors, in areas where chemicals are stored and handled.
10. Avoid use of contact lenses in the laboratory unless necessary; if they are used, inform supervisor so special precautions can be taken.

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11. Wear appropriate gloves when the potential for contact with toxic material exists; inspect the gloves before each use and replace them periodically.
12. Remove lab coats immediately upon significant contamination.
13. Seek information and advice about hazards, plan appropriate protective procedures and plan positioning of equipment before beginning any new operation.
14. Keep work area clean and uncluttered, with chemicals and equipment properly labeled and stored; clean up the work are on completion of an operation or at the end of each day.
15. Be aware of unsafe conditions and see that they are corrected when detected.
16. **SHARP SPECIFIC RULES:**
    a. Generally the Hospital has committed to the use of needless systems where they can be used. When the use of needles (sharps) is necessary all precautions must be taken.
    b. All needles used for arterial puncture must safe sheathing devices to cover or otherwise mitigate rick of staff injury from used needles. No safety device can be modified or otherwise defeated from it's intended use per the manufacturer.
    c. Sharps must be disposed of in the nearest sharp container to the area in which blood is drawn. It is never acceptable to carry a sharp, sheathed or not, back to the Lab.
    d. Sharps, when disposed of, must be in the appropriate container and must always be deposited in such a way that it cannot "fall out" or otherwise injure staff and/or patients. Full containers should be sealed and Housekeeping services notified of the need to replace as soon as possible. Containers can never be "shaken" or otherwise manipulated to make "more room".

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CHEMICAL INVENTORY and STORAGE

A. Inventory:
    1. Chemicals listed are those classified as hazardous by the Department of Transportation (DOT), the Environmental Protection Agency (EPA), or displaying a 2 or greater number in any section of the National Fire Protection Association (NFPA) diamond.
    2. Chemicals are listed alphabetically. The average quantity in storage on a monthly basis, as well as the physical state (e.g., solid, liquid, gas) is included. The NFPA hazard classification, is listed along with the manufacturer's name and address. A comment section is provided to further identify the chemical's location.

B. Storage:
    1. Chemical storage is kept as small as practical. Storage on bench tops is not advisable. There are no flammable liquids used in the Blood Gas Laboratory. All chemical storage for the Rapid Point 500 (RP500) analyzers is contained within a

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cartridge unit and stored in the refrigerator as required by the manufacturer. These cartridges are self-contained and are closed cartridges.

2. Toxic chemicals, including carcinogens, are stored in ventilated storage areas in unbreakable chemical resistant secondary containers. These containers are labeled "CAUTION: HIGH CHRONIC TOXICTY OR CANCER-SUSPECT AGENT". A separate inventory list of carcinogens and suspected carcinogens is maintained by the Chemical Hygiene Officer according to federal and state regulations.

HAZARD IDENTIFICATION-LABELS and SIGNS

A. The 29 Code Federal Regulations (CFR) 1910.1450 eCFR :: 29 CFR 1910.1450 -- Occupational exposure to hazardous chemicals in laboratories contains specific labeling requirements. Labeling must be done on all hazardous chemicals that are shipped and used in the laboratory. Labels must not be removed or defaced. All labels must comply with the Occupational Safety and Health Administration (OSHA) Hazard Communication Standard.

B. Safety Data Sheets (SDS)

1. The SDS are available in the Respiratory Department in a 3-ring binder and on computer desktops in all labs. They can also be accessed by fax-back programs. The laboratory relies on the chemical manufacturer's information to ascertain whether or not the chemical is hazardous.

C. Analyzer Cartridge Labeling

1. Upon receipt, measurement and Automatic Quality Control (AQC) cartridges are refrigerated in the appropriate laboratory and labeled appropriately as required by the manufacturer. The waste/wash self-contained cartridge is stored non-refrigerated and labeled accordingly. These cartridges are self-contained and come in one unit and are disposed of in the same unit with no opening of the cartridges.

D. Location Signs

1. Prominent signs should be posted for the location of emergency safety showers, eyewash stations, safety and first aid equipment, exits and food/beverage consumption storage.

EXPOSURE PREVENTION and MONITORING

A. Personal protective Equipment

1. Personal protective equipment (PPE) is available for all laboratory personnel. They are required to use gloves, laboratory coats, and either safety glasses, chemical splash goggles or face shields whenever working with hazardous chemicals in the laboratory. The SDS and/or container label will provide the employee with the proper personal protective equipment to use for each chemical. An inspection of all protective equipment will be conducted by the user, before use. Defective equipment will be removed and replaced.

2. All personal protective equipment is removed immediately upon leaving the work area.

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3. Gloves – Employees are required to wear gloves when there is the potential for direct skin contact with blood, hazardous chemical and infectious materials. Gloves of the appropriate size for employee are provided by VCMC and SPH. Employees should be sure gloves fit properly- not too loose are too tight. Non- latex gloves are provided for those with identified or suspected latex allergies.
4. Lab coats – are to be worn only in the laboratory work areas and are to be buttoned to protect the employee's clothing. The coats are provided and in most cases disposable coat/covers are used. Some coats may be re-usable and are laundered by VCMC laundry service.
5. Eye protection is to be worn to prevent splashes or sprays of blood, infectious materials, or hazardous chemicals if there is a potential for eye, nose, or mouth contamination. This equipment is located in all Blood Gas Laboratory locations.

B. Engineering Controls

C. Chemical storage cabinets are no longer required for analyzer containers as they are self-contained and in cartridges which require refrigeration. Storage cabinets are available for any chemicals that require storage, but some reagents may be kept in monitored refrigeration. See Manufacture or Vendor guidelines for more information as needed.

D. Emergency Eye Wash Station is available in all areas where analyzers are located. All eyewash stations are serviced/maintained by Facilities Maintenance.

1. **Intensive Care Unit (ICU):** To the left (as you exit) the Laboratory in ICU.
2. **Neonatal Intensive Care Unit (NICU):** In the adjacent entry room to the Lab area.
3. **Emergency Department (ED):** To the left of the Lab station in the location shared with the ED Microscopy.
4. **Pediatric Intensive Care Unit (PICU):** To the immediate right of the analyzer station adjacent to the splash barrier.
5. **SPH:** The main room of the Department just outside the Lab area.
6. **VCMC Laboratory:** Three locations- Pathology/Histology area, Microbiology lab near the door, and next to the chemistry refrigerators across from the time clock.

E. If someone is splashed with a chemical, they are to be taken immediately to the eye wash station. Any clothing affected will be immediately removed as indicated (chemicals used in the Arterial Blood Gas (ABG) Lab are not corrosive). Flushing with water must continue for a minimum of 15 minutes. Medical assistance will be requested immediately.

F. Emergency Equipment is located in the ICU:

1. **VCMC ICU:** Fire Alarm is in ICU, fire extinguisher is on the wall opposite bed D.
2. **VCMC NICU:** Fire Alarm outside in hall, fire extinguisher is outside hall.
3. **SPH:** Fire alarm outside in hall, fire extinguisher in outside hall.

G. Chemical Hygiene Risk Assessment

1. Assessment of significant risk of all operations is made by the Department Manager. Chemical hygiene and safety policies will be established for each task performed and engineering controls of personal protective equipment assigned. Appendix B

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identifies each work station/task in the laboratory and the required controls and equipment.

H. Chemical Spills

1. Chemical spills are contained using the "Think C.L.E.A.N." Plan**.**
    a. **C**ontain the spill with appropriate spill kit.
    b. **L**eave the area-remove patients.
    c. **E**mergency: eye wash, shower, medical care.
    d. **A**ccess SDS
    e. **N**otify a supervisor
    f. Refer to Spill Procedure (Safety Manual, 2.9)
        i. Spills causing toxic fumes or fire-at VCMC call X6666 at SPH call X8666, follow the Fire Plan.
        ii. Call: If major spill (excess of 100 ml) at VCMC X6666, at SPH call X8666.
        iii. To complete clean-up by Lab personnel (if minor spill):
            i. Put on a new pair of gloves.
            ii. Place material in double red bags. Dispose appropriately.
            iii. Thoroughly wash and dry the spill area.

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HOUSEKEEPING

A. Housekeeping personnel will be responsible for the following:

1. Trash Disposal-Removed twice per day with the maintenance of the separation of bio-hazardous and ordinary trash. Glass and needles will have been placed in the appropriate "Sharps" containers.
2. Floors-Daily swept and mopped with appropriate cleaner.

B. Laboratory personnel will be responsible for the following:

1. Prompt cleanup of small, nontoxic spills, using appropriate personal protective equipment and proper disposal. If the spilled substance is highly toxic, a hazardous materials team must be notified at once.
2. Clear access to exits, emergency equipment and utility controls.
3. Clean work surfaces. Bench tops should be clear of unnecessary items.

C. Periodic inspections are conducted by the Department Manager to assess whether:

1. Work area is free of obstruction.
2. Waste is deposited in appropriate receptacles and properly removed from the laboratory.
3. Chemical spills are cleaned according to established protocol.

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4. Proper storage is accomplished to minimize clutter.

MEDICAL PROGRAM

A. All employees needing medical attention are referred to the Emergency Room at VCMC or at SPH.
    1. All medical examinations and consultations are performed by or under the direct supervision of a licensed physician without cost to the employee, without loss of pay, and at a reasonable time and place.

B. The employee is sent for medical evaluation:
    1. Whenever signs and symptoms associated with a hazardous chemical develop.
    2. When environmental monitoring reveals an exposure level routinely above the action level, or in the absence of an action level, the Permissible Exposure Limit (PEL) for an OSHA regulated substance.
    3. Whenever an event takes place in the work area such as a spill, leak, or explosion resulting in a hazardous chemical exposure.

C. The laboratory provides the following information to the physician:
    1. Identity of the hazardous chemical(s) to which the employee may have been exposed.
    2. A description of the conditions under which the exposure occurred-including quantitative exposure data (if available).
    3. A description of the signs and symptoms of exposure.
    4. A copy of the SDS for the chemical(s) involved.

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D. The physician provides a written opinion that will not reveal specific finding of diagnosis unrelated to the exposure but will include:
    1. Any recommendation for further medical follow up.
    2. Results of the medical examination and any associated tests.
    3. Any medical conditions that may be revealed in the course of the examination that may place the employee at increased risk as a result of exposure to a hazardous chemical found in the workplace.
    4. A statement by the physician that the employee has been informed of the consultation/examination results and any medical condition that may require further examination or treatment.

E. Records are maintained on all employee examinations and consultations. Reports should be made to the Department Manager and to the Safety Officer.

RECORD KEEPING

A. The laboratory will maintain the following records in the Blood Gas Laboratory and the Clinical Laboratory:

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1. Chemical Hygiene Plan
2. Blood Borne Pathogens Document
3. Access to SDS via Fax-back

B. The Laboratory will maintain the following records in the Department Manager's Office:
    1. Training Records
    2. Environmental monitoring as may occur
    3. The Respiratory Care Department will maintain calibration and repair records

C. The Bio-Medical Department will maintain the following records:
    1. Instrument/device inspection; repair records, if performed by Biomed
    2. Environmental monitoring records

D. The Employee Health Department of Ventura County will maintain the following records:
    1. Employee medical records
    2. Accident records

CONTAMINATED WASTE REMOVAL/DISPOSAL

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A. The Laboratory, in conjunction with the VCMC and SPH facilities, are considered a small quantity generator according to the EPA.

B. Waste generated in the Laboratories will be accumulated in the appropriately labeled containers. It is removed to a central waste storage area as needed and from the central waste storage at regular intervals.

C. Laboratory chemical wastes are sent to an approved disposal site by a County-contracted hauler.

D. Certain chemicals are permissible for drain disposal. Only those chemicals reasonably soluble in water are suitable for drain disposal. A compound is considered water-soluble if it dissolves to the extent of at least 3%. These compounds are flushed with at least 100 volumes of excess water.

EMPLOYEE INFORMATION AND TRAINING

A. VCMC will provide employees with information and training to ensure that they are adequately informed regarding laboratory operations, its risk, and what to do if an accident occurs.

B. Such information will be provided to all new employee and refresher training will be conducted periodically.

C. The employee will be informed of:
    1. Contents of this standard
    2. Location and availability of the employer's Chemical Hygiene Plan
    3. Permissible exposure limits for OSHA regulated substances or recommended exposure limits for other hazardous chemicals where there is no applicable OSHA

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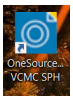
standard.

4. Signs and symptoms associated with exposures to hazardous chemicals used in the Laboratory.
5. Location and availability of known reference literature on the hazards, safe handling, storage and disposal of hazardous chemicals found in the laboratory including, but not limited to, Safety Data Sheets received from the chemical supplier.
6. Laboratory Safety Manual location.
7. Link to OneSource OneSource Docs Icon is displayed in every desktop 

D. The employee will be trained in the following:

1. Methods and observations that may be used to detect presence or release of a hazardous chemical (such as monitoring conducted by VCMC, visual appearance or odor of released hazardous chemicals, etc.).
2. Physical and health hazards of chemicals in the work area.
3. Measures employees can take to protect themselves from hazards, including specific procedures the employer has implemented.
4. Applicable details of the Chemical Hygiene Plan.

COPY

REFERENCE:

College of American Pathologists, Laboratory General Checklist, December 9, 2025.

All Revision Dates

2/26/2026, 11/15/2024

Attachments

Chemical Inventory Addendum.pdf

Approval Signatures

Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator, VCMC & SPH	2/26/2026

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Laboratory Services Department	M. Anwar Molani: Medical Director, Laboratory Services	2/25/2026
Laboratory Services Department	Gayle Haider: Supervisor-Quality Assurance, Laboratory Services	2/24/2026
Laboratory Services Department	Erlinda Roxas: Director, Laboratory Services	2/24/2026

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Status **Active** PolicyStat ID **20004034**

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Effective	1/18/2002		
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L.78 Isolation: Phlebotomy Application

COPY

POLICY

Isolation: Phlebotomy Applications

VCMC/SPH uses Standard Precautions. There are also several categories of isolation procedures which must be followed during the collection of blood specimens by Phlebotomists , including:

Droplet Precautions

Airborne Precautions

Contact Precautions

For patients in isolation, instruction signs will be posted at the entrance to the isolation room. The class of isolation will be listed. For persons entering the room, the sign will list what protective equipment should be worn. See signs on p. 4.9-4.11.

A cart containing gowns, masks (if required), and gloves will be placed by the door of the isolation room. The isolation gown may be worn over the lab coat, or the lab coat may be replaced by the gown. Hands should be washed on entering and leaving the room. Only the equipment necessary is taken into the room. A small label should be taken in to identify the patient chart number. Disposable equipment, including tourniquet, should be left inside the room in appropriate disposal containers. Sharp's Containers are available for needles and blood drawing equipment.

Protective garments, masks, and gloves should be removed before leaving the room. The nurse must be notified if any problems result during procedure in isolation room.

Additional information is included in the VCMC/SPH Infection Control Manual and the Laboratory Safety Manual.

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RELATED POLICIES

1. F.76 Isolation Rooms https://pstat-live-media.s3.amazonaws.com/pdf_cache/policy/17478915/b08439bb-24e0-4896-943d-38f0c83fccae/F-76%20Isolation%20Rooms.pdf
2. 106.028 Isolation Precautions https://vcmc.policystat.com/policy/19717016/latest#:~:text=106.028%20Isolation%20Precautions
3. 106.058 Infectious Disease Surge Planning Guidelines https://vcmc.policystat.com/policy/11421492/latest#:~:text=106.058%20Infectious%20Disease%20Surge%20Planning%20Guidelines

All Revision Dates

3/2/2026

Attachments

F-76 Isolation Rooms.pdf

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Approval Signatures

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Laboratory Services Department	M. Anwar Molani: Medical Director, Laboratory Services	3/1/2026
Laboratory Services Department	Evan Gamad: CLS III	2/28/2026
Laboratory Services Department	Erlinda Roxas: Director, Laboratory Services	2/28/2026

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VENTURA COUNTY HEALTH CARE AGENCY

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L.81 Specimen Collection Tubes

COPY

PROCEDURE

Additive tubes include tubes with clotting activators, with or without gel separators, or anticoagulants, with or without gel separators. The additive tubes containing clot activators should be drawn after the coagulation tube (blue) and before other additive tubes (green, lavender, and gray).

Two types of tubes are used:

1. Clot tube - centrifugation separates the specimen to RBCs and serum
2. Anticoagulated - Clotting is prevented, either whole blood or the plasma after centrifugation is used.

Evacuated tubes are designed to draw a predetermined volume of blood. The exact volume is critical to providing the correct ratio of blood to anticoagulant for coagulation studies. The tube tops are color-coded to indicate the additives.

Color	Common Name	Order of Draw	Yield	Primary Users
Blue	Coag Tube	First	Plasma	Coagulation
Red	Red Top	Second	Serum	Send outs
Goldenrod	SST	...Second	Serum	Send outs
Lt. Gm	Green Top	Third	Plasma	Chemistry
Dk. Gm	Dk. Green Top	Third	Whole Blood	Send outs

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Lavender	EDTA	....Fourth	Whole Blood Or Plasma	Hematology
Grey	Gray Top	....Fifth	Plasma	Chemistry
Pale Yellow	ACD, ACDA	Last	Plasma or WB	Send Outs

The order of draw has been revised to reflect the increased use of plastic blood collection tubes. Plastic tubes containing a clot activator may cause interference in coagulation testing.

The purpose of following the order of draw is to avoid possible contamination from tube additives: Coagulation tube; serum tube with or without clot activator, with or without gel; Heparin tube with or without get plasma separator; EDTA; grey tube with glycolytic inhibitor.

When using a winged collection set for venipuncture and a coagulation tube is the first tube to be drawn, a discard tube should be drawn first to compensate for the dead space so that the proper anticoagulant/ blood ratio is maintained. The discard tube should be a non-additive tube or a blue top tube. The tube should be filled to -10% to +10% of manufacturers recommended volume. (See BD Tube draw volume guide)

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SEE THE ATTACHED INSERTS FROM BD

STORAGE OF BD COLLECTION TUBES:

Store tubes at 4-25 degrees centigrade, unless otherwise noted on the package label. All liquid preservatives and anticoagulants are clear and colorless, except CTAD which is yellow. Do not use if they are discolored or contain precipitate. Powdered additives such as heparin and thrombin are white; fluoride and fluoride/oxalate may be pale pink. Do not use if color has changed. EDTA spray coated additives may have a brownish appearance; this does not affect the performance of the EDTA additive.

Do not use tubes after their expiration date. Tubes expire on the last day of the month and year indicated.

REFERENCES

All Revision Dates

3/2/2026

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Hospital Administration	Jason Arimura: Associate Hospital Administrator, VCMC & SPH	3/2/2026
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Laboratory Services Department	Evan Gamad: CLS III	3/1/2026
Laboratory Services Department	Erlinda Roxas: Director, Laboratory Services	2/28/2026

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VENTURA COUNTY HEALTH CARE AGENCY

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Effective	8/2/2002
Last Revised	3/2/2026
Next Review	3/1/2028
Owner	Evan Gamad: CLS III
Policy Area	Laboratory Services

L.92 Blood Collection Techniques: Venipuncture

COPY

PROCEDURE

1. Wash your hands. Put on appropriate gloves.
2. Identify the patient.
3. Introduce yourself.
4. Reassure the patient. The phlebotomist must gain the patient's confidence and assure the patient that, although the venipuncture might be slightly painful, it won't last long. Never tell a patient, "This won't hurt".
5. Check tests ordered. If any test requires a fasting state, verify that the patient is fasting.
6. Select appropriate tubes and equipment needed for tests. Check Expiration Date. **DO NOT USE EXPIRED TUBES.**
7. Prepare Portex Vacutainer Holder: Remove cap from the rubber-stopper end or a Greiner Vacquette Safety needle. Thread needle into holder and tighten firmly.

   Place first collection tube into holder, carefully pushing tube forward until needle touches stopper.
8. Position patient. The arm should be supported, slightly downward and should not be bent at elbow.
9. Apply tourniquet. The tourniquet should stop blood flow in vein for *less than a minute* before the blood is drawn. A longer application can cause hemoconcentration. If necessary, release the tourniquet and reapply.
10. Have patient close and open hand, not pumping vigorously.

11. Select venipuncture site. See diagram of Superficial Veins of the Anterior Arm Surface.
12. Clean area with appropriate antiseptic solution. Allow skin to dry to prevent hemolysis of the specimen and to prevent patient from having a burning sensation when venipuncture is performed. DO NOT touch vein site after cleaning it.
13. Draw skin tight about 1-2 inches below venipuncture site to 'hold' vein in place..
14. With needle bevel facing up, line up needle with vein. Penetrate skin and enter

    vein at an angle less than 45 degrees. The needle should enter arm quickly and smoothly (without jabbing) to avoid unnecessary pain.
15. Holding flange of needle holder, push first tube forward until back end of needle punctures stopper.
16. Allow tube to fill, remove from holder. The needle's shut-off valve will stop

    blood flow until next tube is inserted. Insert next tube. Gently invert each tube after filling.
17. As last tube is filling, release tourniquet. After tube is filled, remove from holder.
18. Remove needle gently and smoothly while activating the needle safety device by snapping a plastic needle cover on the vacutainer into place with one hand.

    Immediately apply & maintain pressure to puncture site with clean, dry gauze. Tell patient to keep pressure on site for two minutes.
19. Immediately make and label slides for differential.
20. Label tubes with the printed label originally used to ID patient.
21. Check venipuncture site for any bleeding. Apply bandage to site. Tell patient to leave bandage on for at least 1 to 2 hours. Allow patient to leave.
22. Dispose of the needle still attached to disposable vacutainer in 'Sharps' container with safety device activated..
23. Dispose of gauze in trash.
24. Place tubes in holding rack for delivery to appropriate Laboratory Department.
25. Remove gloves, and wash hands.

VENIPUNCTURE - SYRINGE

PROCEDURE

Follow basic procedure used with vacutainers. Take note of the following considerations:

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1. I. The rubber plunger may stick to the wall. To avoid problems, free stickiness before venipuncture, by moving plunger back and forth.
2. Once in vein, blood will fill the syringe as the plunger is pulled back. Pull back only as fast as blood will flow into syringe. Excessive pull is likely to collapse the vein or hemolyze the blood.
3. Activate needle safety device on the Kendall Monoject Magellan Safety needle by pushing the plastic sheath to cover the needle and remove needle from syringe, disposing of protected needle in the sharps container.
4. Using the blood transfer device on the syringe like a vacutainer, transfer blood from syringe to the evacuated tubes required.
5. Dispose of syringe with blood transfer device attached in a biohazard container.

REFERENCE

COPY

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Hospital Administration	Jason Arimura: Associate Hospital Administrator, VCMC & SPH	3/2/2026
Laboratory Services Department	M. Anwar Molani: Medical Director, Laboratory Services	3/1/2026
Laboratory Services Department	Evan Gamad: CLS III	3/1/2026
Laboratory Services Department	Erlinda Roxas: Director, Laboratory Services	2/28/2026

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Effective	2/1/1998		
Last Revised	3/2/2026		
Next Review	3/1/2028		

L.93 Venipuncture: Winged Blood Collection Sets

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PRINCIPLE

The BD Vacutainer Push Button winged blood collection set with the BD One Use Vacutainer holder is used in special circumstances with infants and small children, elderly people with fragile skin, and for combative patients. The venipuncture should be completed following the procedures for the vacutainer or syringe instructions with the following adaptations.

PROCEDURE

Using the BD Vacutainer Push Button winged blood collection set with the BD One Use Vacutainer holder:

1. Peel blister pouch by peeling back the arrowed corner of the package and remove device, allowing the tubing to relax.
2. Firmly thread the Luer Adapter into the one use vacutainer holder.
3. Carefully remove needle sheath away from needle, grasping the wings pinched together or holding one wing and insert the needle..
4. After observing the presence of blood in the chamber, collect blood into an evacuated tube by placing tube into holder, then puncture the stopper by pushing the tube and replace additional tubes as appropriate.
5. Using one hand, retract the needle by gently depressing the button. The needle will slide out of the venipuncture site and lock into place. Do not impede device retraction.
6. Immediately cover the puncture site with a sterile gauze pad and apply pressure.
7. Dispose of all used materials in appropriate containers.

8. Using a 23 gauge butterfly with a12 inch tubing causes A draw loss of 0.350 ml when collecting the initial tube.

Using The BD Vacutainer Push Button winged blood collection set with the BD One Use Vacutainer with a Syringe:

1. Peel blister pouch by peeling back the arrowed corner of the package and remove device, allowing the tubing to relax.
2. Detach the luer multi-sampler collection device from the end of the tubing so that the female luer will fit onto the syringe tip.
3. Carefully remove needle sheath away from needle, grasping the wings pinched together or holding one wing and insert the needle.
4. After observing the presence of blood in the chamber, collect blood in the syringe.
5. Using one hand, retract the needle by gently depressing the button. The needle will slide out of the venipuncture site and lock into place. Do not impede device retraction.
6. Immediately cover the puncture site with a sterile gauze pad and apply pressure.
7. Remove winged device from syringe and place immediately in Sharp's container.
8. Attach opened BD Blood Transfer Device Holder with Pre-Attached Multiple Sample Female Luer Adapter by rotating clockwise to secure the syringe to the hub. Collect blood into an evacuated tube by placing tube into holder, then puncture the stopper by pushing the tube and replace additional tubes as appropriate.
9. Dispose of all used materials in appropriate containers.
10. Using a 23 gauge butterfly with a 12 inch tubing causes a draw loss of 0.350 ml when collecting the initial tube

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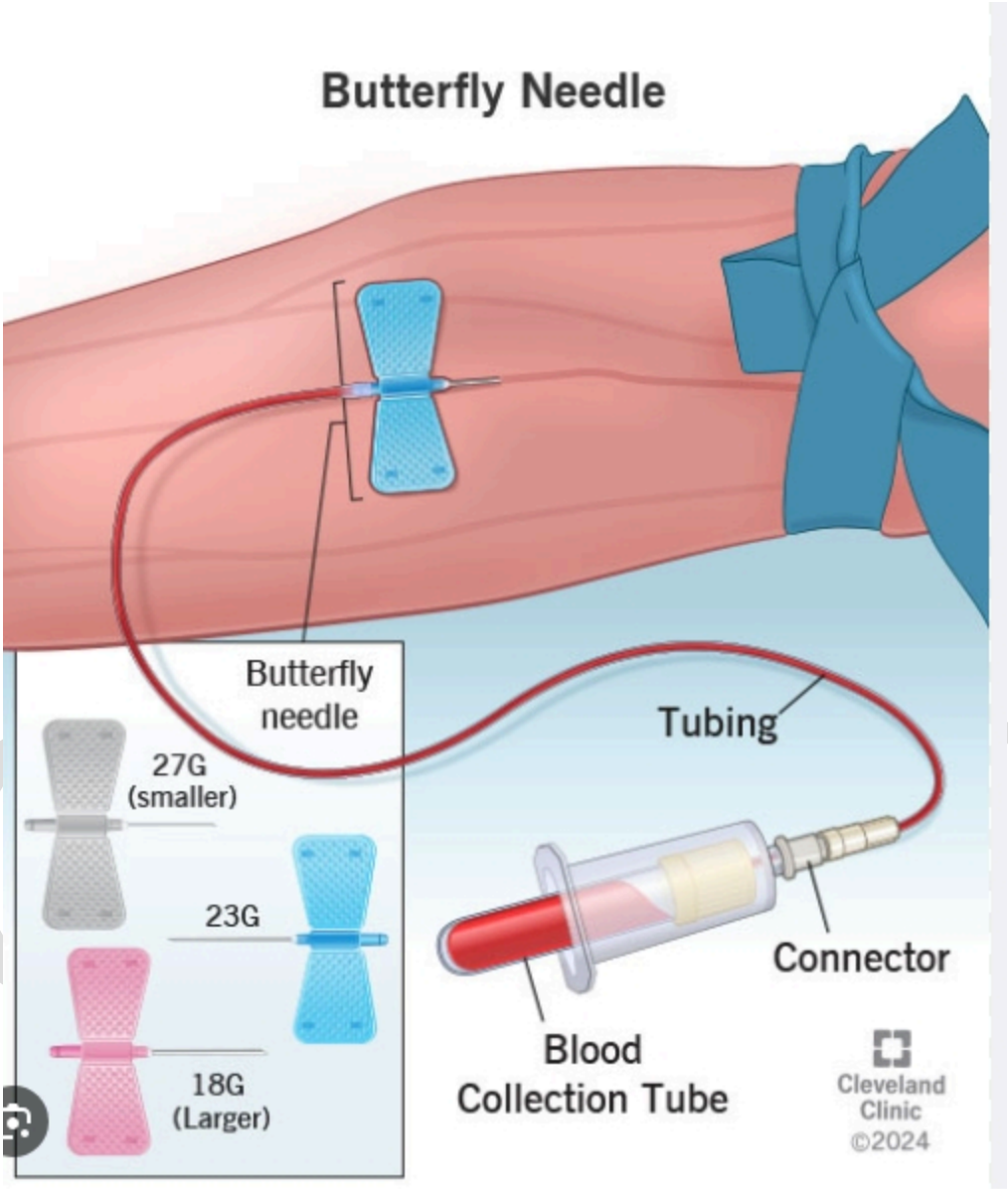

REFERENCES

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Laboratory Services Department	M. Anwar Molani: Medical Director, Laboratory Services	3/1/2026
Laboratory Services Department	Evan Gamad: CLS III	3/1/2026
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COPY

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L.95 Capillary Specimen Collection Heel Puncture

COPY

PRINCIPLE

For infants up to three to six months, a heel puncture is done to obtain capillary blood for testing when blood cannot be obtained from a vein, or when it is not necessary to do so, if a sample of <2.5 ml is required.

The use of finger sticks to collect capillary blood samples is not recommended for neonates. The distance from the skin surface to bone in the thickest portion of the last segment of each finger of newborn infants is minimal and varies with weight. Using a finger may lead to bone penetration and results in injury and infection.

The length and depth of the lancet used for a neonatal heel stick is critical. The distance from the heel skin surface to the calcaneus bone at different places on the heel of infants varies with the size and weight of the infant. The sides of the heel are the preferred sites. (See Diagram p.14) Most blood vessels are located at the dermal subcutaneous junction at a depth of <1.6mm in neonates (not premature).

Equipment

A. The **BD** Quikheel Lancet is a fully automated single use instrument that produces a fine, clean surgical incision for neonate and infant blood sampling. It features an extra thin surgical steel blade which is permanently retractable to minimize possible injury or reuse. The tapered contact surface provides better visibility for the site location. The instant trigger action eliminates the need for safety tabs to prevent blade release.

   The **Quikheel Lancet** for infants assures an incision of uniform depth of 1.0 mm and 2.5 mm in length.

   The **Premie Quikheel Lancet** assures incision of uniform depth of 0.85 mm and a 1.75 mm incision length for premature neonates.

B. Microtainer tubes with EDTA, Lithium Heparin, or clot activator.

PROCEDURE

Sites for Collecting Heel Puncture Blood:

A site on the most medial or most lateral portion of the plantar surface should be selected. See diagram F1 for reference.

Observed the following precautionary measures:

1. **Never perform punctures on the posterior curvature of the heel.**
2. **Never perform punctures on the central area of an infant's heel.**
3. **Avoid any edematous area of site within 2mm of a prior wound,** (accumulated tissue fluid may contaminate the blood specimen).
4. **Never obtain blood from the ear lobe.**

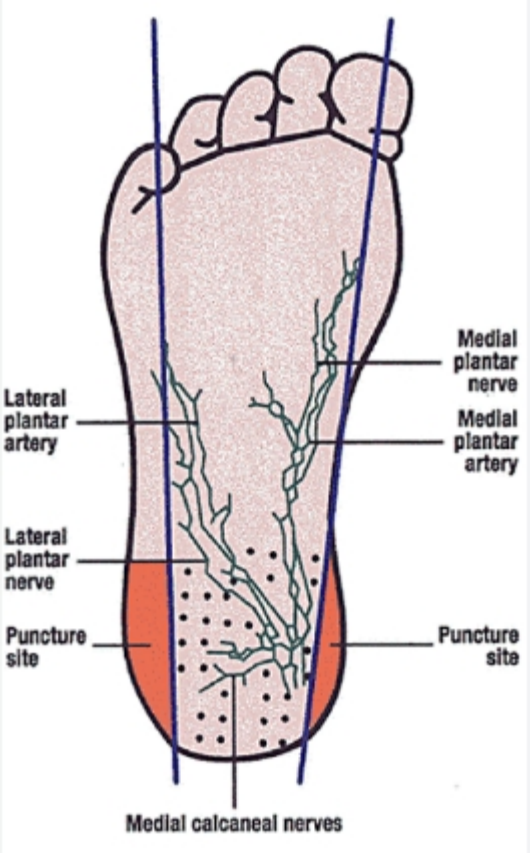

Diagram F1

Heel Puncture Technique:

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1. If necessary, activate a Warm Gel Infant heel warmer, by pinching and rubbing as indicated on the packet. To hold in place, wrap warmer around foot and attach strap to other side. Leave on heel for three minutes. This increases blood flow without burning skin or significantly changing results.
2. Clean puncture site with alcohol. After cleaning, the site must be thoroughly dry before being punctured, since residual alcohol causes rapid hemolysis.
3. Place the Quikheel lancet against the site holding it between your thumb and middle finger with the Quikheel logo facing you. Place the blade slot area securely against the heel at a 90 degree angle to the length of the foot. Using the index finger, firmly and completely depress the trigger.
4. Discard unit into a biohazard sharps container.
5. Wipe away first drop of blood, since it is most likely to contain excess tissue fluid.
6. A rounded drop of blood will form over puncture site, and when tip of a capillary tube touches this drop, blood will flow by capillary action into tube. Care should be taken so that tip of capillary tube is in contact with the blood only, not skin. Do not 'scoop' blood because that can cause hemolysis.
7. Blood flow is enhanced by holding puncture site downward and gently applying continuous pressure to surrounding tissue.
8. Gentle repetitive pressure (milking) should be applied. A strong milking pressure may cause hemolysis or contamination of the specimen with tissue fluid. Hemolysis may also result from residual alcohol on puncture site, or mechanical trauma of pressing or scraping a collection device on skin.
9. After blood collection is complete, elevate the foot above the body, and gently compress site with dry 2x2 gauze until the bleeding has stopped. Use of band aids should be cautioned due to possible skin maceration during removal and possible aspiration by sucking on the band aid.
10. Infection, including cellulitis, perichondritis, osteomyelitis, and abscesses, is the major complication for this procedure.

COPY

REFERENCES

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Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator, VCMC & SPH	3/2/2026
Laboratory Services Department	M. Anwar Molani: Medical Director, Laboratory Services	3/1/2026
Laboratory Services Department	Evan Gamad: CLS III	3/1/2026
Laboratory Services Department	Erlinda Roxas: Director, Laboratory Services	2/28/2026

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Owner	Linda Conboy: Supervisor-Microbiology, Laboratory Services
Policy Area	Laboratory Services - Microbiology
References	, MIC.14583, MIC.10060, MIC.14575

L.MIC.8.0 Quality Control

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PRINCIPLE:

QC programs ensure that information generated by the Microbiology Laboratory is accurate, reliable, and reproducible. This is accomplished by assessing the quality of the specimens; monitoring the performance of test procedures, reagents, media, instruments, and personnel; reviewing test results; and documenting the validity of the test methods.

POLICY:

QUALITY CONTROL PARAMETERS

A. Specimen Collection and Transport

1. Include screening tests (e.g., quantitation of WBCs and squamous epithelial cells in sputum) among the criteria for acceptable specimens.
2. Do not test unacceptable specimens unless it is impossible to re-collect them. When unacceptable specimens must be processed, include a disclaimer in the patient report indicating that the specimen was not acceptable but was processed at the specific request of the physician, whose name has been recorded in the test report.

B. Procedure Manual

1. The CAP requires that laboratories maintain a copy of CLSI document GP2-A4 and that procedures be written in a format largely consistent with those guidelines.

2. Contents of QC Manual: Mechanical Equipment, Specimens, Personnel & Procedures, Patient reports, Media, Stains, Reagents, Disks, Commercial Kits, Stock culture maintenance, Preparation of Inoculum for Testing Media, Water Quality Check (done by Chemistry Dept.).
3. A complete workbook of all laboratory procedures and pertinent Public Health regulations is in appropriate work areas. All new or substantially changed laboratory procedures are to be initially approved and reviewed by the Lab Director, before implementation and thereafter at least every two years by the Microbiology Supervisor, Lab Director or designee. In the event of a change of directorship, the new Director (over a reasonable period of time) ensures that the laboratory procedures are well-documented and under annual review.

C. Personnel

1. Continuing In-Service Education
    a. Microscope slides and projection slides of microorganisms of medical importance are available and all clinical laboratory scientists (CLS) are encouraged to periodically review the slides.
    b. All CLSs are encouraged to attend workshops, seminars, and formal courses and to read journal articles in the field of clinical microbiology.
    c. All CLSs are required to review the Final Critiques of CAP Proficiency Survey results.
2. Document continuing education activities annually. Also needed to re-new California license.
3. Competency assessment and annual evaluation.
    a. Written performance standards.
    b. Document continuing education activities.
    c. Competency assessment requirements and annual review.
    d. Documentation that personnel have read and understand the procedures in Microbiology.
4. Morphological observation and assessment are performed to ensure accuracy and consistency of interpretation.
    a. The quality of smear preparation and staining is reviewed for all microbiology stains for satisfaction by reviewing QC slides and random clinical slides (i.e. Proper smear thickness, free of precipitate, proper cell distribution, appropriate staining reactions, etc.)
    b. Review selected Gram stains to determine training needs and aid in correlating relevant information.
    c. Compare final culture results with gram reports to check for recovery of

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morphologies noted in the gram stain but not recovered in the culture. All CLSs in microbiology are expected to do this review on each culture finalized. Discrepancies should be investigated for errors

5. Annual assessment will be performed using an unknown set of slides with defined staining characteristics, photomicrographs with referee and participant identifications, or digital media .. CLS's that do not meet at least an 80% competency upon slide review of competency will be assigned a 20-slide review to be done with the Microbiology supervisor
6. Proficiency Tests
    a. A minimum of three sets of specimens a year are received from the Survey Program of the College of American Pathologists for Bacteriology, Mycology (yeast only), and Parasitology (blood parasites only). Two sets of specimens are received for Mycobacteriology, India Ink Prep., Blood Culture and Shiga Toxin. The specimens are processed in the same manner as patient specimens. The results are compared and evaluated by the supervisor with the information supplied by the Survey Program. The proficiency test specimens and results are discussed with the staff CLS's and pathologist. Copies of the results are available in the Lab Library for review. Review of Final Critique is also required reading for Competency Assessment.
    b. For tests for which CAP does not require proficiency testing, the laboratory exercises an alternative performance assessment semiannually for determining the reliability of analytic testing by splitting samples to be tested by two CLSs.
    c. The laboratory integrates all proficiency testing samples within the routine laboratory workload and are analyzed by personnel who routinely test patient samples, using the same methods as for patient samples.
7. A Microbiology Section conference is held as needed to discuss problems, potential changes, and other matters of concern to the Microbiology Section. Communication Log is kept notifying staff and co-workers of changes and problems daily.
8. The Supervisor presents an orientation to the philosophy and techniques to all new technical personnel. CLS's and aids are assigned specific duties in the Quality Control program.

D. **QUALITY CONTROL RECORDS**

1. Quality controls are run at least daily or more frequently if specified in manufacturer's instructions, laboratory procedure, or the CAP Checklist, and when changes occur that may impact patient results.
2. An Individualized Quality Control Plan (IQCP) can be implemented to reduce the frequency of quality control as long as the type and frequency of QC defined in the

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plan meets or exceeds minimum QC requirements defined in the CLIA regulations and CAP checklist requirements.

3. All QC results are recorded on appropriate QC logs.
4. Laboratory personnel must evaluate QC for acceptability before patient results are reported.
5. All out of control results will be reported to the Supervisor or designee using corrective action form. Corrective action will be documented on QC log.
6. QC records are to be reviewed at least monthly by the Lab Director or designee.
7. QC records are to be retained for three years.

E. **PATIENT REPORTS**

1. Telephone reports to the requesting physician of the test immediately of any life-threatening situation indicated by test results. Document in LIS when critical results are called. Include who was called, date, time, and whether the results were read back.
2. Preliminary Reports: Report status of test within 24 to 48 hours after receipt of specimen and any updates of results.
3. Final Reports are issued when all identifications and results of antimicrobial susceptibility testing are all completed.
4. Options for detection of errors on patient reports
    a. Review daily the Patient Master Log and document.
    b. Computer flags are used for flagging unusual results.
    c. Where applicable, provide information that is useful for test interpretation (e.g., normal ranges, sensitivity, specificity, precision, linearity, predictive value, accuracy, and test interferences.
5. Patient reports and laboratory records must be retained for at least three years.

F. **INSTRUMENT AND EQUIPMENT PERFORMANCE**

A. Perform preventive maintenance at least as frequently as outlined in QC Activity Schedule for Instruments

B. Mechanical Equipment

1. Thermometers
    a. When taking temperature readings daily, visually check that the liquid column has not separated.
    b. All thermometers must be verified against an NBS-calibrated thermometer before use and thereafter every six months for

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thermometers. With subdivisions of less than or equal to 1° C. Preventative maintenance is performed by Fisher Scientific and records are kept by the Biomedical Engineering Department

2. Incubators
    i. Daily, read and record temperature and check CO2 with Fyrite, if applicable. Refer to Micro 8.9 *Bacharaach Fyrite Gas Analyzers for Measuring CO²*.
    ii. Check that the beaker of water for humidity in the CO2 incubator is filled to 100 ml mark. Refill as needed. Indicate when filled on temperature log
    iii. See Equipment Performance Limits for expected results.
3. Heat Block
    i. Daily, read and record temperature.
    ii. See Equipment Performance Limits for expected results.
4. Refrigerators and Freezers
    i. Daily, read and record temperatures.
    ii. See Equipment Performance Limits for expected results.
5. Anaerobic Incubation Conditions QC
    i. Use methylene blue indicator (BBL Dry Anaerobic Indicator) for testing of anaerobic conditions. A blue color on the test strip/ pill signals that anaerobic conditions were not met, and remedial action must be taken. Anaerobic environment is to be checked daily and documented on daily temperature log.
    ii. Subculture Fusobacterium nucleatum onto a reduced ana-Bru plate and place in anaerobe holding jar prior to beginning anaerobe workup. Incubate either in anaerobe jar to be used or Biobag Type A as biological control for holding jar function.
    iii. Wash jars after each use with soap and water and air dry.
    iv. Check for cracks and integrity of gaskets. Replace as needed.
6. Compressed Gas Cylinders
    i. Daily, check and record pressure of cylinder. Change to new cylinder if pressure goes below 200 lb/square inch. Also check and record pressure of second-stage regulator.

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ii. Record date each fresh cylinder is placed into use.

7. Microscope
    i. The microscope is serviced semi-annually by a professional microscope technician. (*Records are maintained in the Biomed department*)
    ii. After daily use, wipe oil from objective, condenser, and stage with lens paper. Turn off the microscope light source.
    iii. Monthly, or more frequently as needed, clean objective, eye pieces, condenser, and field diaphragm with lens-cleaning fluid. Apply fluid with lens paper. Do not put fluid directly onto the part. Remove slide holder from stage, and clean.
    iv. Ocular micrometer is calibrated when put into service and recalibrated each time the eyepieces or objectives are changed.
8. Pipettors and Calibrated Loop
    i. Calibration checks for MLA pipettors are done annually and documented.
    ii. Calibrated loops are certified by the manufacturer. Retain copy of document for each lot.
9. Biological Safety Cabinet
    i. Daily routine disinfection. While the cabinet is running but before you begin work, wipe down the cabinet surfaces, including the back and side walls, with 70% alcohol. Also, clean glass surface with glass cleaner, front and back.
    ii. Daily, check blower function by listing for the blower and observing that airflow check strips are drawn in toward the workspace of the cabinet.
    iii. Daily, record gauge reading.
    iv. Change absorbents mat each day and as needed.
10. Vitek
    i. Perform daily QC maintenance functions as outlined on record sheet.
    ii. Perform weekly QC maintenance functions as outlined on record sheet.
    iii. Perform monthly QC maintenance functions as outlined on

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record sheet.

11. Virtuo
    i. Daily review of temperature for values outside of 36°C-38°C.
    ii. and weekly printout to be reviewed and signed by microbiology supervisor or designee.
    iii. Record temp in the View under Record Temperature Log.
    iv. Follow Daily Workflow.
12. Cepheid
    i. Daily, clean work area
    ii. Weekly, reboot Software and Computer
    iii. Monthly, archive runs, disinfect bay area, disinfect plunger rods, clean fan filters.
    iv. Yearly, Calibration of GX.
13. Biofire
    i. Daily, clean work area

    Quarterly, archive runs

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G. **MEDIA**

A. Commercially prepared media (exempt from QC by the user) are purchased from reliable manufacturers and logged upon receipt as to the type of medium, commercial source, date of receipt, lot number, and expiration date. In addition, each package is dated upon receipt.
    1. The primary isolation media listed in NCCLS M22-A3, Table 3, are exempt from QC testing by the user (except for Campylobacter media, and media for the selective isolation of pathogenic Neisseria spp., MTM) provided that the manufacturer follows NCCLS criteria for QC. The manufacturer must indicate by label, package insert, technical manual, or other document that the media conform to NCCLS standards. The laboratory must maintain a record of this information.
    2. A record of vendor, lot number, date received, and acceptable QC for all medium shipments must be kept.

B. User- or commercially prepared media requiring QC testing.
    1. Test each new lot number of dehydrated mediums, reagent, or ingredient in parallel with an approved lot before it is released for use. Maintain a record of amount prepared, source, lot number, sterilization method, preparation date, pH, expiration date, and name of preparer.
    2. Check for contamination. Incubate medium for 48 h at the temperature

at which it will be used and then for another 48 h at room temperature.

3. QC organisms should be derived from well-characterized strains.
4. The QC method should conform to NCCLS M22-A3 recommendation.
5. Media requiring QC must be checked for ability to support growth, selectivity and/or inhibition, and biochemical response for each new lot and/or shipment. Results are recorded on Media QC Lot.
6. Storage
    a. Put date of receipt on each package and if QC is needed, place "Not Calibrated" red sticker on package. Refrigerate unless otherwise specified. Thioglycolate broth and pre-reduced anaerobe media are examples of media stored at room temperature. As a rule, media should be protected from light.
    b. All media received are to be visually inspected and checked for:
        I. Cracked Petri plates
        II. Unequal filling of plates
        III. Cracked medium in plates
        IV. Hemolysis (blood agar)
        V. Freezing
        VI. Excessive number of bubbles or pits
        VII. Contamination
    c. An "OK" and the technologist's initials will designate that the media has passed the above visual inspection criteria. Just prior to use, media is to be inspected to ensure the visual inspection criteria is still met. If, at any time, the media should fail to meet the visual inspection criteria, the date, the type of media, the lot number, expiration date, and the date of receipt is recorded onto the Unusable Media Log, removed from use, and the supplier notified.

H. **STAINS and REAGENTS**

A. Stains

1. Quality control of gram stain reagents is performed for intended reactivity and recorded for each new batch or lot, and shipment of stains and at least weekly against known gram-positive and gram-negative QC organisms.
2. All stains being used are to be used within their stated expiration date.

B. Reagents

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1. Positive and negative controls are tested as per manufacturer, and results recorded for each new batch, lot number, and shipment of reagents, disks/strips, and stains
2. The chemicals purchased are of approved quality and all bottles are dated upon receipt. The material, date received, and expiration date are recorded in the Reagent QC Log as needed for QC. The chemicals are stored according to the product insert.
3. Some chemical reagents are prepared in the laboratory and others are purchased ready for use. For those reagents that are prepared in the laboratory, the date of preparation and the name of the preparer are recorded in the Reagent QC Log.
4. All reagents are performance-tested in the same manner as patient specimens for correct reactions before use on patient specimens. All results of controls must be verified for acceptability before reporting patient results. Chemical reagents are retested according to their QC schedule. The results are kept in the Reagent QC Log.
5. All reagents being used are to be used within their stated expiration date.

C. Disks

1. All disks are obtained from reputable manufacturers and stored with desiccant. Antimicrobial susceptibility testing disks are stored at -20°C or lower and other disks are stored in the refrigerator at 2-8° C.
2. The disks are tested on a lot number basis before use on clinical specimens. The antimicrobial susceptibility disks for Kirby-Bauer method are retested at weekly intervals after passing the initial validation procedure. The results are recorded in the Kirby-Bauer QC Log. Other disks are tested weekly, each new lot, or whichever is applicable. Refer to Micro 9.3 *Antimicrobial Disk Diffusion Susceptibility Testing, Quality Control.*
3. All disks being used are to be used within their stated expiration date

D. Identification System QC

1. Appropriate positive and negative control organisms are tested, and biochemical results recorded for each new lot and shipment of reagents used in bacterial identification systems. Refer to Micro 10.1 *Vitek® Identification Systems.*
2. Results are recorded and maintained in the VITEK QC LOG

I. **COMMERCIAL KITS**

A. For all **WAIVED and Non WAIVED** tests, QC is performed with each new lot and/or shipment according to the manufacturer's instructions before testing on patient

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specimens. If there are multiple components of a reagent kit, the laboratory uses components of reagent kits only within the kit lot, unless otherwise specified by the manufacturer.

B. New reagent lots and/or shipments are checked against old reagent lots or with suitable reference material before being placed in service and results are documented.

C. Minimum crosschecking includes testing at least one known positive and one known negative sample with the new reagent lot or shipment. It is preferable to do these validations with patient samples that have been tested previously or can be tested simultaneously with the old reagent lot. Although patient specimens are preferred, it is acceptable to use external quality control materials to check new reagent lots or shipments if the quality control material has been previously verified and exhibits no matrix effects.

D. Internal controls must be documented, at a minimum, once per day of patient testing.

E. Testing personnel or supervisory staff must review quality control on days when

F. Evidence of compliance includes this written procedure and records of verification for each device.

G. controls are run prior to reporting patient results of reagent/shipments.

J. **STOCK CULTURE MAINTENANCE**

A. Refer to Micro 8.5 *Stock Culture Maintenance*

K. **PREPARATION OF INOCULUM FOR TESTING MEDIA**

A. There are two types of inocula. One is used to test the growth supportive characteristics of the medium, the other tests the inhibitory characteristics of a selective medium. See Micro 8.3 *Quality Control Testing for Primary Culture Media*.

L. **WATER QUALITY CHECK**

A. Specimen to be collected by Chemistry Department monthly.

B. *Refer to Chemistry Manual Policy 9.4 Water Quality for Procedure and reporting form*

C. Total bacterial counts are done monthly, and results entered on Chemistry form developed for this purpose.

REFERENCES:

- Balows, Albert, Practical Quality Procedures for the Clinical Microbiology Laboratory,Cumitech 3, ASM, Washington, D.C., September 1976, pages 4-5.
- Isenberg, Henry et al, CMPH, 2nd edition, Vol. 3, ASM, Washington, D.C., 2004, section 14.
- CAP Microbiology CheckList, Revised 09/27/2007.
- CAP Microbiology CheckList, Revised 04/21/2014, MIC.10060; MIC. 14575; MIC.14583

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3/3/2026

Attachments

REF SUPPLIES TO BE TAGGED.XLS

Approval Signatures

Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator, VCMC & SPH	3/3/2026
Policy Owner	Erlinda Roxas: Director, Laboratory Services	3/3/2026
Policy Owner	M. Anwar Molani: Medical Director, Laboratory Services	3/2/2026
Policy Owner	Linda Conboy: Supervisor-Microbiology, Laboratory Services	3/2/2026

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L.108 Malaria (Parasite) Smears

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MALARIA (PARASITE) SMEARS

PRINCIPLE:

During some stages in their life cycle, there are blood parasites that are detectable in human blood. Species identification of all blood parasites are usually made from a thin film slide, a thick film slide, or both. The films can be made from whole or anticoagulated blood. All requests for malaria must be handled on a STAT basis since the disease can escalate rapidly.

PROCEDURE:

Blood for detecting parasites may be obtained by either finger stick or venipuncture. Blood samples for malaria are preferably collected without anticoagulants. However, EDTA is recommended by most parasitologists for use with malaria parasites if whole, anticoagulated blood is used, and films for reliable staining of malaria parasites should be made immediately, or within one hour of collection. The specimen should be kept at room temperature.

Malaria Smear is the test to order a malaria smear in Laboratory Information System.

Preparation of blood films:

Blood films for parasites should be made on clean, standard glass microscope slides. All slides, even new "precleaned" slides, should be dipped in alcohol and polished with a lint free towel or Kim wipe to remove any grease or dirt before the films are made.

Thin Film: The thin film is identical to a slide prepared for a differential. Since it can be stained quickly, it may allow a quick diagnosis if a patient has a high degree of parasitemia.

Thick Film: The thick film is recommended for the routine detection of most parasites. The rbc's are lysed during the staining process so only the parasites, platelets and wbc's remain.

1. Place a drop of blood on the center of a cleaned glass slide about 1/2 inch from the end.
2. Using either the corner of another cleaned glass slide, or an applicator stick, spread the blood into a circle about the size of a dime.
3. Allow the film to air dry in a horizontal position, protected from dust for several hours (6-8 hours). Do not attempt to speed the drying process by applying any type of heat, because heat will fix the rbc's, and they will not lyse in the staining process.
4. Caution: If the smears are prepared from anticoagulated blood that is more than one hour old, morphology of the parasites may not be typical, and the film may wash off the slide during the staining process.
5. Call VCMC to alert microbiology that there is an order for a malaria smear, so that the special reagents may be prepared by the time the specimen reaches the department.

SEND BLOOD FILMS TO VCMC STAT

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REFERENCES

Microbiology procedure "Blood Parasite Detection" procedure, prepared by Laura Whyte, effective 07/13/09.

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Hospital Administration	Jason Arimura: Associate Hospital Administrator, VCMC & SPH	2/26/2026
Laboratory Services Department	Erlinda Roxas: Director, Laboratory Services	2/26/2026

Laboratory Services Department	M. Anwar Molani: Medical Director, Laboratory Services	2/25/2026
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VENTURA COUNTY HEALTH CARE AGENCY

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Policy Area	Laboratory Services

L.68 Phlebotomist Responsibilities: General

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POLICY

PRIMARY RESPONSIBILITIES OF THE PHLEBOTOMIST:

1. Phlebotomy should be performed according to the status of the order (routine, timed draws, and stats) for adult, pediatric and neonatal patients as in-patients and as out-patients, using proper identification and labeling procedures while maintaining a professional demeanor at all times. It is the responsibility of each phlebotomist to wear the hospital identification badge at all times and to wear personal protective equipment including gloves, a lab coat, and masks or eye goggles when necessary and to use the protective devices for phlebotomy correctly. Lab coats must not be worn outside of clinical areas.
2. Each phlebotomist on all shifts is required to sign out for a cell phone, so he or she may be reached on the floors when out of the lab. Each phlebotomist is expected to carry the phone during that shift at all times. Each phlebotomist must also be responsible for returning the phone and signing it in.
3. Since most of the wings of the hospital have security doors, each phlebotomist is assigned an electronic key that they are responsible for.
4. For the day shift and for the evening shift, each phlebotomist working is assigned to cover an "area" of special responsibility, including the ff:
    A. Drawing Room
    B. Emergency Room
    C. Floors: Stats and Timed Draws

D. Floors: Routines and Nursery

E. Float: Psych, Drawing Room and Floors.

F. Day Clinics: AFMCUC, Immunology and Hematology

5. The assignments only define what the major responsibility for each phlebotomist is. Overlapping tasks and helping each other are very important parts of how teamwork should evolve. Please refer to the.AM Phlebotomy Assignment Sheet posted at the entrance in the office.
6. For the graveyard shift, the phlebotomist must prioritize draws according to the status of the order. When the phlebotomist is away from the lab, the technical staff must be made aware that they will be responsible for answering the phones and watching for the flashing ceiling light that indicates a specimen is in the pneumatic tube system. The bell that beeps when a specimen is in the tube system is not audible in the laboratory, only in the office.
7. A **STAT** order should be collected within 20 minutes of the submission of the order in the Laboratory Information System. An **Urgent** order is consider as STAT. A **Routine** order should be collected as soon as possible depending on the priorities of the STAT, Urgent and Time draws.

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REFERENCES

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Hospital Administration	Jason Arimura: Associate Hospital Administrator, VCMC & SPH	3/2/2026
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Laboratory Services Department	M. Anwar Molani: Medical Director, Laboratory Services	2/25/2026
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Owner	Evan Gamad: CLS III
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L.69 Trauma Response

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POLICY

TRAUMA RESPONSE

Beginning July1, 2007 a three tier Trauma System will be used to alert responders to a code yellow in the ER.

In this system, a "TIER I trauma" will indicate a high probability that the trauma patient will require immediate surgical intervention, and the trauma team along with blood products for emergency transfusion will be in place in advance of the patient's arrival in the ER. If the trauma code is TIER 2 or TIER 3, the trauma patient's condition is not anticipated to be as critical as in a TIER I, so the laboratory will respond to ER as usual.

When a "Code Yellow TIER 1" is paged overhead, the Blood Bank Tech will immediately prepare an ice chest with 2 units of type 0 Negative packed cells or Whole Blood, along with the emergency blood release form. The ice chest will be delivered immediately to the ER and given to the charge nurse. The Charge Nurse will sign the Emergency Blood Issue form on the "Issued to" line and will fill in as much information as possible in the patient identification box. If the blood is transfused, this form must be signed by the physician within 24 hours and returned to the Blood Bank.

AM SHIFT:

When a Code Yellow TIER 1 is announced, one of the techs assigned to blood bank will immediately prepare the ice chest with 2 units emergency release type 0 Negative packed cells. The ice chest will be delivered to the charge nurse in the ER by the Blood Bank Tech, Lab Asst, or Phlebotomist depending on staffing, availability and daily assignments. There is an electronic access key to enter ER in the Blood Bank to be used only for trauma responders.

PM SHIFT:

When a Code Yellow TIER 1 is announced a phlebotomist will respond directly to the ER. The second phlebotomist will report to the blood bank and pick up the ice chest with the emergency release blood which has been prepared by the blood bank tech. This phlebotomist will deliver the ice chest to the charge nurse in ER who will sign the release form. This form must be returned to the blood bank. In case the second phlebotomist is unavailable to respond, a Lab Aide or CLS will deliver the ice chest to the ER Charge Nurse.

GRAVE SHIFT:

When the Code Yellow Tier 1 is paged, the blood bank CLS will prepare the emergency release blood as above. Response to the ER will have to be flexible depending upon staffing. When two phlebotomists are on duty, one will respond to ER and the other will report to Blood Bank to pick up the ice chest with the emergency release blood.

In cases where there is no second phlebotomist available, the non-blood bank tech could deliver the blood to ER. In cases where this tech leaving the lab could jeopardize patient care, the blood bank tech should call ER and tell the charge nurse that there is no available staffing to deliver the blood and ask if someone from ER could pick it up.

RETURN OF UNUSED BLOOD TO THE BLOOD BANK:

After 30 minutes the ER will be called regarding return of unused emergency released blood. The Trauma Surgeon must give the approval to return the unused blood. The blood bank tech or designee will call to inquire about the return of unused blood. The released unused blood may be returned to the lab by a member of ER staff, OR picked up by the phlebotomist when available.

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REFERENCE

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Hospital Administration	Jason Arimura: Associate Hospital Administrator, VCMC & SPH	3/2/2026
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Policy Area	Laboratory Services

L.70 Orientation Checklist

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POLICY

Every phlebotomist in California must obtain a certificate issued by Laboratory Field Services (LFS) in one of the three new categories defined in the new Statutes and Regulations effective 4/9/03 by 1/1/07. See Phlebotomy Program Overview p.1.24.7.

During that interval, the phlebotomists newly hired will have to have either over six months experience or a Certified Phlebotomy Technician 1 Certificate (CPT 1: capillary and venipuncture's) issued by the State.

Since the errors that can occur during the collection and handling of blood specimens range from improper patient identification, inaccurate identification of specimens, the use of incorrect anticoagulants, the formation of hematomas, and hemconcentration, standards for venipuncture can reduce or alleviate many of these errors .

To ensure a high standard for specimen collection, each newly hired phlebotomist must be oriented and checked off by an experienced VCMC phlebotomist using the Training Check List that begins on the following page.

REFERENCES

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Attachments

Phleb 2.4 PHLEBOTOMIST ORIENTATION CHECK-LIST.DOC

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L.71 Phlebotomy Competency Assessment

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PROCEDURE

PHLEBOTOMY COMPETENCY ASSESSMENT:

The employment annual review will consist of 1) a written performance appraisal and interview, and 2) a competency assessment that is completed by the employee's immediate supervisor. Age specific competency will be evaluated where applicable.

The Competency Assessment for Phlebotomy form that follows, provides the analysis of performance based on several areas:

1. Direct Observation:

   The supervisor directly observes routine test performance, including as applicable, patient identification and preparation.

2. Monitoring:

   Proper labeling, specimen collection requirement-use of resources (QUEST)

3. Review of documentation of cancel Specimens.
4. Direct observation of timeliness of stats and time draws.
5. Assessment of completing the assignment.
6. Evaluation of problem – solving skills, and communication with Supervisor.
7. In-Service:

   Phlebotomists increase the basis of knowledge in phlebotomy, i.e. new

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equipment, or new techniques, through completing of on line CEU's, Media Labs, or direct observation.

8. Notifications: When an error is made, it is written up on the "Internal Laboratory Notification form" The supervisor discusses the specific details with the Phlebotomist involved. The phlebotomist must demonstrate a change in Behavior or further verbal counseling or written reprimand will follow.

After completing the Orientation Check Lists, competency of Full Time and Per Diem phlebotomists will be evaluated at six months of employment and annually thereafter.

The Competency Assessment is a tool to ensure that persons performing the same task are conforming to the standards and procedures established by Ventura County Medical Center laboratory and it's licensing agencies.

REFERENCES

COPY

All Revision Dates

3/2/2026

Attachments

Phleb 2.6 Phlebotomy Competency 032013.pdf

Phleb Phlebotomy Competency Santa Paula Hospital 032013.pdf

Approval Signatures

Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator, VCMC & SPH	3/2/2026
Laboratory Services Department	Erlinda Roxas: Director, Laboratory Services	2/28/2026
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L.72 Phlebotomy Supply and Ordering

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POLICY

SUPPLY ORDERING

Weekly orders are placed with Medline directly through Central Supply at VCMC. These products are listed on the order forms that follow.

The order is usually placed every Mondays by 1100, faxed to 652-6182, to the attention of the Central Purchasing Specialist. Telephone inquiries may be made by calling 6247. The order arrives the following day. If a problem arises after the Monday order is placed, another order may be submitted without a problem.

Fisher orders are usually placed every Thursday via the Fisher website by the General Laboratory Supervisor at www.new.fishersci.com. The applicable order sheet follows. The order arrives the following Monday unless there is a holiday. Then the order is delivered on Tuesday.

REFERENCES

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Hospital Administration	Jason Arimura: Associate Hospital Administrator, VCMC & SPH	3/2/2026
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L.73 Patient Identification

PROCEDURE:

PATIENT IDENTIFICATION:

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1. **Identify yourself:**

"Good morning (afternoon, evening), I'm from the laboratory, and 1 am here to collect a blood specimen for some tests your doctor ordered."

Stress the words, "your doctor ordered." This emphasizes the procedure's importance and its necessity to the patient's care.

The phlebotomist must not perform blood collection against the patient's or guardian's consent. In that event, report the patient's objections to the physician/nurse station.

2. **Identify the patient:**

Identification of the patient is crucial. The phlebotomist must ensure that the blood specimen is being drawn from the individual designated on the request form or label. The phlebotomist must not rely on a bed tag, or on charts or records placed on the bed or nearby tables, or equipment. Two patient identifiers are required for patient identification.

Patient Who is Conscious:

Outpatient:

Ask for *Full Name* and *Date of Birth.*

"What is your FULL name?" In Spanish - "Como se llama?"
Verify with Lab Labels

Inpatient/ Emergency Room:

Ask patient for his/her *Full Name* and check the *patient name band.* The date of birth may be used as a further check.

Do not say, "Are you Mr. Jones?"

Patient MUST BE wearing the patient identification band.

Check Lab Labels to verify name and medical record number with Patient ID band.

Patient Who Is Semiconscious, Comatose, or Sleeping:

The phlebotomist must take special care when drawing blood from semi-conscious, comatose, or sleeping patients to anticipate any unexpected movements or jerks either while introducing the needle, or while it is in place in the arm. Sleeping patients should be awakened before drawing blood. A gauze pad should be readily available and the tourniquet quickly released in the event the needle is violently removed or repositioned. If the needle accidentally goes much deeper into the arm, the phlebotomist must inform the physician/nurse station. If unable to identify the patient, then contact the nurse or physician.

Patient Who Is Unconscious, Too Young, Mentally Incompetent, or Does Not Speak the Language of the Phlebotomist:

Ask nurse, a relative, or friend to identify the patient by name, address, identification number, or date of birth. If unable to identify the Patient, then contact the nurse or physician. Compare these data with the information on the request form and the patient's identification wristband, which must be attached to the patient. Report any discrepancy, however minor, to the nurse or physician. Have the patient identified by name and Identification number before drawing any specimen.

If the patient doesn't speak English, try to find an interpreter. If no one can be found in the immediate area, page the nursing supervisor. She has a list of languages available in the employee pool. There is also a Language Identification Card in the Office Policy and Procedure manual that contains all of the Languages available through Language Line Services 1-800-874-9426.

Procedure for Identifying Unidentified Emergency Patients:

The patient must be positively identified when the blood specimen is collected. When a fictitious name is assigned to a patient usingthe STAT Registration Policy (see Administrative Policy 100.063 STAT Patient Registration), his/her sample will be used for testing, Cross matching, issuing and transfusing until he/she is stable. At that time a new sample will be obtained and tested using the proper name.

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REFERENCE

1.

GEN.40490	Patient Identification, College of American Pathologist Accredation Checklist, December 2025	

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Hospital Administration	Jason Arimura: Associate Hospital Administrator, VCMC & SPH	3/2/2026
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L.74 Patient Interactions: Age Specific/Special Considerations

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POLICY:

AGE SPECIFIC/SPECIAL CONSIDERATIONS:

Certain issues need to be considered with infants, toddlers, teenagers, adults and the elderly:

1. What are his/her fears and specific concerns?
2. What types of behavior should be expected from this patient?
3. How can communication be better?
4. How can the patient be made more comfortable?
5. What will make the patient feel safer?
6. Does the patient have special needs, i.e. hearing problems, a wheel chair or restraints?

When in-patients have wrist restraints, phlebotomists must be careful not to interfere. A wrist restraint may be removed only to perform a venipuncture, and then reapplied. Any unusual event should be reported to the nurse. Side rails are considered restraints. Leave down if found in the down position when entering room. Return to locked position if found up.

Infants and Children:

Infants and children are not small adults; this is important to remember in obtaining specimens and doing procedures on an infant or child. These procedures are particularly difficult for young children whose verbal skills are not completely developed. Because children frequently develop conditioned anxiety responses, it is important to minimize the impact of painful procedures.

The age of the patient will impact where the procedure is performed. Usually, for patients that are less than three months old, a heel stick is recommended unless large quantities of blood are required. A heel or finger stick can be done with the patient on the parent's lap. A child should always be told exactly what is going to happen; however, if a child begins to cry and become difficult to manage without listening to what the procedure is going to entail, trying to allay their fears will probably not be effective. At that time it is best to get the help needed and complete the procedure.

The parent(s) should be involved as much as possible. First, they will understand the procedure and what the child will be going through. Secondly, it will help minimize any fears they have and reduce any anxiety communicated to the child.

Refer to chart "Age-Specific Considerations and Competencies for Phlebotomists."

The Elderly:

The chronically ill patient requires an extraordinary sensitivity on the part of the phlebotomist. A profoundly multiply handicapped child or an elderly adult may not be able to communicate, but still may be able to hear and therefore be sensitive to comments or nonverbal gestures.

Elderly patients may arrive with fears of being unable to read, have difficulty hearing properly or understanding directions. They may fear the pain of a procedure, or even the expense of the visit. They may be in frail health and have trouble moving from the waiting room to a treatment room. They may have tremors and have difficulty holding still during a venipuncture procedure. They may be relieved to get some assistance holding their arm.

It is important for phlebotomists to be aware of physical or emotional needs that each individual patient may have. Elderly patients may not be able to see well, or may be unfamiliar with sign-in procedures or fasting requirements. A reassuring and gentle approach is helpful in calming fears. Helping to obtain a necessary wheel chair can make a patient feel very cared for.

It is important to use minimum amounts of blood for testing. When skin is fragile and veins are small, a 23 gauge, or even a 25 gauge needle, should be used. Band-Aids should not be left on longer than twenty minutes to avoid irritating sensitive skin.

When geriatric in-patients have vests or wrist, phlebotomists must be careful not to interfere. A wrist restraint may be remove only to perform a venipuncture, and then reapplied. Any unusual event should be reported to the nurse. Side rails are considered restraints. Leave down if found in the down position when entering room. Return to locked position if found up.

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Hospital Administration	Jason Arimura: Associate Hospital Administrator, VCMC & SPH	3/2/2026
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L.75 Patient Interaction

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PROCEDURE

OTHER PATIENT: PHLEBOTOMIST INTERACTIONS:

Bathroom or Shower: Return later. Let the nursing station know the status.

Combative Patient: If you feel unsafe, remove yourself from the area. Notify Nurse or physician about situation.

Inquiry: If the patient inquires about the tests, it is best to tell them to ask the doctor. the patient has the right to know and the question should be answered in the context of the complete history.

Missed Draw: Notify patient of unsuccessful draw. Limit to two attempts only. Notify Central Processing Coordinator to reassign draw to another Certified Phlebotomy Technician. Document in Laboratory Information System.

Refusal: Do not argue with the patient. Report the objection to the nurse and document the refusal in the computer.

Request for Services: Do not give the patient any water, etc. unless you have checked with the nurse. Leave bedside rail in the position it was in when entering the room.

Standing Patient: Request the patient to sit or lie down. Do not draw a patient who is standing. This prevents the potential of injury if patient falls.

Visitors: May be asked to leave the room, especially if there is some difficulty with the draw or the patient's behavior is expected.

POSSIBLE COLLECTION COMPLICATIONS:

Collapsed veins:

Reduce pull (suction) on vein.

Continued bleeding:

1. The phlebotomist should watch for excessive bleeding.
2. If a hematoma develops or bleeding persists longer than five minutes, a nurse should be alerted so that the attending physician can be notified.
3. Ask patient about anti-coagulants.
4. Pressure, applied with a gauze pad, must continue at the site as long as necessary to stop the bleeding.
5. Wrap a gauze bandage tightly around the arm to keep the pad in place and tell the patient to leave the bandage on the site for at least 15 minutes.

Convulsions:

1. Without restraining the patient completely, prevent self-injury.
2. Lay patient down and call pathologist, nurse or ER physician immediately.

Fainting (Syncope):

1. Stop the procedure - remove tourniquet and needle from patient's arm.
2. Have other staff notify the pathologist.
3. If the patient is sitting, lower head and arms. Loosen tight clothing.
4. Break Ammonia Inhalant. Place near, not directly under, patient's nose. The patient will respond by coughing.
5. Apply cold compresses to the forehead and the back of the neck, if necessary.
6. If the patient doesn't respond, notify a physician.
7. Outpatient — Offer water or orange juice. Make certain the recovery is complete before release. This should be at least 15 minutes.
8. Fill out the Phlebotomy Adverse Effects Log.
9. Inpatient - notify the nurse in charge of the patient of the problem

Hematoma:

To prevent a hematoma when performing a venipuncture:

1. The phlebotomist should make sure that the needle fully penetrates the uppermost wall of the

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vein (partial penetration may allow blood to leak into the soft tissue surrounding the vein) without going through the vein.

2. Remove the tourniquet before removing the needle.
3. Use the major superficial veins.
4. Apply appropriate pressure to site after needle removal.

Nausea:

1. Make patient as comfortable as possible.
2. Instruct the patient to breathe deeply and slowly.
3. Apply cold compresses to the patient's forehead.

Respiratory or Cardiac Emergency:

1. Dial 6666 and report "Code Blue Laboratory."
2. See following Chart for more specific instructions that is on the wall in phlebotomy.

Vomiting:

1. Give the patient an emesis basin or carton.
2. Have tissues ready.
3. Give the patient water to rinse out his/her mouth.

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REFERENCES

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Hospital Administration	Jason Arimura: Associate Hospital Administrator, VCMC & SPH	3/2/2026
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L.76 Minimum Volumes for Nursery Draw

PRINCIPLE

Whenever an infant is drawn for multiple tests, it is advisable to contact the laboratory to see what the minimum specimen requirement would be. Cutting down a test means to reduce the amount of sample drawn to a lesser volume.

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The amount may vary due to several factors:

What is the least amount required to perform the test once, without repeating?

1. What is the least amount required in the original tube? in a micro tube?
2. Will a repeat or check of the results be necessary?
3. Can the test be done using an alternate method that requires fewer samples?
4. What is the reason for reducing the volume drawn? Patient, parent or physician request? Difficult or extremely difficult draw?

There are reasons that an order shouldn't be cut down:

1. Some tube volumes have strict filling guidelines. I.e. prothrombin, ptt
2. A short draw brings potential problems:

   Longer processing time.

   Longer testing time.

   Less accurate results.

   Elimination of rechecks.

   Increased error possible.

   Additional inquiry at all levels of collection, processing and testing.

   Delayed results.

   No stored serum available for additional testing.

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Removal of large volumes of blood on small patients can result in:

Iatrogenic anemia

Nosocomial infection

Complications of cardiac arrest if greater than 10% of the total blood volume is removed at one time.

Situations vary Newborns, for example, usually have very high Hematocrits. There is very little serum to perform the test. Whereas, preemies may be very anemic, and the same amount of blood drawn would generate much more plasma for the test. The chart following demonstrates quantities necessary for the average full term newborn.

MINIMUM VOLUMES FOR COMMON LABORATORY TESTS
NEWBORNS AND DIFFICULT DRAWS

Lab Test	Minimum Volume	Tube
1.Bilirubin, Total and Direct	600 line	green top microtainer
2. Blood Culture	0.5 - 4.0 ml aerobic bottle	Draw anaerobic if anaerobe suspected
3. BUN (ordered by itself)	600 line	Green top microtainer
4. Calcium (ordered by itself)	600 line	Green top microtainer
5. CBC Diff	500 line	Lavender top -mix well
6. C Reactive Protein	600 line	Green top microtainer
7. Creatinine (ordered by itself)	600 line	Green top microtainer
8. Electrolytes	600 line	Green top microtainer
9. Gentamycin Trough, Peak	600 line	Green top microtainer
10. Magnesium (ordered by itself)	600 line	'Green top microtainer
11.Neonatal Chem PanelIncludes: Electrolytes, Ca, Phos, ALK Phos,	600 line	Green top microtainer
12. Neonatal TPN Panel Includes Electrolytes, Creatninie, Ca, Phos, ALK Phos, T. Bill, Triglyc, Albumin	Two - 600 line	Green top microtainer
13. Phenobarbital Level (ordered by itself)	600 line	Green top microtainer
14.Prothrombin Time	1.8 Whole Blood (Venipuncture only)	Small blue top tube — citrate
15.Theophylline Level (ordered by itself)	600 line	Green top microtainer

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Lab Test	Minimum Volume	Tube
16.Urine Drug Screen	10 mi. Minimum -- 20 ml.	Sealed urine container
17. Complete metabolic Panel	600 Line X2	2 Green top micro containers.

REFERENCES

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Hospital Administration	Jason Arimura: Associate Hospital Administrator, VCMC & SPH	3/2/2026
Laboratory Services Department	Erlinda Roxas: Director, Laboratory Services	2/28/2026
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L.80 Specimen Labeling Requirements: General

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PROCEDURE

I. GENERAL INFORMATION

A. Most laboratory draws are generated by the computer/barcode labels used by the phlebotomists. However, when a nurse draws a specimen, a LIS label with a non-lab bar code that is encoded with patient information may have to be used until the lab computer/barcode labels are placed on the tube by the CLS. The specimen should only be drawn **after identifying the patient** according to the protocols in the procedure "*Patient Interactions: Patient Identification*" in the Specimen Collection Procedure Manual.

1. Tubes should be labeled AFTER the specimen has been collected.
2. Do not label an empty tube before drawing the patient.
3. Complete labeling at the patient's bed/chair side.
4. Do not re-label specimens.
5. If the patient is drawn using an incorrect Medical Record Number, the results cannot be transferred to the correct Medical Record Number. The patient needs to be redrawn because of improper patient identification.

B. The sample should be drawn from a fresh venipuncture site. If intravenous tubing is used, see procedure *"Intravenous Lines"* in the Specimen Collection Procedure Manual.

II. Hematology, Chemistry, Immunology, Serology, Send outs

A. **The person that draws the blood should place the lab computer label(s) or the non-lab barcode label(s) on the tube at the patient bedside/chair side.** The completed labels must include:

1. Patient's name: last, first
2. Hospital/Chart Number
3. Collection date/time
4. Legible LIS ID of the phlebotomist or nurse that drew the blood. If a nurse drawing the specimen is accompanied by a phlebotomist, the LIS ID of both individuals should be on the label.

B. **Phlebotomists: Attach a completed computer label(s) to the tube(s) at the bedside/chair side.**

1. Place the label length wise on the tube with the left edge of the label near the top of the tube.
2. For the analyzers to read the barcode properly:
   a. The Chemistry barcode labels should be placed so that the top of the label is in the area of the top of the permanent colored strip on the tube.
   b. The Hematology barcode labels should be placed close to the bottom of the cap.
   c. For urine tests, body fluids, and sedimentation rates, place a small label on the specimen and send the barcode label with the specimen to the department.

C. **Nurses:** If no orders are placed in the computer at the time of the draw, attach a printed LIS label with a non-lab bar code that is encoded with patient information on the tube. The LIS ID and the date and time of the draw must be written on the tube.

If orders have been placed in the computer, a lab bar code will print out, the LIS ID, date and time of draw should be handwritten on the tube.

III. Blood Bank Specimens – Identification, Labeling and Rejection

See Blood Bank – 1.10 procedure

REFERENCES

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Hospital Administration	Jason Arimura: Associate Hospital Administrator, VCMC & SPH	3/2/2026
Laboratory Services Department	Erlinda Roxas: Director, Laboratory Services	2/28/2026
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L.85 Send Out Tests

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PROCEDURE

SEND OUT TESTS:

Since the complexity and sophistication of the tests available at a reference laboratory increases weekly, it may be difficult to ensure the accuracy of the order. Often the physician has to be contacted to clarify what test he/she is ordering. Since the specimen requirements are also very specific, the office staff and phlebotomy staff are a very important part of Send Out Testing.

The Laboratory Information System (**LIS**) is interfaced with the computer reporting system of **Quest.** Laboratories. This interface offers the following advantages:

1. specificity of test name and number
2. accuracy of specimen type, and
3. availability of results in the Laboratory Information System.

The Send Out Test Dictionary in **LIS** represents approximately 90% of the tests available. This has made the ordering and reporting of these tests much more structured. The person ordering can search the list of choices in the computer: the list is alphabetic by test name.

When a Send out is ordered that is included in the Test Dictionary, an accession number is generated. When the label is printed, the “state” of the specimen is included at the bottom right hand corner of the label.

FZ - Send outs on the interface that must be **FROZEN.**

RF - Send outs on the interface that must be **REFRIGERATED.**

RM - Send outs on the interface that may/must be **ROOM TEMP.**

When the label is printed, the type of specimen that is required is printed on the label. If two labels print with the type of tube on the label that indicates that two tubes are required by the lab that is going to perform the test. By using the Transfer Specimen function in the **LIS,** the lists of tests are printed and sent to Quest with the Courier pickup. Monday through Friday, there are two pickups daily. Saturday and Sunday there is one pickup.

When the test is performed, results are interfaced to the **LIS** and are automatically verified. The

result is available in the LIS as efficiently as those tests performed in-house.

The Miscellaneous Send out test requires that the MOAII who is ordering the test in the computer checks for the exact name of the test and/or the specimen requirement. For inpatients, the chart is often difficult to read, and the lab or doctor must be contacted for clarification. When the test is entered in the Comment screen, the specimen requirements are not automatically available. The phlebotomist may also check in the Quest Laboratory Test Directory, or on the on-line modem -connected computer to Quest. The diligence of the MOAII or phlebotomist may ensure that the patient does not have to return and be redrawn.

For very complex miscellaneous send outs, the MOA and phlebotomist are encouraged to contact a supervisor, the staff in the Send Out Department, or the Chemistry supervisor. Often there are patient histories required to accompany the specimen. Examples are: West Nile Virus and Enterovirus, C. botulinum Toxin, and BRACA Analysis. The forms required must be filled out by the physician ordering the test. The necessity of a patient history is documented in the Quest test directory. The applicable form can also be printed from the procedure summary in the Quest test directory.

In order to process the Miscellaneous Send out, the Send out department must order the test in the Quest computer system to create a transfer list that accompanies the specimen to the lab performing the test. When the test is performed, a report prints out in the VCMC lab via modem that must be Verified. The copy of the Quest (or whatever reference lab is used) report is to medical records to be scanned into the EMR record so the physician has access to the record in the LIS.

The following tests **must** have the appropriate form filled out by the physician and signed by the patient:

Newborn Screen Comprehensive Testing

Prenatal Genetic MSAFP lst Trimester Screening

Prenatal Genetic MSAFP 2nd Trimester Screening

PUBLIC HEALTH TESTS:

The following tests are performed in the Public Health Laboratory:

HIV 1-2 Ab/Ag EIA

GC/Chlamydia by PCR

Fungus Culture

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AFB Culture

AFP-OB (with form filled out by physician office)

NEWS (Newborn Screen Comprehensive Testing)

In **LIS**, the Transfer List function procedure is used to track those specimens sent to Public Health

REFERENCES

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L.91 Venous Blood Specimen Collection

VENOUS BLOOD SPECIMEN COLLECTION

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PRINCIPLE

Identification of the patient is crucial. The phlebotomist and/ registered nurse (RN) must ensure that the venous blood specimen is being drawn from the individual designated on the request form or labels. The phlebotomist and/ RN must not rely on a bed tag, or on charts or records placed on the bed or nearby tables, or equipment, or event the order itself.

PROCEDURE

Most laboratory draws are generated by the computer/barcode labels used by the phlebotomist. However when a Nurse draws a specimen charting/registration labels are used until the computer/barcode labels are placed on the tubes by the CLS.

A. Patient Identification:

1. For an in-patient, verify that Wristband Name & Medical Record Number match request and/or label.
2. For an out-patient, ask patient to state his/her name and date of birth. Verify that the response matches the request and/or label.
    a. Tubes should be labeled AFTER the specimen has been collected.
    b. Do not label an empty tube before drawing the patient.
    c. Complete labeling at the patient's bed/chair side.
    d. Do not re-label specimen.

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The sample should be drawn from fresh venipuncture site. If intravenous tubing is used, follow the IV and Line draw Protocol.

B. Blood Collection

1. Note specimen type indicated on barcode label.
2. See Laboratory Directory of Tests and Services X.4-39 included or QUEST Laboratory Test Directory for test requirements.
3. Fasting Status:
    a. Fasting should occur for 12-14 hours.
    b. Water, only, may be consumed.
    c. Coffee and cigarettes should be avoided.
4. Therapeutic Drug Monitoring
    a. Trough - collect 15-30 min. prior to next dose.
    b. Peak - check with Lab for optimum collection time for specific drug.

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PROTOCOL

A. If a patient has an IV running, the phlebotomist/RN should use the opposite arm, if possible. Satisfactory samples may be drawn **below** the intravenous infusion site by:

1. Requesting the nurse in charge of the patient to turn off the IV for at least two minutes, and
2. Applying the tourniquet below the IV infusion site.

B. Contact the nurse in charge of the patient when the blood sample has been obtained to restart the IV. The phlebotomist/RN should report that the specimen was drawn from an arm which had an intravenous infusion running and the contents of the IV bottle to the technologist or Supervisor.

C. If a patient has an IV running, **UNDER NO CIRCUMSTANCES** should the phlebotomist/N draw a specimen above the IV site without contacting the Supervisor. Drawing above an IV compromises the specimen collected, and the results may have critical effects on the patient and his treatment.

D. If there is no suitable choice below the IV site, the phlebotomist/RN should return to lab with the label and inform the supervisor. The course of action should not be decided by the phlebotomist/RN. The Supervisor needs to field the decision because the quality of the specimen collected effects the results that the laboratory will be reporting.

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E. The Supervisor may:

1. Send another phlebotomist/RN for a second opinion,
2. Contact the nurse in charge of the patient to discuss the possibility of stopping the IV for 30 minutes so that the blood could be drawn without contamination from the IV solution, or
3. The doctor may be contacted if an arterial draw is required.

LINE DRAW PROTOCOL

A. A line is a piece of tubing inserted into a patient's vein or artery for administering fluids and medications, monitoring pressures, and obtaining blood samples for diagnostic tests. Phlebotomists/RN should not draw from indwelling cardiovascular (arterial, central venous), or umbilical lines.

B. Blood specimens may be drawn from a vascular access device (VAD) using a blood collection system or a needleless syringe. Obtaining blood specimens from indwelling lines or VAD's may be a problem and a potential source of test error because of incomplete flushing at the collection site resulting in contamination and/or dilution of the specimen contributing to inaccurate results.

C. **Whether or not blood must be discarded depends on the type of line used.**

1. A venous or arterial central line with a sampling device is a closed system with a built in "discard" that is given back to the patient.
2. If the system is not "closed," the line must be flushed to reduce the risk of thrombosis. A flushed line must be cleared of the fluid before blood specimens can be drawn for diagnostic testing. An adequate amount of blood must be withdrawn from the line and discarded before drawing a specimen to ensure that the actual specimen is not diluted or contaminated with the flush solution.
3. Discard volume is dependent on the dead space volume of the particular line. Discarding two times the dead space volume is recommended for non-coagulation testing, and 5 ml of six times the dead space for coagulation tests.
4. Collection of the blood through lines that have been previously flushed with heparin should be avoided, if possible. If it is necessary, the line should be flushed with 5 ml of saline, and the first 5 ml of blood or six dead space volumes of the VAD discarded.
5. An indwelling winged infusion set can be left in a vein from 36-48 hours for intravenous administration of medication or as a vein source to obtain a blood specimen. This "heparin or saline lock" is used to "save" veins for therapeutic use and causes fewer traumas to the patient. Because it is not necessary to keep the vein open with a continuous intravenous infusion, the patient is more comfortable

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and more mobile.

D. **No Coagulation tests should be drawn from an indwelling line or heparin lock.**

A fistula is an artificial shunt connection done by a surgical procedure to fuse the vein and artery together that is only used for dialysis. An arm with a fistula should not be used routinely for blood drawing since it is permanent.

REFERENCES

All Revision Dates

2/26/2026

Approval Signatures

Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator, VCMC & SPH	2/26/2026
Laboratory Services Department	M. Anwar Molani: Medical Director, Laboratory Services	2/25/2026
Laboratory Services Department	Erlinda Roxas: Director, Laboratory Services	2/25/2026
Laboratory Services Department	Evan Gamad: CLS III	2/25/2026

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L.CGL 1.2 Coagulation Reference Ranges

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PRINCIPLE:

Reference intervals are essential for clinical laboratory test interpretation and patient care. It is common lab practice to define the reference range or interval of a laboratory test as the central 95% interval bounded by the 2.5 and 97.5 percentiles of the selected patient population.

For details on the establishment of VCMC Coagulation Reported Reference Ranges see the Sysmex CS2500 Validation Binders.

The following reference ranges results were established by Instrumentation Laboratory, validated and adopted at Ventura County Medical Center.

VCMC Reported Reference Ranges

Analyte	Reference Ranges	Unit
Prothrombin Time	10.2 - 12.9	seconds
Activated Partial Thromboplastin Time	25 -36	seconds
Fibrinogen	200 - 393	mg/dL
D-Dimer	0 – 0.50	mg/L
Heparin, Anti-Xa	0.1 – 1.5	IU/mL

The **Heparin, Anti-Xa** test measures the amount of heparin in a plasma sample. Heparin is not found in patients not receiving heparin; thus 0.0 IU/mL would be found in patients not receiving heparin.

Samples with low-molecular weight heparin **(LMWH)** concentration **above 1.5IU/mL** be diluted manually by mixing **two parts of the sample with one part of STANDARD PLASMA.**

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The result of the manually diluted samples must be **multiplied by the dilution factor 1.5** prior to reporting.

REFERENCES:

Dade®- Innovin® Reagents, Dade®FSL Reagents, Dade®Ci-Trol®1, and Dade®Ci-Trol®3 package Inserts. Dade®Thrombin Reagents, Innovance® D-Dimer Reagents, Innovance® D-Dimer Contol 1&2. Innovance® Heparin Reagents, Innovance® Hparin UF Control 1&2, Innovance® Hparin LMW Control 1&2 package Inserts

CAP Accreditation Program – Hematology and Coagulation Checklist 08.24.2023

CAP Checklist Requirements

COM.29950Reference Intervals

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Laboratory Service Dept	M. Anwar Molani: Medical Director, Laboratory Services	2/24/2026
Laboratory Service Dept	Samah Meshreky: Supervisor-Hematology, Laboratory Services	2/24/2026
Laboratory Service Dept	Erlinda Roxas: Director, Laboratory Services	2/24/2026

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VENTURA COUNTY HEALTH CARE AGENCY

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Owner	Samah Meshreky: Supervisor-Hematology, Laboratory Services
Policy Area	Laboratory Services

L.CGL 1.3 Critical Results - Coagulation Department

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PRINCIPLE:

Critical results are tests results that represent a life threatening state to the patient and require rapid communication to the physician or responsible licensed caregiver (limited to Nurse Practitioner, Physicians Assistant, Registered Nurse, or Licensed Vocational Nurse). It is the policy of Ventura County Medical Center (VCMC) & Santa Paula Hospital (SPH) to safeguard patients by defining the process of reporting critical results. Critical results are established by the VCMC/SPH Medical staff and are reviewed every two years and reported to the Performance Improvement Coordinating Council (PICC) quarterly.

All hematology critical results should be communicated immediately to the ordering physician or licensed responsible caregiver. Report must be verbally communicated no more than thirty (30) minutes from the availability of critical results.

This policy is derived from **Administrative Policy: 100.030 Critical Test Results** and is designed to fit the workflow of the hematology department.

PROCEDURE:

The following results have been established as critical results in the VCMC Hematology Department by the VCMC Medical Staff:

Test	Low Critical Result	High Critical Result
Hemoglobin	≤6.9 g/dL	≥23.0 g/dL
Hemoglobin patient age >65	≤6.9 g/dL	
Hematocrit	≤18%	≥70%

Platelets	≤20 x 10^3/mcL	≥700
White Blood Cell (WBCs)	≤1.0 x 10^3/mcL	≥50K
Absolute Neutrophil Count (ANC/ Neutrophil#)	<0.5 x 10^3/mcL	
International normalization ratio (INR)		≥4.0
Partial Thromboplastin Time (PTT)		>118 sec.
D-Dimer		>7.5
Fibrinogen	<100 µg/dL	
Heparin, Anti-Xa (UF)	Call all result or Tiger Text	
Heparin, Anti-Xa (LMW)	Call all result or Tiger Text	
Cerebrospinal fluid (CSF) White Blood Cell Count	≥ 10	

RESULTS:

1.	Under Accession Result Entry in Cerner, go to the appropriate result entry mode (i.e. Instrument Queue, Accession, Worklist) for accepting patient test result.
2.	The result would have transmitted from analyzer to patient's accession. If you manually enter result, do not convert result to free text or critical prompt will not appear.
3.	Right click the result and select comment. **NOTE:** If there are multiple critical results on the same patient's test, uncheck all results from the test except the critical results. Right click one of the critical results and select Batch comments → All selected.
4.	Under result comments the following prompt should be present: "Called to (name):_ Location:_ Time:_ Called results read back to Lab? (Y/N):_" **NOTE:** If the above prompt is not present, Press F2 and under Name, type mnemonic LCALL and select ok. **OR :** Tiger text to the physician who is in charge for the patient.
5.	Call licensed care giver or physician and fill call prompt ensure there is a "read-back" of the critical results. Record FIRST and LAST name of personnel receiving critical results. *For clinic's (outpatient) results analyzed during off hours (1700-0700) page the operator at x7-6075. The operator will contact the on-call clinic physician and report critical result to on-call physician. **NOTE:** Due to CAP regulations, first name alone is NOT sufficient for documenting critical results.
6.	Save and close comment box and verify results.

REFERENCES:

Administrative Policy: 100.030 - Critical Test Results

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CAP Checklist Requirements

COM.30000 Critical Result Notification

COM.30100 Critical Result Read-Back

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Laboratory Service Dept	Erlinda Roxas: Director, Laboratory Services	3/26/2026
Laboratory Service Dept	M. Anwar Molani: Medical Director, Laboratory Services	3/25/2026
Laboratory Service Dept	Samah Meshreky: Supervisor-Hematology, Laboratory Services	3/25/2026

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Policy Area	Laboratory Services

L.CGL1.4 Canceling & Reordering Tests for Unacceptable Specimens - Coagulation Department

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PRINCIPLE:

Specimen integrity is extremely important in accurately testing and reporting patient results by laboratory personnel. In whole blood testing platforms, unacceptable specimens may be discovered during pre-analytical, analytical & post-analytical sample analysis. For acceptability criteria on pre-analytical see hematology procedure: **Specimen Rejection, Acceptability and Stability Criteria.** For acceptability criteria on analytical and post analytical see corresponding test procedure.

PROCEDURE:

A- CANCEL/CREDIT REJECTED SPECIMEN TEST ORDER

A.

1.	Call the physician or responsible licensed caregiver of the patient which test was ordered. *For clinic's (outpatient) results analyzed during off hours (1700-0700) ONLY cancel ordered test and leave a printout of test canceled and reason in Sendout CPT III box. Sendout CPT III will contact clinic physician during clinic hours and alert them of canceled test. The clinic will reorder test if needed.
2.	To patient's licensed caregiver, communicate test to be canceled, reason for cancellation and offer to reorder and redraw test. Record the personnel's name and the time of communication.
3.	In Cerner open icon Order Result Viewer→ enter patient Accession number → Ok.
4.	Select test to be canceled →Task→ Cancel Order. (OR select Cancel Order icon)

	NOTE: Only tests not resulted can be canceled. If test was resulted, cancel by performing a corrected report.
5.	Under Reason, enter reasons for cancelling test (i.e. QNS, specimen clotted, e.t.c)
6.	Select comment icon→ add comment→ type: personnel called, time of call, and whether test will be reordered→ Save comment → Ok

B- ORDER TEST TO BE REDRAWN

1.	In Cerner open icon Department Order Entry→ enter patient MRN (medical record number) number → Ok.
2.	Under order, find test which were canceled
3.	For: a. Collection priority → ST (stat) order ALL redraw as stat order b. Label Comment → type Prev: (and the reason previous draw was cancelled)
4.	Select Task→ Submit Order. (OR select Submit Order icon)

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Laboratory Service Dept	Samah Meshreky: Supervisor-Hematology, Laboratory Services	2/24/2026
Laboratory Service Dept	Erlinda Roxas: Director, Laboratory Services	2/24/2026

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L.CGL 1.5 Disseminated Intravascular Coagulopathy (DIC)

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PRINCIPLE:

Disseminated Intravascular Coagulopathy (DIC) is a complicated systemic disorder of the body's hemostatic process that involves a combination of hemorrhaging and microvascular coagulation. It is a repeating cycle of clot formation and fibrinolysis of the clot, leading to the depletion of platelets and coagulation factors, including the constant release of anticoagulants. The depletion of the platelets and coagulation proteins results in the inducement of severe bleeding.

DIC is an acquired disorder that occurs in a variety of clinical conditions. The common causes are infectious disease, particularly septicemia, severe trauma, in particular, trauma to the brain tissue, abruptio placentae and amniotic fluid embolism.

There is no single laboratory test establishing the definitive standard for diagnosing or ruling-out DIC. A combination of tests is performed when a patient presents with a clinical condition known to be a triggering factor.

Specimen integrity is extremely important in accurately testing and reporting patient results by laboratory personnel. In order to ensure consistent reliable results all specimen requirements should be strictly followed regarding post draw stability of coagulation specimens.

PROCEDURE:

The DIC panel includes the following tests: Prothrombin time (PT), Activated Partial Thromboplastin Time (aPTT), Fibrinogen, D-Dimer and a Platelet Count. The following specimen containers are collected to run the subsequent tests:

- Light Blue Top (Sodium citrate anticoagulant): PT, aPTT, Fibrinogen, D-Dimer

- Lavender Top (EDTA anticoagulant) : Platelet Count

Note: See Procedures: L.CGL**1.1 - Specimen Rejection, Acceptability and Stability Criteria - Coagulation Procedure** and L HEM **1.1 Specimen Rejection, Acceptability and Stability Criteria - Hematology Procedure** for specimen collection and stability requirements.

REFERENCES:

Baglin T. Fortnightly review: Disseminated intravascular coagulation: diagnosis and treatment. *British Medical Journal.* 1996; 312*:* 683-686.

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CAP Accreditation Program – Hematology and Coagulation Checklist 08.24.2023

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CAP Checklist Requirements

HEM.37150 DIC

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Laboratory Service Dept	Samah Meshreky: Supervisor-Hematology, Laboratory Services	2/24/2026
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Policy Area	Laboratory Services

L.CGL 2.1 Daily Quality Control – Sysmex® CS2500 (PT & PTT)

COPY

PRINCIPLE:

Quality Control (QC) is performed routinely to ensure that an instrument is consistently reporting reliable sample results. Control specimens are tested and reviewed by personnel in the same manner as patient samples. Sysmex®CS2500 control is performed by running coagulation Quality Control samples.

VCMC hematology department requires two levels of coagulation QC samples per test to be performed:

- Every 8 hours of patient testing
- With every new reagent bottle placed on the analyzer
- After any (applicable) test calibration is performed
- After any major maintenance or repair is performed

EQUIPMENT:

Sysmex CS2500

CONTROLS: REAGENTS/MATERIALS:

Dede® Innovin (PT reagent)

Dede® Actin®FSL (PTT reagent)

CaCl2 (ready to use)

Dede® Ci-Trol®1

Dede® Ci-Trol®3

CA Clean®II(ready to use)

Reagent Grade or deionized (diH_2O) Water.

Calibrated Pipette and pipette tips

PROCEDURE:

QC must be valid for every **8 hours** of patient testing. The following QC should be performed every **8 hours**:

RUNNING PT & APTT CONTROLS:

Reconstitute (Dede® Innovin PT Reagents

A.

1.	Remove PT reagents (Dede® Innovin Reagent) from designated fridge.
2.	Reconstitute with exactly 10mL de-ionized water, swirl to mix and allow to clear.
3.	Load reconstituted reagent on **Reagent Table**. (Once this reagent is reconstituted it should be stored on board 10°C for up to 72hrs and 10 days refrigerated (2-8°C.) **NOTE:** Analytical temperature requirements are monitored by the analyzer, any temperature alerts/discrepancies must be addressed before testing

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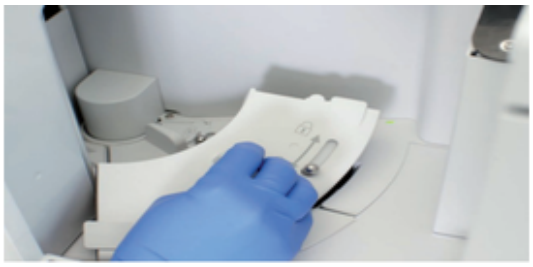
B. ## Reconstitute (Dede® Actin®FSL (PTT reagent)

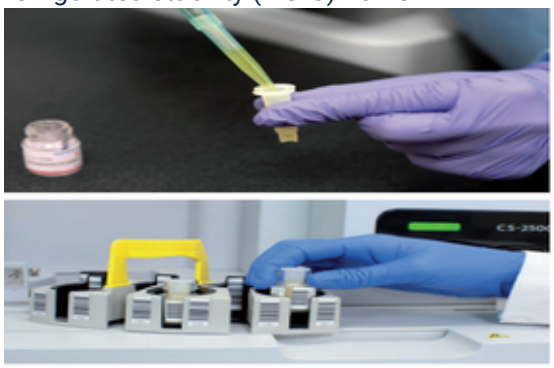
1.	Remove Dede® Actin®FSL (APTT Reagent) & Calcium Chloride from designated fridge.
2.	Let the two reagents stand at room temperature for 15 minutes, then mix thoroughly (5-8 times)
3.	Load reagents on **Reagent Table** (Once these reagents are opened, they should be stored on board the analyzer 10°C for up to 72hrs and 7 days refrigerated 2-8°C.)

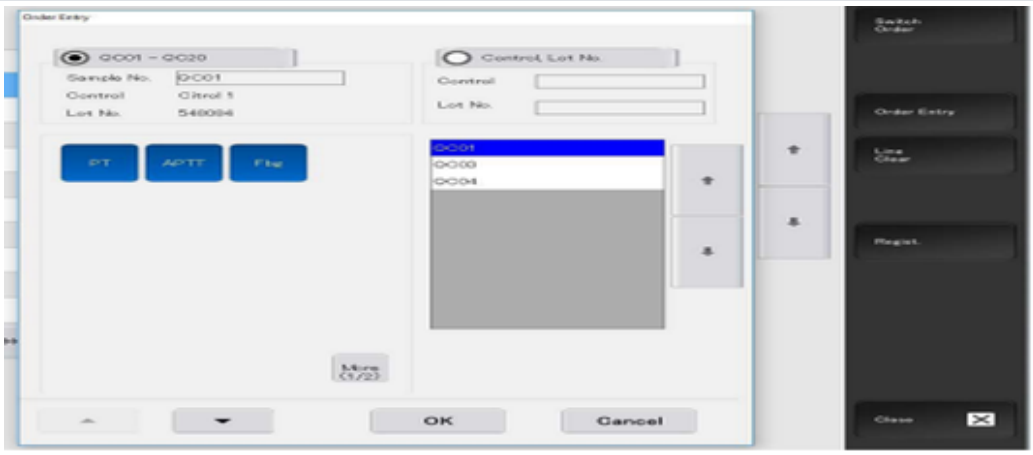
NOTE: Reagent Table Loading:

1. Press Reagent icon on toolbar.
2. Highlight a reagent position for removal then press **Change/Add.**
3. Lift the reagent section lid.
4. Verify reagent table cover LED is solid green, slide the lock lever and remove cover.
5. Lift out rack and remove empty/ expired reagents. And add a new vial with 1D barcode showing.
6. Load rack into the reagent table, replace cover, and slide the lock lever.
7. Close the reagent section lid then press **OK and** wait for barcode reading to finish.
8. On reagent screen, touch **reagent position** just loaded, and press **Change** to update date and time.



III. Reconstitute and Run Dede®Ci-Trol®1& Dede®Ci-Trol®3

1.	Remove Dede®Ci-Trol®1& Dede®Ci-Trol®2 from designated fridge. And let it equilibrate for 15 mins.
2.	Reconstitute the controls with 1mL of Reagent Grade Water or diH_2O. Let stand for 15mins, Swirl contents gently to mix.
3.	Load reconstituted QC on Reagent Table (**SLD mini cup**) in **C rack**. On board stability (10°C) 24hrs refrigerated stability (2-8°C) 16hrs.  **Note:** SLD mini cup is for C-rack only.
4.	**Processing from the reagent table: QC files** • Select **Order** then **Switch Order.** • Select **Holder QC Order** and press **Order Entry.** • Select **QC01-QC20** radio button. • Select **QC file** from the list on the right. • Select the appropriate assay and press the down arrow to order the next control. • Select QC01-QC20 radio button to continue ordering controls. • Press **OK** then **Start.**



5. ## Processing from the reagent table: Control Lot

- Select **Order** then **Switch Order.**
- Select **Holder QC Order** and press **Order Entry.**
- Select control materials from the list.
- Place the curser in the **Lot NO.** box and select the lot number from the list then select the appropriate assays.
- Press the arrow down to order the next control then OK once all controls have been ordered, Press **Start.**

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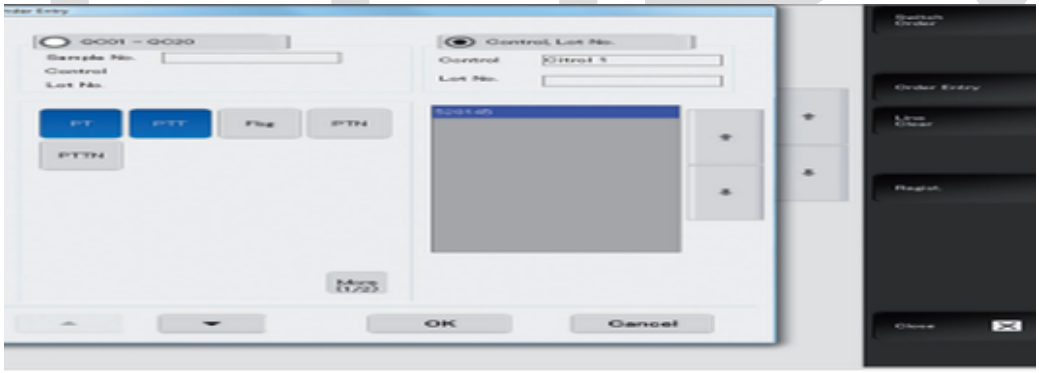
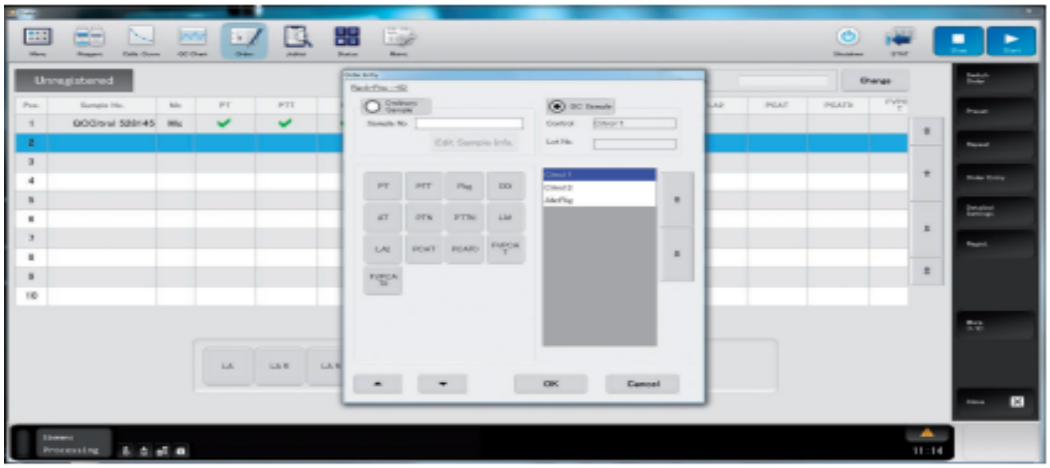


6. ## Processing from the Sample Rack

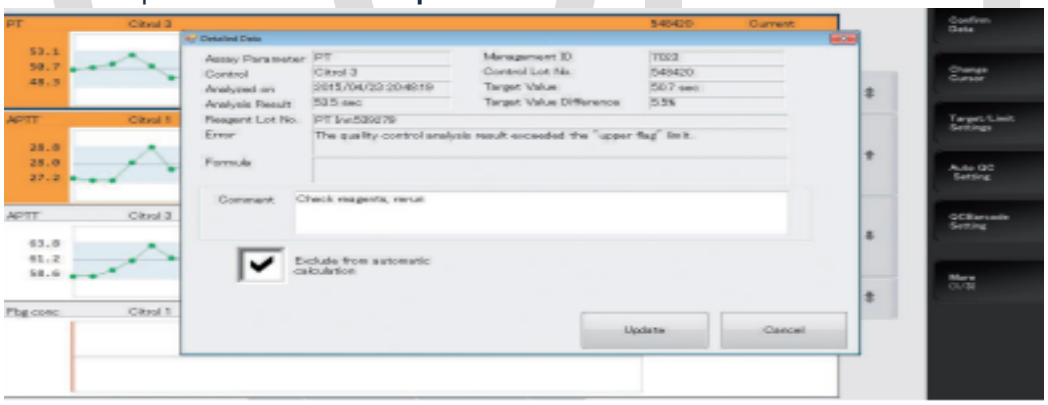
- Place QC in cup and place in sample rack.
- Select **Order** then **Switch Order.**
- Select **Rack and** tube position.
- Select **Order Entry**
- Select **QC Sample** radio button.
- Select control from the list and place curser in in the Lot NO. box and select lot number from the list**.**
- Select the appropriate assay keys.

- Press the arrow down to order the next control. Then **OK.**
- For **Micro Mode**, Check the **MC** column for each control.
- Press **Start.**



7. **Review QC Chart**

When QC analysis is completed review QC chart.
To add a comment press **QC chart,** highlight specific QC Chart place the cursor on point then **Confirm Data** key and enter comment in field.
To exclude point **check box** then **Update.**



8. When QC analysis is completed, review QC results in Cerner.
Under Cerner QC Inquiry, all completed QC results must be reviewed by the performing CLS and any failed QC result must be accompanied by a corrective action comment.

9. Results for both levels of controls must be reviewed for acceptability before reporting patient results.
NOTE: If any control is found out of range, see troubleshooting QC below.

TROUBLESHOOTING QC:

If a control is found to be "out of range":

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1. Inspect control appearance, temperature, and expiration date. If all listed parameters are valid, when resulting QC ***select/attach comment: repeat, same control vial***, and rerun controls. If control continues to result as "outside of target range" proceed to (2).
   NOTE: If any control is found out of range DO NOT rerun control more than 1 time without performing AND documenting corrective actions.
2. Open a new sample (same lot) of that level of control and rerun (***select/attach comment: new bottle control***). If the new bottle control opened results outside of target range proceed twice to (3).
3. Contact Instrumentation Laboratory Service and record reference number and possible solution obtained. When resulting QC ***select/attach comment: other***. Specify actions taken to resolve QC in results section. 10 days

Notify staff when QC processes causes interruptions in workflow. During "off hours," call operator in order to notify Emergency Department and House Supervisor of possibly delay in patient results due to instrument malfunction.

Guidelines on VCMC applied Quality Control Limits are outlined in procedure L.**HEM 6.5 - Quality Control Tolerance Limits**. Quality control results are reviewed monthly by CLS supervisor.

Routine Reagent Preparation Guide:

PT/INR Dade® Innovin® Reagents

Reagent	Prep	Placement	On-Board Stability (10°C)	Refrigerated Stability (2-8°C)
Dade® Innovin	Reconstitute with volume of de-ionized water specified on bottle, swirl to mix, allow to clear	Reagent Table	72 hours	10 days
Dade® Ci-Trol® 1	Reconstitute with 1mL de-ionized water, let stand for 15 mins, swirl to mix	Reagent Table (SLD mini Cup, C rack)	24 hours	16 hours
Dade® Ci-Trol® 3	Reconstitute with 1mL de-ionized water, let stand for 15 mins, swirl to mix	Reagent Table (SLD mini Cup, C rack)	24 hours	16 hours
CA Clean® II	Ready to Use	Reagent Table	120 hours	2 months (5-35°C)

aPTT Dade® Actin® FSL Reagents

Reagent	Prep	Placement	On-Board Stability (10°C)	Refrigerated Stability (2-8°C)
Dade® Actin® FSL	Mix by gentle inversion (5-8 times)	Reagent Table	72 hours	7 days
CaCl2	Ready to Use	Reagent Table	72 hours	8 weeks
Dade® Ci-Trol® 1	Reconstitute with 1mL de-ionized water, let stand for 15 mins, swirl to mix	Reagent Table (SLD mini Cup, C rack)	24 hours	16 hours
Dade® Ci-Trol® 3	Reconstitute with 1mL de-ionized water, let stand for 15 mins, swirl to mix	Reagent Table (SLD mini Cup, C rack)	24 hours	16 hours

REFERENCES:

Sysmex CS-2500 System Quick Reference Guid

Dede® Innovin, Dede® Actin®FSL, Dede® Ci-Trol®1, Dede® Ci-Trol®3- package Inserts

CAP Accreditation Program – Hematology and Coagulation Checklist 08-24-2023

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CAP Checklist Requirements

HEM.19360Daily QC – Nonwaived Tests

HEM.20050Numeric QC Data

HEM.20120QC Handling

HEM.20140QC Confirmation of Acceptability

HEM.20143QC Corrective Action

HEM.20146Monthly QC Review

HEM.37300Coagulation Quality Control

COM.30350Reagent Storage and Handling- Nonwaived Tests

COM.30400Reagent Expiration Date

All Revision Dates

2/24/2026

Attachments

image1.png

Approval Signatures

Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator, VCMC & SPH	2/24/2026
Laboratory Service Dept	M. Anwar Molani: Medical Director, Laboratory Services	2/24/2026
Laboratory Service Dept	Samah Meshreky: Supervisor-Hematology, Laboratory Services	2/24/2026
Laboratory Service Dept	Erlinda Roxas: Director, Laboratory Services	2/24/2026

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Status **Active** PolicyStat ID **19762115**

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Owner	Samah Meshreky: Supervisor-Hematology, Laboratory Services
Policy Area	Laboratory Services

L.CGL 2.2 Daily Quality Control Sysmex CS2500 (D-dimer, Fibrinogen, and Heparin, Anti-Xa)

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PRINCIPLE:

Quality Control (QC) is performed routinely to ensure that an instrument is consistently reporting reliable sample results. Control specimens are tested and reviewed by personnel in the same manner as patient samples. Sysmex CS2500 quality control is performed by running coagulation Quality Control samples.

Hemosil coagulation controls for Fibrinogen (Fib), D-Dimer and Heparin, Anti-X*a* are intended to be used as assayed quality control to monitor the effectiveness of the coagulation testing protocol and the accuracy of the analyzer.

VCMC hematology department requires two levels of coagulation QC samples per test to be performed:

- Every **8 hours** of patient testing. Anti- Xa QC is performed on an as needed basis, within every 8 hours of patient testing.
- With every new reagent bottle placed on the analyzer
- After any test calibrations are performed
- After any major maintenance or repair is performed

EQUIPMENT:

Sysmex CS 2500

CONTROLS, REAGENTS/MATERIALS:

INNOVANCE® D-Dimer Reagents:

NNOVANCE® D-Dimer Reagent

INNOVANCE® D-Dimer Buffer

INNOVANCE® D-Dimer Supplement

INNOVANCE® D-Dimer Diluent **(load it on the Buffer Table)**

INNOVANCE® D-Dimer Control1

INNOVANCE® D-Dimer Control 2

INNOVANCE® D-Dimer Calibrator.

Fibrinogen Dade® Thrombin Reagents:

Dade® Thrombin

Dade® OVB **(load it on the Buffer Table)**

Dade® Ci-Trol® 1

Data-Fi® Abnormal Fibrinogen Control

CA Clean® I

Standard Human Plasma(calibrator)

INNOVANCE® Heparin Reagents:

INNOVANCE® Heparin Reagent

INNOVANCE® Heparin Substrate

Dade® OVB **(load it on the Buffer Table)**

INNOVANCE® Heparin LMW Control 1, INNOVANCE® Heparin LMW Control 2

INNOVANCE® Heparin UF Control 1, INNOVANCE® Heparin UF Control 2

INNOVANCE® Heparin Calibrators 1-5

CA Clean® I

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PROCEDURE:

QC must be valid for every **8 hours** of patient testing. **Anti-Xa** QC is performed **every 8 hours of corresponding patient testing**, **Fibrinogen and D-Dimer** QC should be performed every **8 hours**.

Additionally, calibrations for the **Fibrinogen, D-Dimer** and **Anti-Xa** MUST be valid for each test system before commencement of patient testing**.**

RUNNING FIB & D-DIMER CONTROLS:

I. Reconstitute Reagents Dade® Thrombin

1.	Remove Dade® Thrombin from designated fridge.
2.	Reconstitute Thrombin reagent with **1mL** of Reagent Grade Water or diH_2O., let stand for 15 mins. Swirl and mix contents gently.

3.	OVB ready to use at room temperature. Pour OBV in the cup and load it on the Buffer table. OVB on-board stability (10°C) is 24hrs, and 8 weeks refrigerated at (2-8°C)
4.	Load reconstituted reagent on **Reagent Table**. (Once this reagent is reconstituted it should be stored on board 10°C for up to 72hrs and 5 days refrigerated (2-8°C.) **NOTE:** Analytical temperature requirements are monitored by the analyzer, any temperature alerts/ discrepancies must be addressed before testing

II. Reconstitute D-Dimer Reagents

1.	INNOVANCE® D-Dimer Reagents from designated fridge.
2.	Reconstitute the reagent with **4mL** of Reagent Grade Water or diH_2O., let stand for 15 mins. Swirl and mix the contents gently. **NOTE:** Always load all reagents together. DO NOT load one reagent without the other or mix sets.
3.	Load reconstituted reagent on **Reagent Table**. (Once this reagent is reconstituted it should be stored on board 10°C for up to 48hrs or extended to 96 hours if using the Reagent Cap and 4 weeks refrigerated (2-8°C.) **NOTE:** - Load INNOVANCE® D-Dimer **Diluent** on the Buffer Table. - Analytical temperature requirements are monitored by the analyzer, any temperature alerts/ discrepancies must be addressed before testing

NOTE: Reagent Table Loading:

See procedure L.CGL 2.1

NOTE: Buffer Table Loading:

A. Loading barcoded vial:

1. Verify buffer table cover LED is green., open buffer table cover.
2. Place reagent in an adaptor with barcode facing out, place into the STAT/buffer table and close cover.
3. Press OK on barcode reading screen.
4. On Reagent screen, touch reagent position just loaded, and press Change to update the set date and time.

B. **Loading 4 mL cup:**

1. Verify buffer table LED is green, place cup into adaptor and load.
2. Close STAT/buffer table cover, press OK on barcode reading screen.

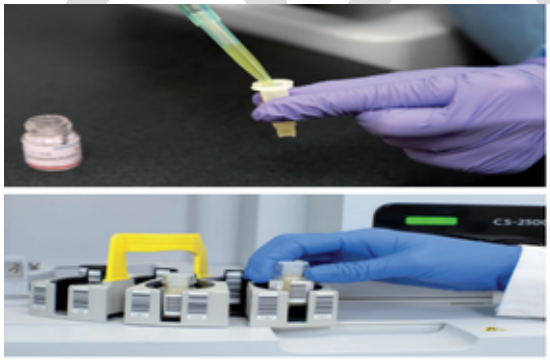
3. On Reagent screen, see position display as red question mark.

4. Highlight red question mark position, press **Edit Reagent Info** operation key.

5. Select reagent name, vial type is 4 mL cup, verify lot number, press OK.

. 6. With cup position highlighted, press Change to update date and time.

III. Reconstitute and Run Controls

1.	Remove Dade® Ci-Trol® 1, Data-Fi® Abnormal Fibrinogen Control, INNOVANCE® D-Dimer Control1, INNOVANCE® D-Dimer Control 2 Controls from designated fridge.
2.	Reconstitute the controls with 1mL of Reagent Grade Water or diH_2O. Let stand for 15mins, Swirl contents gently to mix.
3.	Load reconstituted QC on Reagent Table (**SLD mini cup**) in **C rack**. On board stability (10°C) 24hrs refrigerated stability (2-8°C) for Dade® Ci-Trol® 1, Data-Fi® Abnormal Fibrinogen Control 16 hrs & 7 days for INNOVANCE® D-Dimer Control1, INNOVANCE® D-Dimer Control 2.  **Note:** SLD mini cup is for C-rack only.
4.	**Processing from the reagent table: QC files** • Select **Order** then **Switch Order.** • Select **Holder QC Order** and press **Order Entry.** • Select **QC01-QC20** radio button. • Select **QC file** from the list on the right. • Select the appropriate assay and press the down arrow to order the next control. • Select QC01-QC20 radio button to continue ordering controls. • Press **OK** then **Start.**

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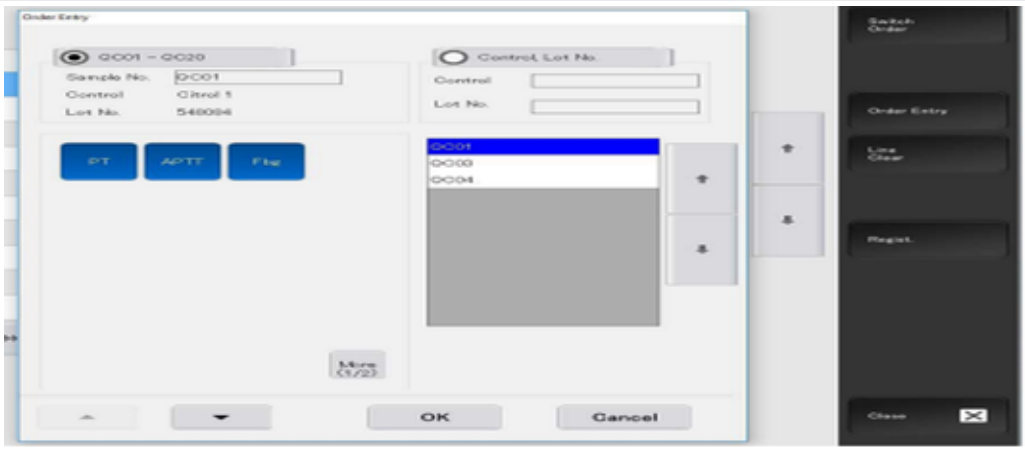

5.

Processing from the reagent table: Control Lot

- Select **Order** then **Switch Order.**
- Select **Holder QC Order** and press **Order Entry.**
- Select control materials from the list.
- Place the curser in the **Lot NO.** box and select the lot number from the list then select the appropriate assays.
- Press the arrow down to order the next control then OK once all controls have been ordered, Press **Start.**

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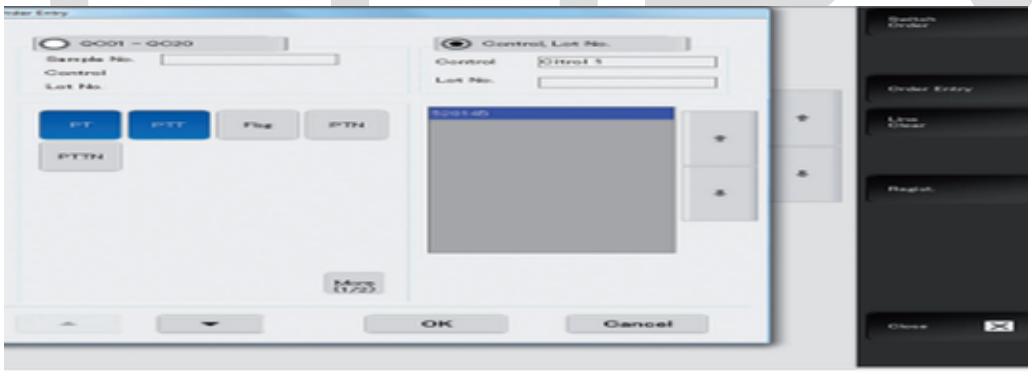
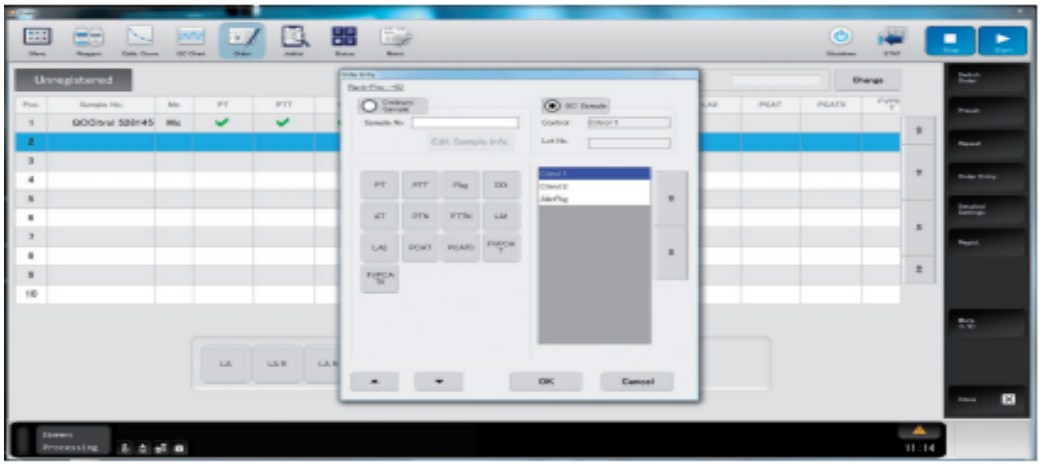


6.

Processing from the Sample Rack

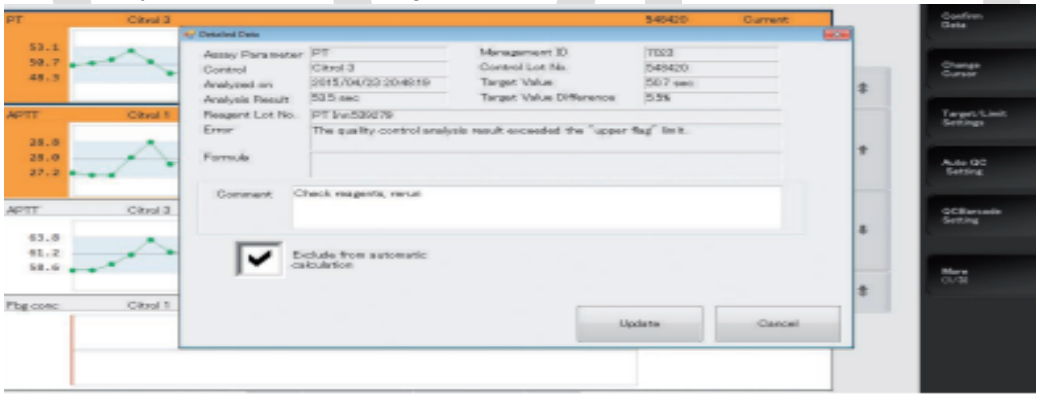
- Place QC in cup and place in sample rack.
- Select **Order** then **Switch Order.**
- Select **Rack and** tube position.
- Select **Order Entry**
- Select **QC Sample** radio button.
- Select control from the list and place curser in in the Lot NO. box and select lot number from the list**.**
- Select the appropriate assay keys.

- Press the arrow down to order the next control. Then **OK.**
- For **Micro Mode**, Check the **MC** column for each control.
- Press **Start.**



7. **Review QC Chart**

When QC analysis is completed review QC chart.
To add a comment press **QC chart,** highlight specific QC Chart place the cursor on point then **Confirm Data** key and enter comment in field.
To exclude point **check box** then **Update.**



8. When QC analysis is completed, review QC results in Cerner.
Under Cerner QC Inquiry, all completed QC results must be reviewed by the performing CLS and any failed QC result must be accompanied by a corrective action comment.

9. Results for both levels of controls must be reviewed for acceptability before reporting patient results.
NOTE: If any control is found out of range, see troubleshooting QC below.

RUNNING ANTI-Xa CONTROLS:

I. Prepare Anti-Xa Reagents

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1.	Remove INNOVANCE® Heparin Reagent INNOVANCE® Heparin Substrate, and Dade® OVB from designated fridge. (ready to use)
2.	Load reagents on reagent table on board and OVB on Buffer table. Once these reagents are opened, they **MUST BE UNLOADED** from the analyzer AFTER analysis and stored refrigerated. On board stability(10°C) 72hrs and refrigerated stability (2-8°C) 8 weeks.

II. Reconstitute and Run UF Low, UF High, LMW Low & LMW High Controls

1.	Remove any of the following UF Low, UF High, LMW Low & LMW High controls required for run from the designated fridge.
2.	Label controls with the appropriate open and expiration dates. Opened expiration date: 8 hrs on board 10°C and 48 hours refrigerated 2-8°C)
3.	Reconstitute the controls with 1mL of Reagent Grade Water or diH_2O. Swirl to mix contents gently.
4.	Let the controls equilibrate for 15 minutes.
6.	All Anti-Xa controls **MUST BE UNLOADED** from the analyzer AFTER analysis and stored refrigerated.
6.	Process the QC **See steps4,5, and 6 in D-dimer and fibrinogen QC.**
7.	When QC analysis is completed, review QC results in Cerner. Under Cerner QC Inquiry, all completed QC results must be reviewed by the performing CLS and any failed QC result must be accompanied by a corrective action comment.
8.	Results for both levels of controls must be reviewed for acceptability before reporting patient results. **NOTE:** If any control is found out of range, see troubleshooting QC below.

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TROUBLESHOOTING QC:

If a control is found to be "out of range":

1. Inspect control appearance, temperature and expiration date. If all listed parameters are valid, when resulting QC ***select/attach comment: repeat, same control vial***, and rerun controls. If control continues to result as "outside of target range" proceed to (2).
   NOTE: If any control is found out of range DO NOT rerun control more than 1 time without performing AND documenting corrective actions.
2. Open a new sample (same lot) of that level of control and rerun (***select/attach comment: new bottle control***). If the new bottle control opened results outside of target range twice proceed to (3).
3. Contact Instrumentation Laboratory Service and record reference number and possible solution obtained. When resulting QC ***select/attach comment: other***. Specify actions taken to resolve QC in results section.

Notify staff when QC processes causes interruptions in work flow. During "off hours," call operator in order to notify Emergency Department and House Supervisor of possibly delay in patient results due to instrument malfunction.

Guidelines on VCMC applied Quality Control Limits are outlined in procedure **HEM 1.6.5 - Quality Control Tolerance Limits**. Quality control results are reviewed monthly by CLS supervisor.

Routine Reagent Preparation Guid:

INNOVANCE® D-Dimer Reagents

Reagent	Prep	Placement	On-Board Stability (10°C)	Refrigerated Stability (2-8°C)
INNOVANCE® D-Dimer Reagent	Reconstitute with 4mL de-ionized water, let stand for 15 mins, swirl to mix	Reagent Table	48 hours 96 hours†	4 weeks
INNOVANCE® D-Dimer Buffer	Ready to Use	Reagent Table	48 hours 96 hours†	4 weeks
INNOVANCE® D-Dimer Supplement	Ready to Use	Reagent Table	48 hours 96 hours†	4 weeks
INNOVANCE® D-Dimer Diluent	Ready to Use	Buffer Table	48 hours 96 hours†	4 weeks
INNOVANCE® D-Dimer Control 1	Reconstitute with 1mL de-ionized water, let stand for 15 mins, swirl to mix	Reagent Table (SLD mini Cup, C rack)	24 hours	7 days
INNOVANCE® D-Dimer Control 2	Reconstitute with 1mL de-ionized water, let stand for 15 mins, swirl to mix	Reagent Table (SLD mini Cup, C rack)	24 hours	7 days
INNOVANCE® D-Dimer Calibrator	Reconstitute with 1mL de-ionized water, let stand for 15 mins, swirl to mix	Reagent Table (SLD mini Cup, C rack)	n/a*	n/a*

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*The on-board stabilities of INNOVANCE® D-Dimer Reagent, Buffer, Supplement, and Diluent can be extended from 48 hours to 96 hours when employing the Reagent Cap S GW5 (SMN: 10628684) and Compatible Cover Ring GW5 (SMN: 10628686).

* INNOVANCE® D-Dimer Calibrator is only used for calibration and does not have on-board stability. Once reconstituted it should stay at room temperature and must be used within 4 hours.

Fibrinogen Dade® Thrombin Reagents

Reagent	Prep	Placement	On-Board Stability (10°C)	Refrigerated Stability (2-8°C)
Dade® Thrombin	Reconstitute with volume of de-ionized water specified on bottle, swirl to mix, allow to clear	Reagent Table	72 hours	5 days
Dade® OVB	Ready to use at room temperature	Buffer Table	24 hours	8 weeks
Dade® Ci-Trol® 1	Reconstitute with 1mL de-ionized water, let stand for 15 mins, swirl to mix	Reagent Table (SLD mini Cup, C rack)	24 hours	16 hours
Data-Fi® Abnormal Fibrinogen Control	Reconstitute with 1mL de-ionized water, let stand for 15 mins, swirl to mix	Reagent Table (SLD mini Cup, C rack)	24 hours	16 hours
CA Clean® I	Ready to Use	Reagent Table	120 hours	1 month
Standard Human Plasma	Reconstitute with 1mL de-ionized water, let stand for 15 mins, swirl to mix	Reagent Table (SLD mini Cup, C rack)	n/a*	n/a*

* Standard Human Plasma is only used for calibration and does not have on-board stability. Once reconstituted it should stay at room temperature and must be used within 4 hours.

INNOVANCE® Heparin Reagents

Reagent	Prep	Placement	On-Board Stability (10°C)	Refrigerated Stability (2-8°C)
INNOVANCE® Heparin Reagent	Ready to Use	Reagent Table	72 hours	8 weeks
INNOVANCE® Heparin Substrate	Ready to Use	Reagent Table	72 hours	8 weeks
Dade® OVB	Ready to use at room temperature	Buffer Table	72 hours	8 weeks
INNOVANCE® Heparin LMW Control 1	Reconstitute with 1mL de-ionized water, let stand for 15 mins, swirl to mix	Reagent Table (SLD mini Cup, C rack)	8 hours	48 hours
INNOVANCE® Heparin LMW Control 2	Reconstitute with 1mL de-ionized water, let stand for 15 mins, swirl to mix	Reagent Table (SLD mini Cup, C rack)	8 hours	48 hours
INNOVANCE® Heparin UF Control 1	Reconstitute with 1mL de-ionized water, let stand for 15 mins, swirl to mix	Reagent Table (SLD mini Cup, C rack)	8 hours	48 hours
INNOVANCE® Heparin UF Control 2	Reconstitute with 1mL de-ionized water, let stand for 15 mins, swirl to mix	Reagent Table (SLD mini Cup, C rack)	8 hours	48 hours
INNOVANCE® Heparin Calibrators 1-5	Reconstitute with 1mL de-ionized water, let stand for 15 mins, swirl to mix	Reagent Table (SLD mini Cup, C rack)	8 hours	48 hours
CA Clean® I	Ready to Use	Reagent Table	120 hours	1 month

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REFERENCES:

Sysmex CS-2500 System Quick Reference Guid

Dede® Innovin, Dede® Actin®FSL, Dede® Ci-Trol®1, Dede® Ci-Trol®3- package Inserts

CAP Accreditation Program – Hematology and Coagulation Checklist 08-24-2023.

CAP Accreditation Program – Hematology and Coagulation Checklist 08.24.2024

CAP Checklist Requirements

HEM.19360Daily QC – Nonwaived Tests

HEM.20050Numeric QC Data

HEM.20120QC Handling

HEM.20140QC Confirmation of Acceptability

HEM.20143QC Corrective Action

HEM.20146Monthly QC Review

HEM.37300Coagulation Quality Control

COM.30350Reagent Storage and Handling- Nonwaived Tests

COM.30400Reagent Expiration Date

All Revision Dates

2/24/2026

Approval Signatures

Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator, VCMC & SPH	2/24/2026
Laboratory Service Dept	M. Anwar Molani: Medical Director, Laboratory Services	2/24/2026
Laboratory Service Dept	Samah Meshreky: Supervisor-Hematology, Laboratory Services	2/24/2026
Laboratory Service Dept	Erlinda Roxas: Director, Laboratory Services	2/24/2026

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Owner	Samah Meshreky: Supervisor-Hematology, Laboratory Services
Policy Area	Laboratory Services

L.CGL 2.3 Running Patient Specimens – Sysmex CS2500

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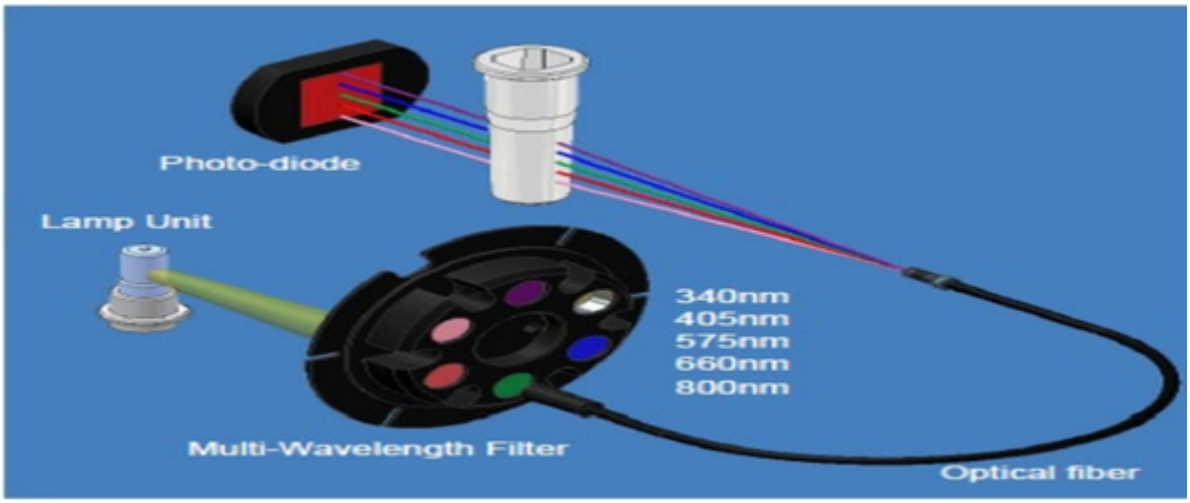
PRINCIPLE:

This procedure provides instruction for the analysis of Prothrombin Time (PT), activated Partial Thromboplastin Time (aPTT or PTT), quantitative Fibrinogen (Fib), high sensitivity D-Dimer (D-Dimer HS) and Heparin, liquid Anti Xa (Anti Xa) on the Sysmex CS2500 analyzer.

Describe the Multi-Wavelength Detection System:

The light source on the Sysmex CS-2500 System provides simultaneous multi wavelength scanning of reactions at 340, 405, 575, 660, and 800nm.

For clotting assays, multiple wavelengths can be evaluated by each detector well. A sample is evaluated by a primary wavelength and a secondary wavelength at the same time. If the result from the primary wavelength has analysis errors, the result from another wavelength may be displayed on the Job list. The function of using the result of a sub-wavelength is called a Wavelength Switch. This function makes it possible to obtain a result on the first run thereby minimizing repeats.



Wavelength Switch

Error Code	Benefit of Wavelength Switch
No Coagulation Slight Coagulation	A sample with a weak clot @ 660 nm may demonstrate a stronger clot (higher dH) @ 800 nm and therefore be reportable with the first analysis.
Turbidity Level Over	Optically challenged samples tend to exhibit interference @660 nm; this interference is typically minimized @ 800 nm.
Trans Light High	Extremely clear samples may demonstrate a higher dH with 800 nm

Coagulation Principle Clotting assay (PT, PTT)

on the CS-2500 use an evaluation method called Percentage Detection Method. The analysis of the reaction is plotted on a graph.

X-axis- Time in seconds

Y-axis- Transmitted light intensity in milli-absorbance units or mA

This graph is called the reaction curve. The sample/reagent mixture in the reaction cuvette is placed into a 37° C detection well. Light is transmitted through the cuvette. The light transmission in milli absorbance units is measured over time.

First, the analyzer determines the starting point of the reaction. This is called the baseline or bH. The baseline (bH) or starting point is called the 0% point of the curve.

As the sample starts to clot and gets more turbid, the transmitted light intensity decreases, and the reaction curve slopes downward. This should be a constant decrease in transmitted light as the coagulation factors convert to fibrin. When all the coagulation factors are converted to fibrin and the clotting reaction is complete, the reaction curve levels out and reaches the endpoint.

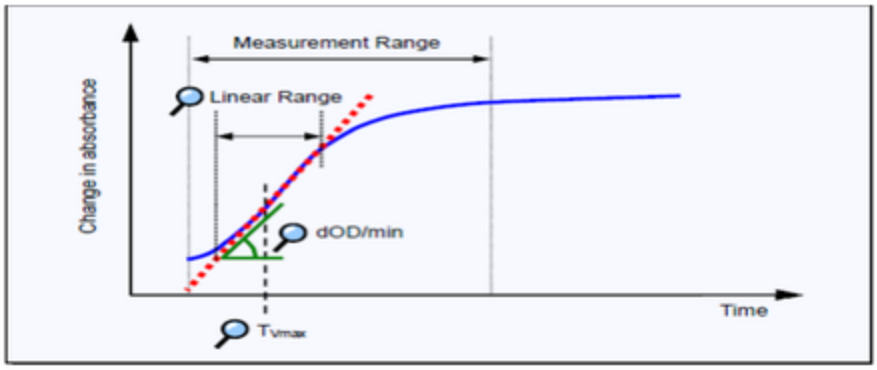
The endpoint is called the 100% point of the curve. The difference in transmitted light between the baseline and the endpoint is called the dH.

The dH indicates the intensity of the coagulation reaction. The clotting result is typically taken at the 50% point on the graph. This point is where the greatest change in light intensity occurs.

Immunoassay Principle (D-Dimer):

Immunoassay tests on the CS-2500 use the VLin Integral Method for evaluation. This is a process of antibody-sensitive reagent reacting with antibodies. This method measures the change in light absorbance.

Every sample is plotted onto a graph to create a reaction curve. On the X-axis is seconds and on the Y-axis is the Change in absorbance at the time point when the reaction reaches its steepest increase.



Chromogenic Principle Heparin, Anti-Xa (UFH and LMWH):

Chromogenic tests on the CS-2500 use the Rate Method for evaluation. The Rate method is the process of color emission by a chromogenic synthetic substrate. This method measures the change in absorbance.

Every sample is plotted onto a graph to create a reaction curve. On the X-axis is seconds and on the Y-axis is the Change in absorbance.

When the sample is first introduced into the reaction cuvette the kinetic reaction begins. The system then evaluates a predetermined Start Point and End Point to the reaction curve. The program then calculates the change in absorbance from the Start Point to the End Point.

EQUIPMENT:

Sysmex CS2500

QUALITY CONTROL:

Two levels of corresponding QC must be valid for every **8 hours** of patient testing. Anti-Xa controls must be valid for its corresponding Heparin, Anti-Xa test UFH or LMWH respectively.

PROCEDURE:

A. RUNNING PATIENT SAMPLES:

1.	Upon receipt of Sodium citrate (blue) top tube refer to procedure **Specimen Rejection, Acceptability and Stability Criteria** to verify specimen acceptability and stability. **NOTE:** Specimens for PT, PTT, Fib, D-Dimer and Anti-Xa must be spun in a Coagulation approved centrifuge and evaluated for acceptability BEFORE specimen testing. Errors in specimen integrity will cause erroneous coagulation results.
2.	If a sample appears to have significant hyperbilirubinemia or lipemia, the primary caregiver should be immediately notified to schedule a redraw for a time when patient conditions may reduce such interferences.
3.	**LIS order processing:** a. Place rack with barcoded sample tubes on the sampler. b. Check host connection (HC) status. HC status icon must be green or orange. c. Press Start. d. After barcode reading, confirm sample order status and progress on the Joblist screen.
4.	**Manual order processing:** 1. Press Order. 2. Enter Rack number. 3. Select tube position. 4. Press Order Entry. 5. Place cursor in Sample No. and input sample ID if sample does not have a barcode. 6. Select assays to be analyzed. 7. Press the down arrow to order the next sample. 8. Press OK

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9. then Start.
10. Place sample rack with tubes/cups on the sampler.
11. Confirm sample order status on the Joblist.

5.

Micro mode:

1. Follow Manual order Processing steps on previous page to ID sample and order test.
2. Press Mc column on Order screen.
3. Press Start.
4. Place sample rack with cups/uncapped tubes onto system.

6.

Change to longer measurement time:

1. Follow Manual Order Processing steps on page 27 to ID sample and order test. 2. Press Detailed Settings button.

3. Click box below Measurement Time.
4. Select measurement time.
5. Select OK.

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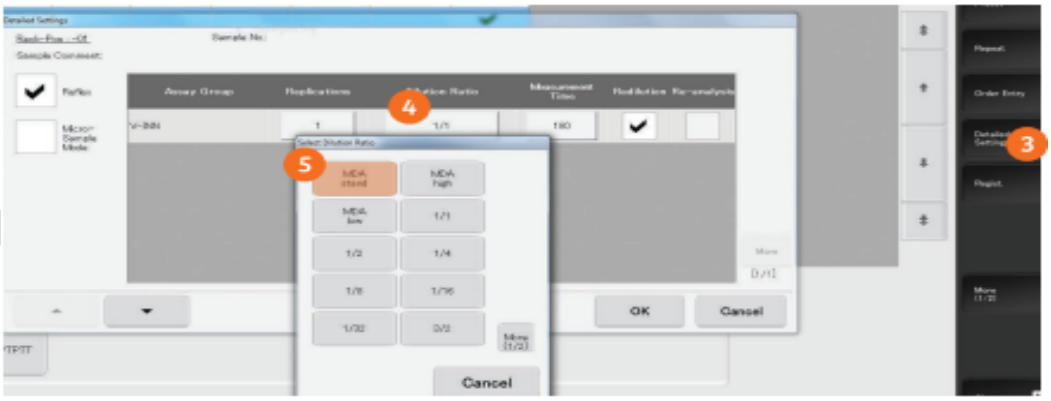
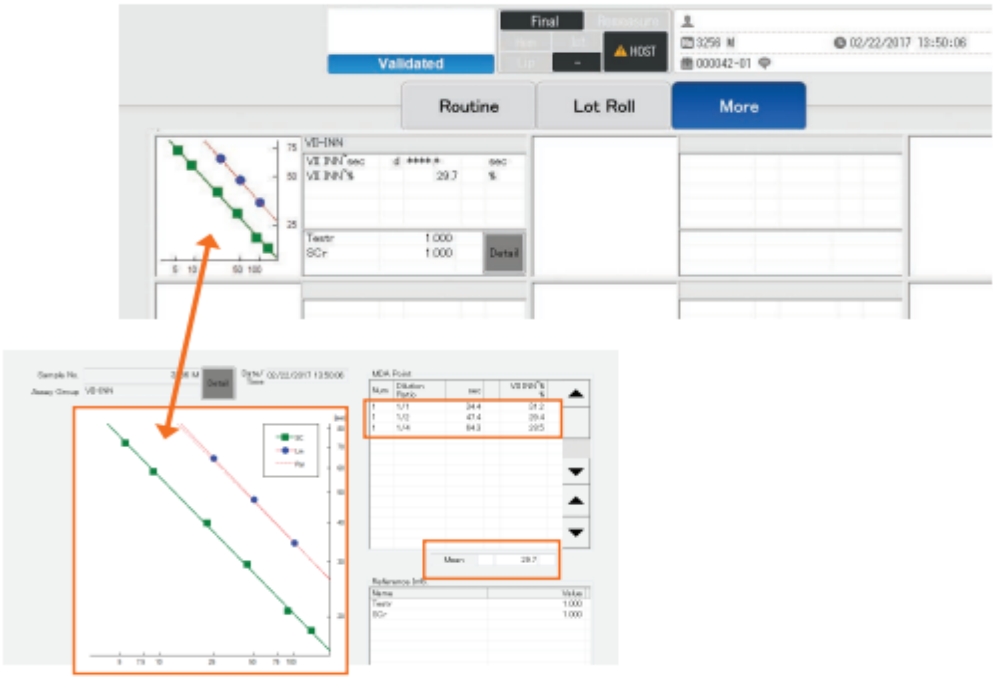
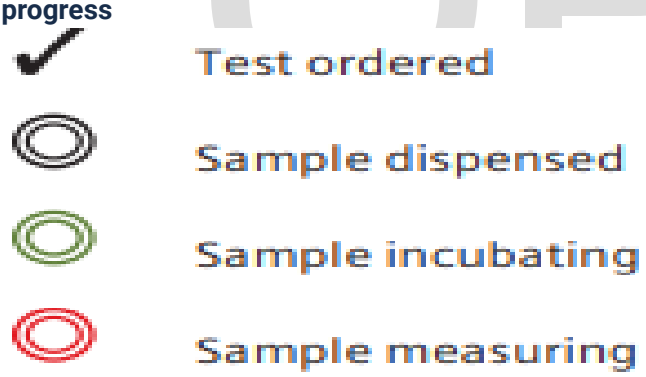
	6. Select Start
7.	**Patient sample requiring dilutions or repeat testing. Multiple dilution analysis:** 1. Press Order. 2. Order a factor assay on a specimen. Follow Manual Order Processing directions. 3. Press Detailed Settings operation key. 4. Select 1/1 key under Dilution Ratio. 5. Select MDA dilution. 6. Press OK. 7. Press Start.  **View results** 1. Press Joblist. 2. View Sample ID. View results for three MDA dilutions and mean . 3. Highlight mean result. 4. Press Browser key. 5. Press graph to display large graph. – View graph of results – View dilutions with results – View mean result.

MDA name	Dilution ratio		
MDA stand	1/1	**1/2**	**1/4**
MDA high	1/2	**1/4**	**1/8**
MDA low	1/1	**3/2**	2/1



B. REVIEWING SAMPLE RESULTS:

1. After loading the specimen on the Sysmex CS2500 check the specimen status.
Analysis progress



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Status	Meaning
Pending	Order is registered but analysis has not started.
Processing	Assay groups are being analyzed.
On Hold	All assay groups have been analyzed but a validated calibration curve is missing.
(Blank)	Analysis of all assay groups has been completed normally.
Review	Analysis completed but requires confirmation due to an analysis error.
Error	A hardware or reagent error has occurred.

2. Double click the sample of interest to review, validate or print patient results.
3. For more information on reviewing coagulation clot and reaction curves see **HEM 2.3.2 – Coagulation Results and Clot Curve Interpretations**.

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PROCEDURE NOTES:

INSTRUMENT TEST LINEARITY

Sysmex CS2500 analytical tests are only verified within the following ranges:

Sysmex CS2500 Clinical Reportable Range			
Test	**Lower Range**	**Upper Range**	**Dilution**
Prothrombin Time	8.7 seconds	90 seconds	N/A
Activated Partial Thromboplastin Time	20 seconds	139 seconds	N/A
Fibrinogen (and Low Fib)	50 mg/dL	860 mg/dL	Auto-Concentration
D-Dimer	0.19mg/L FEU	35.20 mg/L FEU	Automated (x10)
Heparin, Anti-Xa	0 IU/mL	1.5 IU/mL	N/A

INSTRUMENT FLAGS:

Sysmex CS2500 Common Data Flags		
Data Flag	**Description**	
*	Low reliability flag	
d	Dilution analysis	
<	Below report limit	
>	Above report limit	

R	Reanalyzed	
*** **	No result due to error	
XXX XX	No calibration curve	

LIMITATIONS:

PT and **APTT** results may be affected by many commonly administered drugs and further studies should be made to determine the source of unexpected abnormal results.

- **Fibrinogen** assay results may be affected by degradation (fibrin or fibrinogen) in the plasma assayed.

D-Dimer Immunoassay tests on the CS-2500 use the VLin Integral Method for evaluation. This is a process of antibody-sensitive reagent reacting with antibodies so the assay result may be affected by interference of Hemoglobin, lipid, and Bilirubin.

There is no interference for the following tests on the Sysmex CS2500 for analytes up to:

Sysmex CS2500 Interference Limitition

	Hemoglobin	Lipid	Bilirubin
PT	1000 mg/dL	288.8 mg/dL	60 mg/dL
APTT	1000 mg/dL	263.6 mg/dL	60 mg/dL
Fibrinogen	600 mg/dL	537.5 mg/dL	60 mg/dL
D-Dimer	1000 mg/dL	1327 mg/dL	18 mg/dL
Heparin, Anti-Xa	300 mg/dL	294.3 mg/dL	60 mg/dL

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REFERENCES:

Sysmex CS-2500 System Quick Reference Guide

Sysmex application sheets

CAP Accreditation Program – Hematology and Coagulation Checklist 08.24.2023

CAP Checklist Requirements

HEM.37400Alternative Method Criteria

HEM.37925D-dimer - Evaluation of VTE

HEM.37980Factor Assay Criteria

HEM.37984 Inhibitor Interference

All Revision Dates

2/24/2026

Attachments

image1.png

Approval Signatures

Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator, VCMC & SPH	2/24/2026
Laboratory Service Dept	M. Anwar Molani: Medical Director, Laboratory Services	2/24/2026
Laboratory Service Dept	Samah Meshreky: Supervisor-Hematology, Laboratory Services	2/24/2026
Laboratory Service Dept	Erlinda Roxas: Director, Laboratory Services	2/24/2026

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Status **Active** PolicyStat ID **19762407**

Origination	1/17/2024	Owner	Samah Meshreky: Supervisor-Hematology, Laboratory Services
Last Approved	2/24/2026		
Effective	1/17/2024	Policy Area	Laboratory Services
Last Revised	2/24/2026		
Next Review	2/24/2028		

L.CGL 2.4 Coagulation Testing Review Criteria

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PRINCIPLE:

Many laboratories have adopted guidelines or applied criteria for review of coagulation results from automated analyzers.

Review criteria are generated by instrument suspect flags, messages codes or specimen abnormalities. Rules which trigger a review of automated results can be caused by a variety of situations potentially leading to further testing.

PROCEDURE:

DELTA CHECKS

The following delta limits are setup in the LIS system and may NOT flag on the Sysmex CS2500 instrument. Delta limits are often exceeded due to an intravenous line or a recent transfusion. A patient's medical condition or medication can also trigger delta checks such as anti-coagulant therapy, dehydration, dialysis, etc.

The *corrective action* for delta checks is to evaluate specimen integrity (check for clots, lipemia, icterus, QNS or stability limit) and check patient status or history to identify the cause of the delta flag. Add a comment in the LIS system such as result checked, nurse notified, patient transfused, etc. to confirm that laboratory personnel is properly performing quality assurance on released patient results.

VCMC Coagulation Delta Limits

Analyte	Delta Limit	Time Period (within)
INR	1 unit	7 days

FIB	50%	5 days

REVIEW HIGH/LOW AND CRITICAL RESULTS

Review and critical limits are a guide to inform the physician that a coagulation result(s) is/are abnormal.

For a majority of cases the *corrective action* for a review low/high time is to check the specimen for a clot and rerun patient sample. For critical results corrective action, see coagulation **Critical Results Procedure**.

VCMC Hematology Review & Critical Values

Analyte	Critical High	Review Low	Review High	Review Low/High Corrective Action
INR	≥3.9			
PTT	≥118	<21	≥118	Review low: check specimen for clot, recollect specimen to confirm. Review high: check specimen for clot, rerun to confirm.
FIB		<100	>860	Review law: check specimen for clot, rerun to confirm. Review high: perform specimen dilution to confirm
D-DIMER	>7.5		>7.5	Review high: see analyzer automated dilution or perform specimen dilution to confirm
Heparin Anti- Xa	0.70			

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PROCEDURE NOTES:

Misleading results can occur if:

- The specimen is not properly collected, stored or transported;
- Specimen contains clots (which causes false results for all parameters). Always use good laboratory practices for inspecting specimens for clots and verifying results.

REFERENCES:

Sysmex Cs2500 Quick Reference Guide – version01-70

CAP Accreditation Program – Hematology and Coagulation Checklist 08.24.2023

CAP Checklist Requirements

HEM.36920Specimen Quality Assessment – Coagulation

All Revision Dates

2/24/2026

Approval Signatures

Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator, VCMC & SPH	2/24/2026
Laboratory Service Dept	M. Anwar Molani: Medical Director, Laboratory Services	2/24/2026
Laboratory Service Dept	Samah Meshreky: Supervisor-Hematology, Laboratory Services	2/24/2026
Laboratory Service Dept	Erlinda Roxas: Director, Laboratory Services	2/24/2026

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Status **Active** PolicyStat ID **19762449**

VENTURA COUNTY HEALTH CARE AGENCY

Origination	1/17/2024
Last Approved	2/24/2026
Effective	1/17/2024
Last Revised	2/24/2026
Next Review	2/24/2028
Owner	Samah Meshreky: Supervisor-Hematology, Laboratory Services
Policy Area	Laboratory Services

L.CGL 3.1 High Hematocrit (HCT) Correction

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PRINCIPLE:

A patient with high hematocrit, greater than 55%, will result in less plasma after centrifugation. The plasma fraction will contain an increased concentration of sodium citrate anticoagulant.

The increased concentration may result in falsely prolonged test results for Prothrombin Time (PT) and Activated Partial Thromboplastin Time (aPTT). The anticoagulant must be reduced in the tube before filling with whole blood. The adjustment is to assure the plasma: anticoagulant ratio (not the blood: anticoagulant ratio) stays consistent.

EQUIPMENT:

Blood Venipuncture Syringe

2.0 or 3.0 mL, 3.2% buffered sodium citrate blue top tube

Calibrated adjustable pipette and pipette tips

PROCEDURE:

1.	Using a pipette and the ***Anticoagulant Adjustment Guideline*** chart, remove the appropriate amount of sodium citrate.
2.	Give the tube to the phlebotomist or collecting personnel along with a draw syringe. With instructions to collect blood venipuncture via syringe and immediately dispense the appropriate amount of blood into the adjusted anticoagulated tube.
3.	After specimen is collected, mix by inversion, process, centrifuge and test as normal.

PROCEDURE NOTES:

Anticoagulant Adjustment Guideline for High HCT Specimens				
Hematocrit	Tube Size	Required Anticoagulant	Required Blood	**Amount of Anticoagulant to Remove**
56 – 59%	2.0 mL	150 µL	1.85 mL	**50 µL**
> 60%	2.0 mL	100 µL	1.90 mL	**100 µL**
56 – 68%	3.0 mL	200 µL	2.80 mL	**100 µL**
> 69%	3.0 mL	150 µL	2.85 mL	**150 µL**

REFERENCES:

CLSI Guideline for reference is "Collection, Transport, and Processing of Blood Specimen for Testing Plasma-Based Coagulation Assays and Molecular Hemostasis Assays: Approved Guideline – Fifth Edition," H21-A5 Vol. 28 No. 5.

Midyett, R. "Under the blue top: coags, corrections, and 'crits"; Medical Laboratory Observer (MLO), February 2005, pages 20/22. Legacy Health

Marlar, R., et.al, Effect on routine and Special Coagulation Testing Values of Citrate Anticoagulant Adjustment in Patients with High Hematocrit. Values; Am J Clin Pathol, 2006, 126: 400-405

CAP Accreditation Program – Hematology and Coagulation Checklist 08.24.2024

CAP Checklist Requirements

HEM.36900Elevated Hematocrits – Coagulation

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All Revision Dates

2/24/2026

Approval Signatures

Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator, VCMC & SPH	2/24/2026
Laboratory Service Dept	M. Anwar Molani: Medical Director, Laboratory Services	2/24/2026

Laboratory Service Dept	Samah Meshreky: Supervisor-Hematology, Laboratory Services	2/24/2026
Laboratory Service Dept	Erlinda Roxas: Director, Laboratory Services	2/24/2026

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Status **Active** PolicyStat ID **19762592**

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Effective	1/17/2024
Last Revised	2/24/2026
Next Review	2/24/2028
Owner	Samah Meshreky: Supervisor-Hematology, Laboratory Services
Policy Area	Laboratory Services

L.CGL 3.2 Coagulation Results and Clot Curve Interpretations

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PRINCIPLE:

Coagulation results can be flagged by the analyzer as "failed" when data fails to meet defined criteria for that assay. These "failures" shown by error flags, may be associated with pre-analytical variables as well as pathological conditions. Flags may indicate a problem with the results such as values that exceed critical limits, inability to detect an accurate end-point, or values outside of the linear range.

The Sysmex CS2500 analyzer graphs the formation of the clot. A clot curve is a visual representation of the coagulometric or absorbance reaction taking place in a cuvette on the analyzer. The clot signature curve is a valuable tool for investigation abnormal or questionable results.

Flawed specimen integrity, such as the following, can also trigger flags:

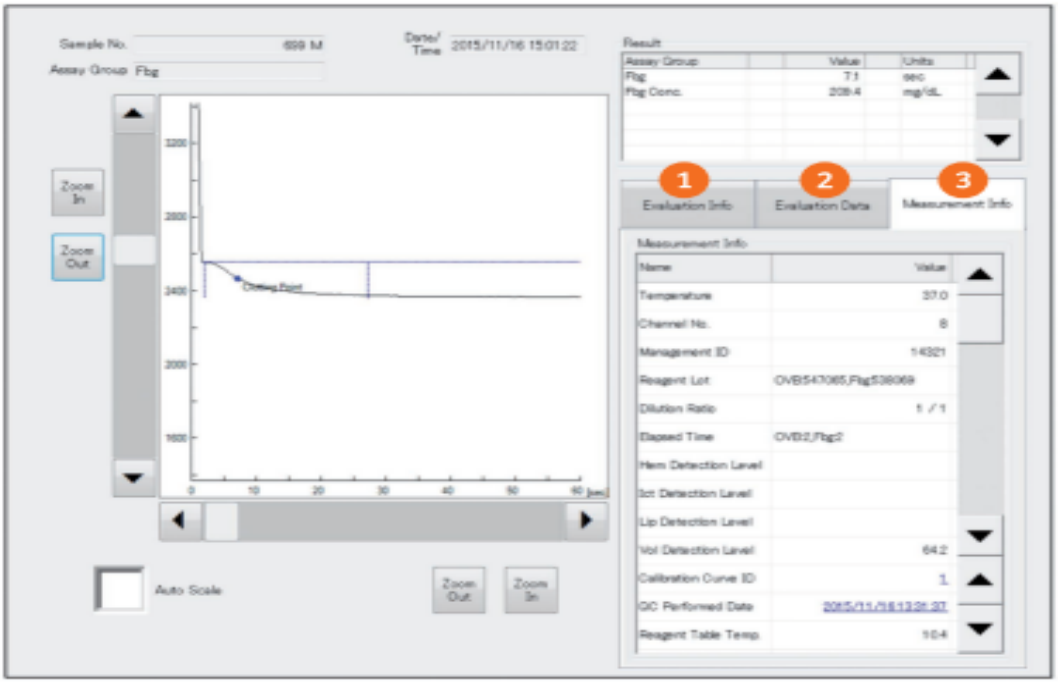
- **Clotted**: will cause falsely shortened clotting times because of premature activation of coagulation factors and platelets that generate FVIIa and thrombin.
- **Lipemia:** may cause falsely prolonged clotting times because of interference with light transmittance.
- **Hemolysis:** may cause falsely shortened clotting times because of premature activation of coagulation factors and platelets that generate FVIIa and thrombin.
- **Icterus (bilirubinemia):** indicates liver dysfunction that may lead to prolonged clotting times because of inadequate clotting factor production.

EQUIPMENT:

Sysmex CS2500

PROCEDURE:

1.	See Procedure L.CGL **2.3 - Running Patient Specimens – Sysmex CS2500** for instructions regarding running specimens and selecting sample results for review. NOTE: All coagulation samples should be investigated before testing for hemolysis, lipemia, icterus,

	stability limit and proper fill. Errors in specimen integrity will cause erroneous coagulation results.
2.	The Sysmex CS2500 analyzes patient samples by Multi-Wavelength Detection System If a sample appears to have significant hyperbilirubinemia or lipemia, the primary caregiver should be immediately notified to schedule a redraw for a time when patient conditions may reduce such interferences.
3.	**Reaction curve** • Press graph on Browser to view reaction curve. • View the reaction curve shape. • Press the three tabs for more information. 1. Evaluation Info tab displays: – bH: baseline – dH: reaction intensity – Coag %: where clot time is read – Wavelength: alternative wavelength used – Start and end time for chromogenic/DDi 2. Evaluation Data tab displays 1%–100% time for reaction curve 3. Measurement Info tab displays: – Reagent lot used – Dilution ratio – Reagent elapsed time-hours onboard – Hem detection level – Lip detection level – Vol detection level – QC performed date – Reagent table temperature 
4.	The standard curve

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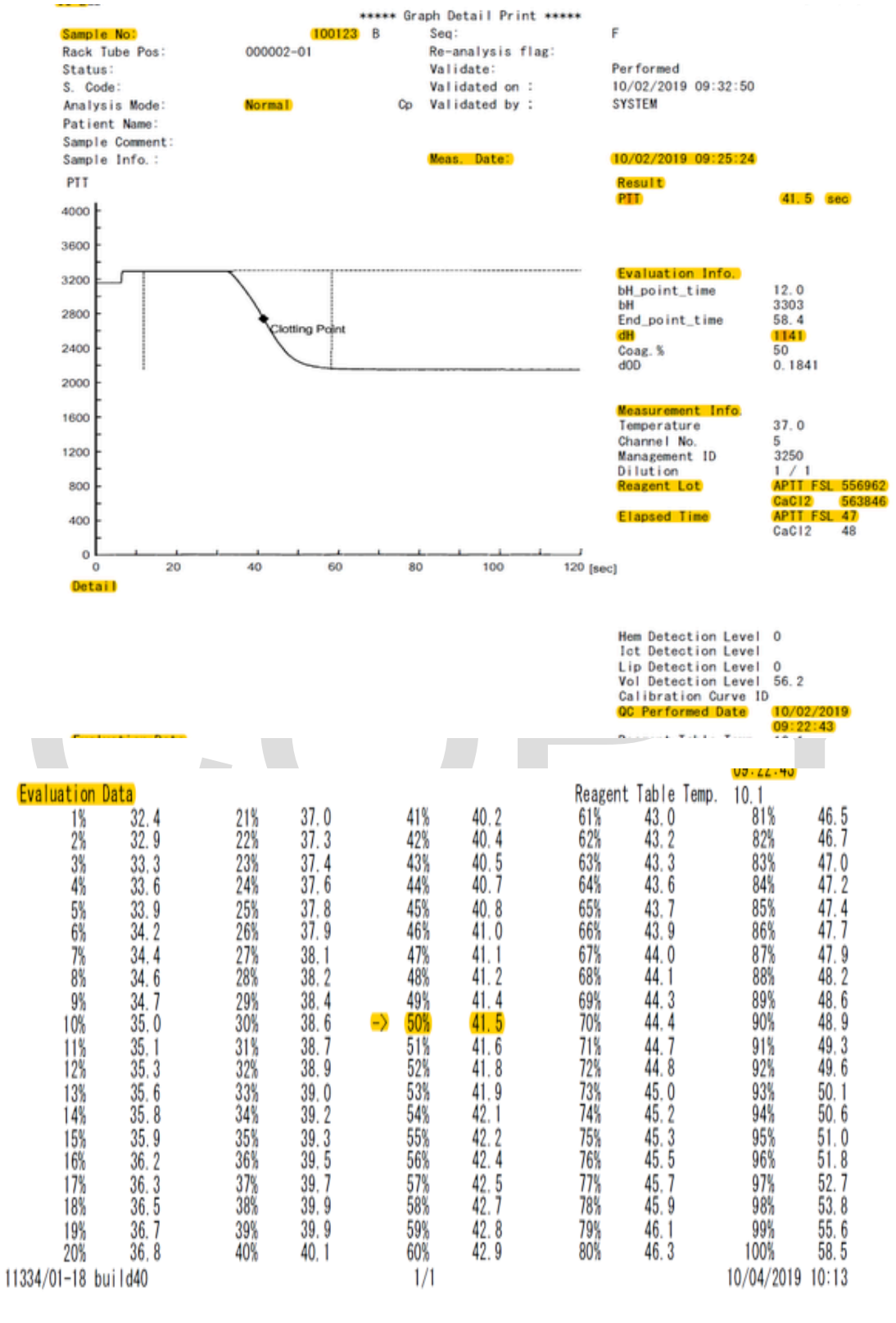
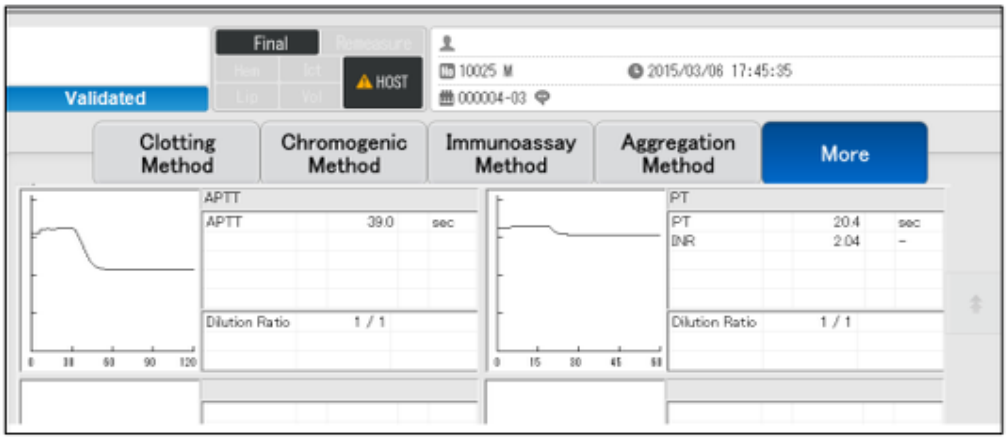
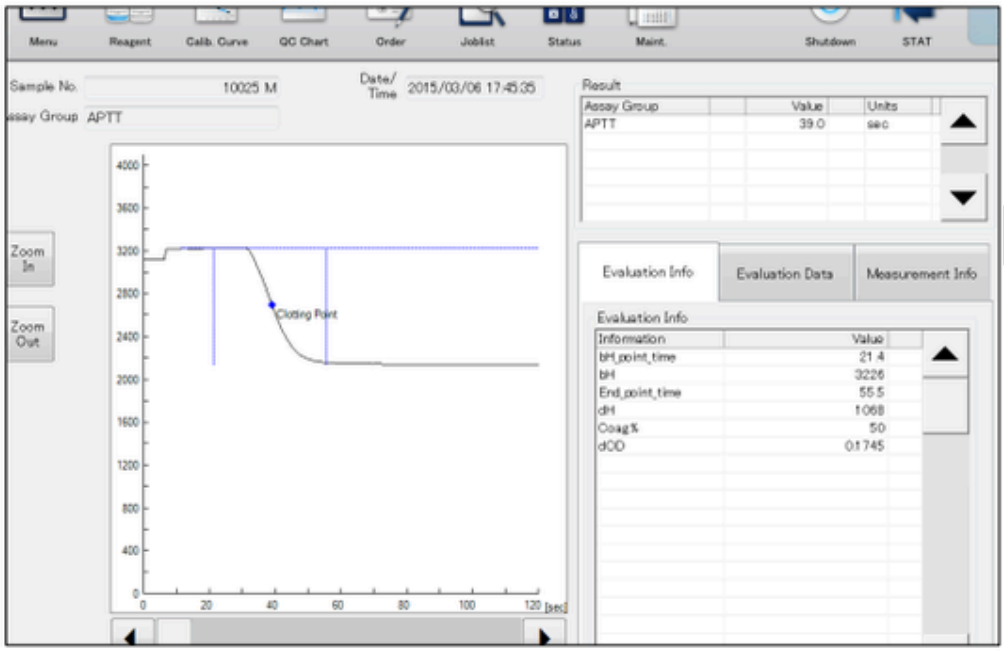
	
5.	Normal Result:

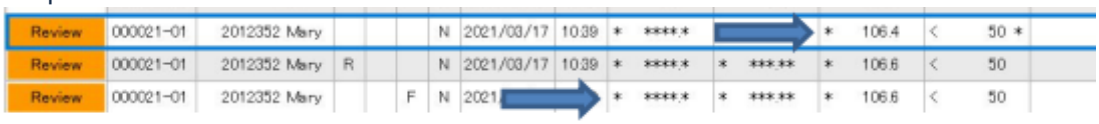
Browser screen



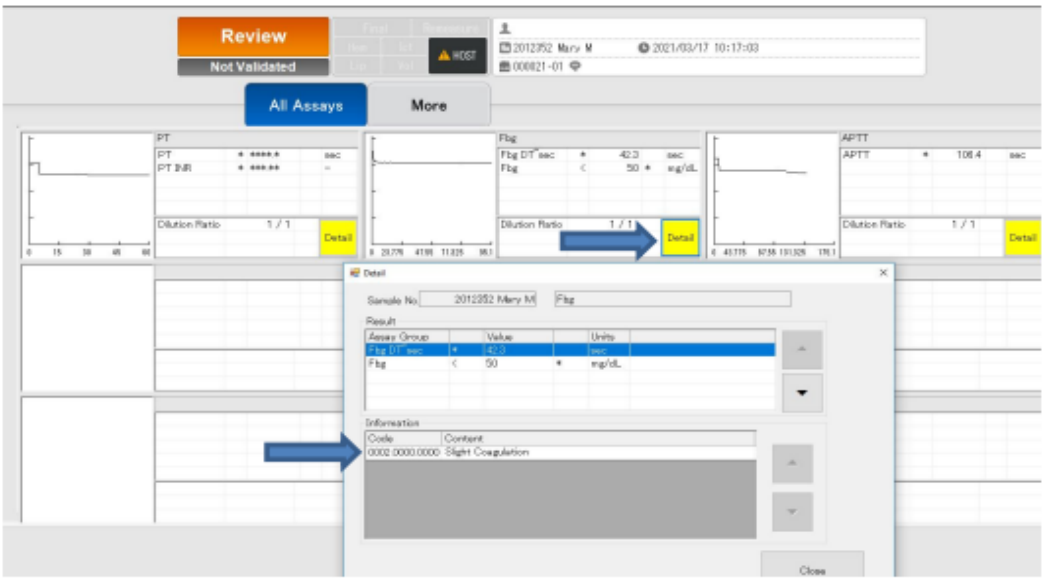
Reaction Curve



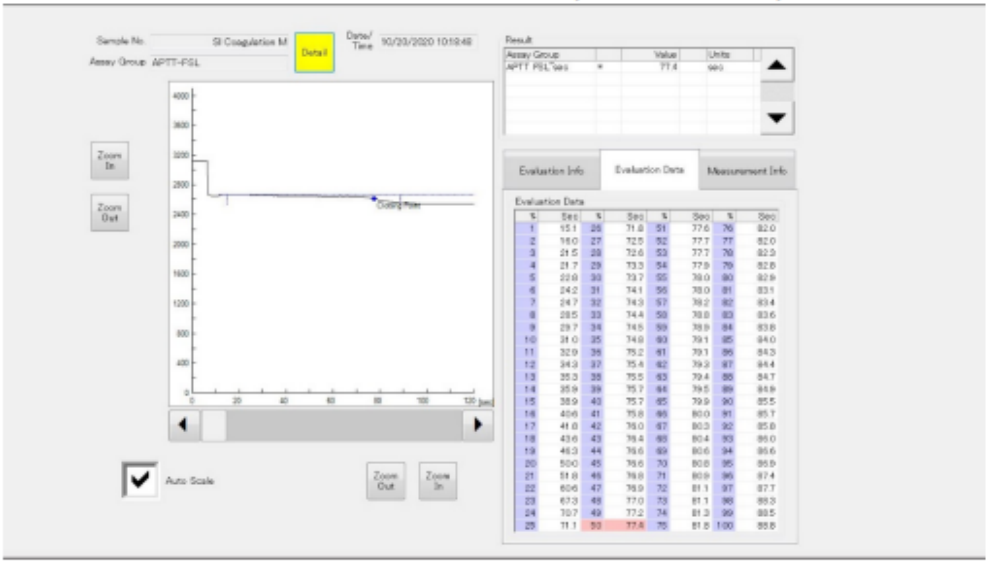
6. Abnormal Result- **Review**:
Joblist screen: Status is Review. Results are displayed as asterisks or flagged with an asterisk. The sample result is abnormal.



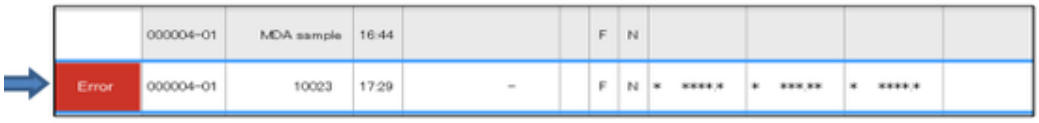
Browser screen: Flagged results have a yellow Detail key. Select the Detail key for information. Review results are due to sample abnormality. Detail key: Displays the Analysis Result Error.



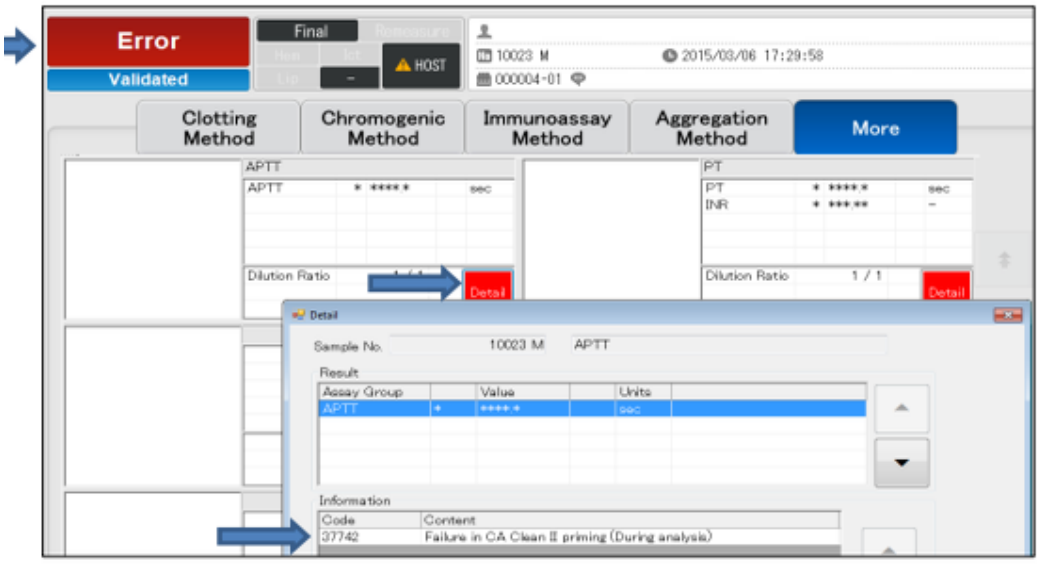
Reaction Curve screen: View tabs Evaluation Info, Evaluation Data, Measurement Info.



7. Abnormal Result – **Error:**
Joblist screen: Status is Error. Results are displayed as asterisks only.



Browser screen: Error results have a red Detail key. Select the Detail key for information. Errors are due to a system error. These are not due to sample abnormalities.

	
8.	If the clot curves are acceptable, AND a numerical result was given, **Validate Results**
9.	If clot curves are not acceptable, OR a numerical result is not available, (ensure specimen integrity is NOT affected, i.e. hemolysis, fill, lipemia, stability limit e.t.c) request a redraw of patient sample.
10.	If **Step. 8** applies to redrawn specimen, notify the primary caregiver that coagulation was not observed, and report results as "No Coagulation Seen". Print instrument results with reaction curves and file for secondary review.

COPY

Examples for Reviewing Clot Curves:

Example #1

Test- PT

Result- *16.7 sec, 1.68 INR

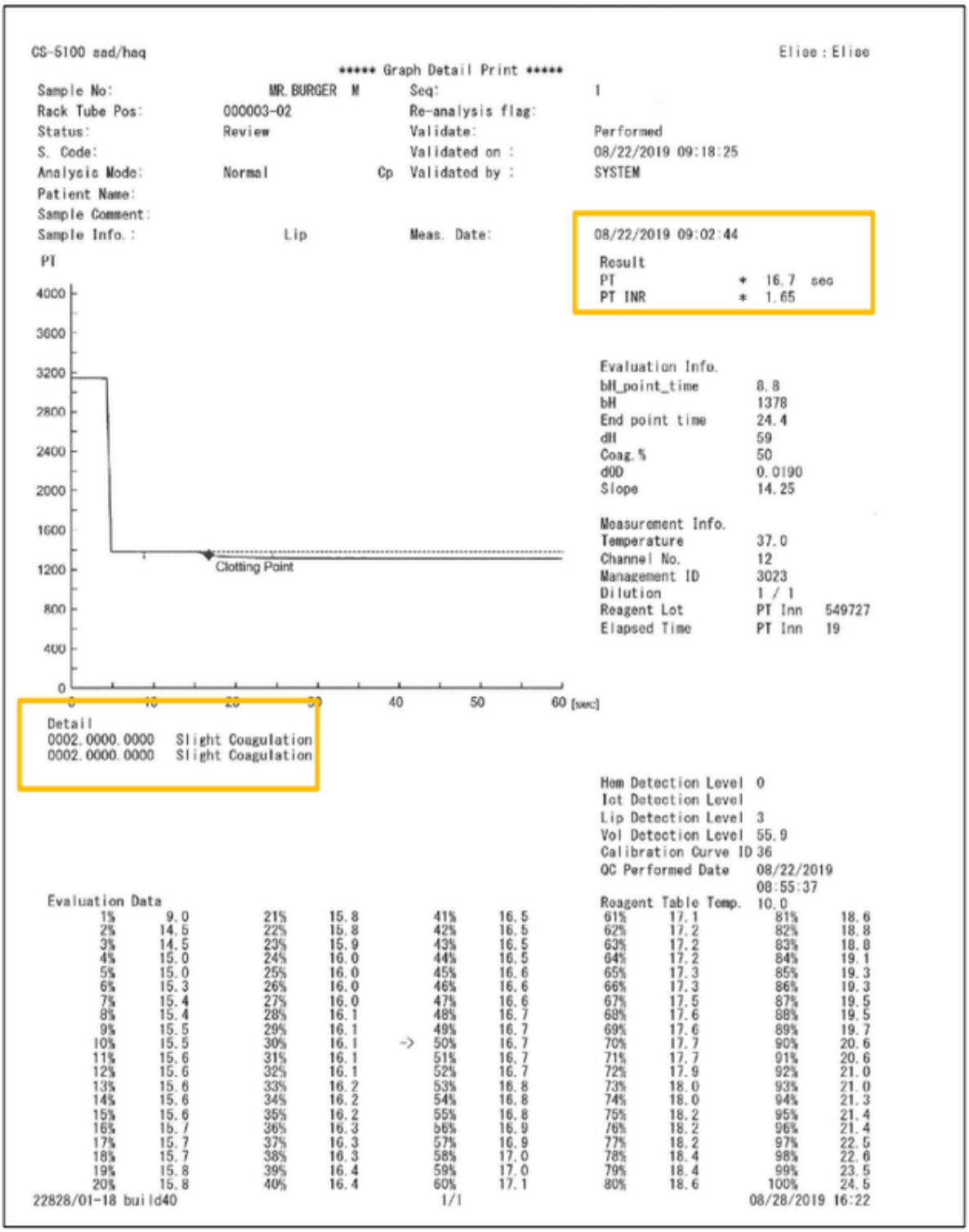
Error- Slight coagulation

Automatic reanalysis- Yes

Action steps- Verify reagent and sample integrity. Verify QC.

An automatic reanalysis will be performed.

Reportable result- If reanalysis produces a result without an error, it may be reported. If reanalysis produces a Slight Coagulation error again with comparable results, it may be reported.



Example #2

Test-PTT

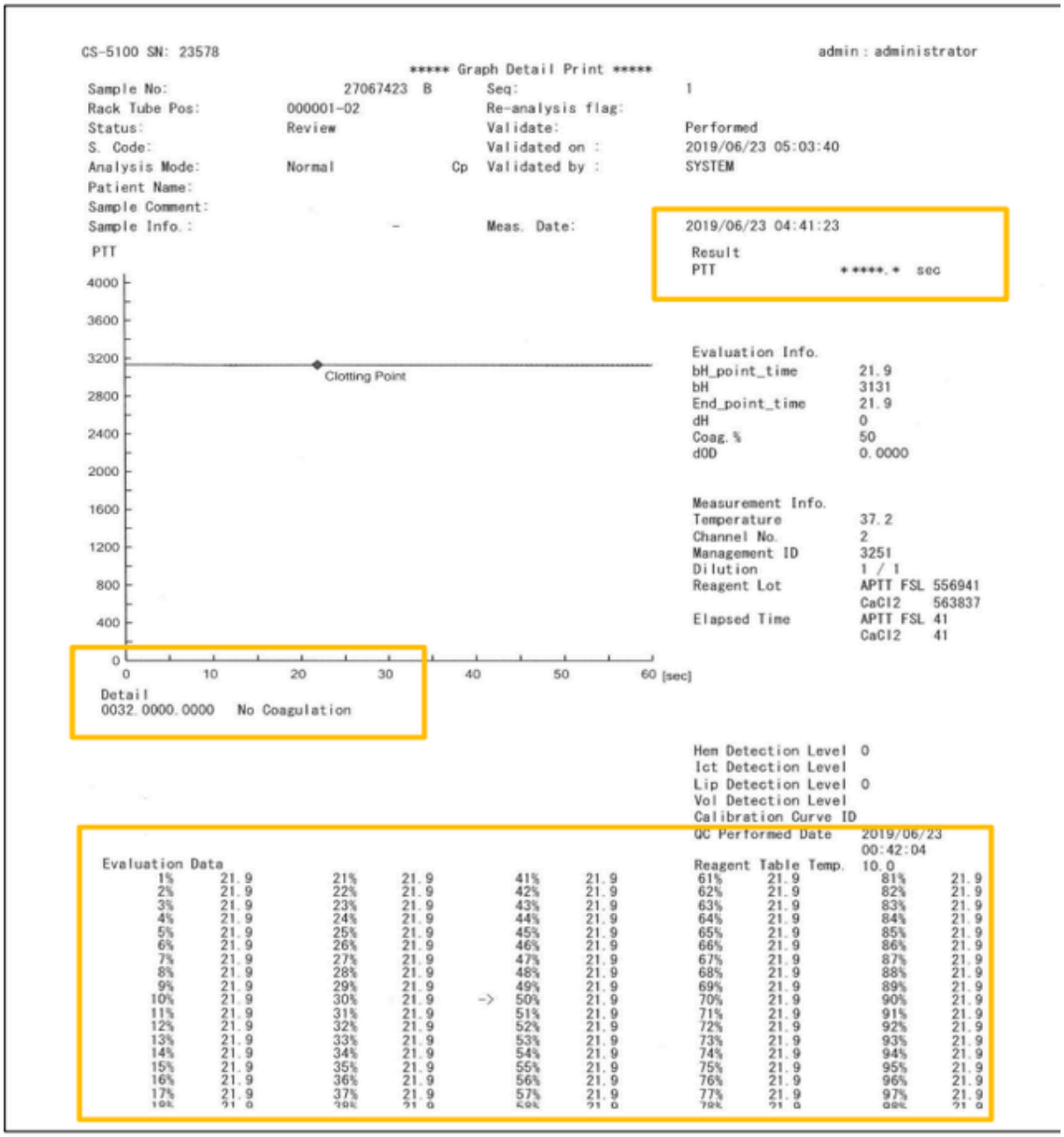
Result-***.* No numerical result

Curve- no baseline, no clotting phase, no endpoint. A straight line.

Error-No Coagulation Automatic reanalysis- Yes

Action steps- Verify reagent and sample integrity. Verify QC. An automatic reanalysis at a longer measurement time will be performed.

Reportable result-If reanalysis produces result without error, it may be reported. If reanalysis produces No Coagulation again, determine if result is plausible. Check sample integrity. It may be reported as greater than your Reportable limit.



Example #3

Test-PTT

Result-*115.3 sec

Error-Analysis Time Over

Automatic reanalysis-Yes

Action steps-Check sample for possible anticoagulant contamination. Verify reagent and sample integrity.

Check patient history-are they on heparin. Verify QC.

An automatic reanalysis at a longer measurement time will be performed.

Coagulation Curve reanalysis at longer measurement time

Result-127.3 sec

Error- no error

Reportable result-The Reanalysis result does not have an error. Report the result.

Initial Run:

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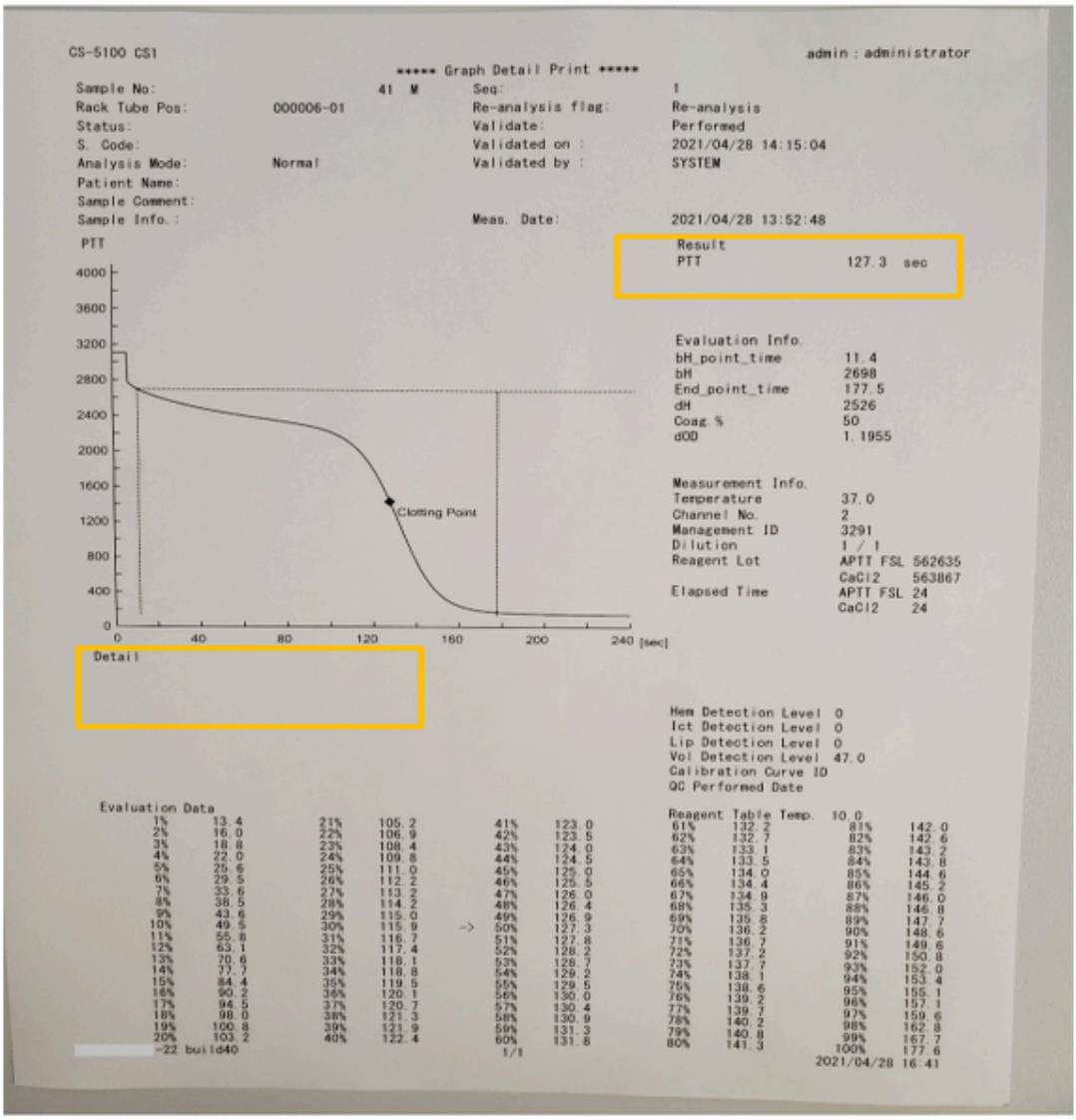
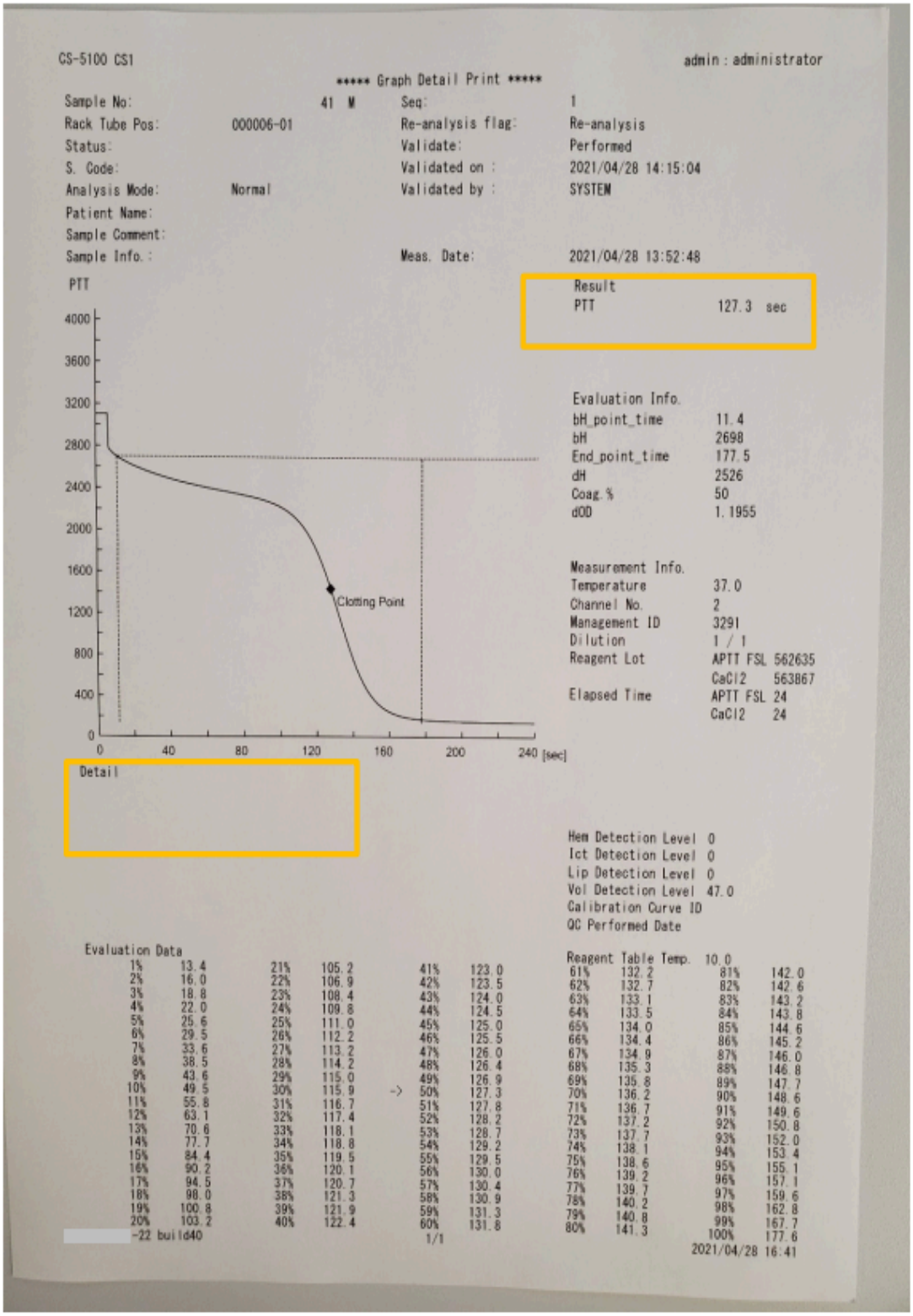


Reanalysis at longer measurement time:



Example #4

Test-PTT

Result-***.* No numerical result

Error-Early Reaction Error-Early %

Automatic reanalysis- Yes

Action steps- Verify reagent and sample integrity.

Verify error code. (Early %) An automatic reanalysis will be performed.

Check the Evaluation data- the 8% value is less than 16.8 sec- Do not report.

Reportable result- Do not report. Recollect specimen.

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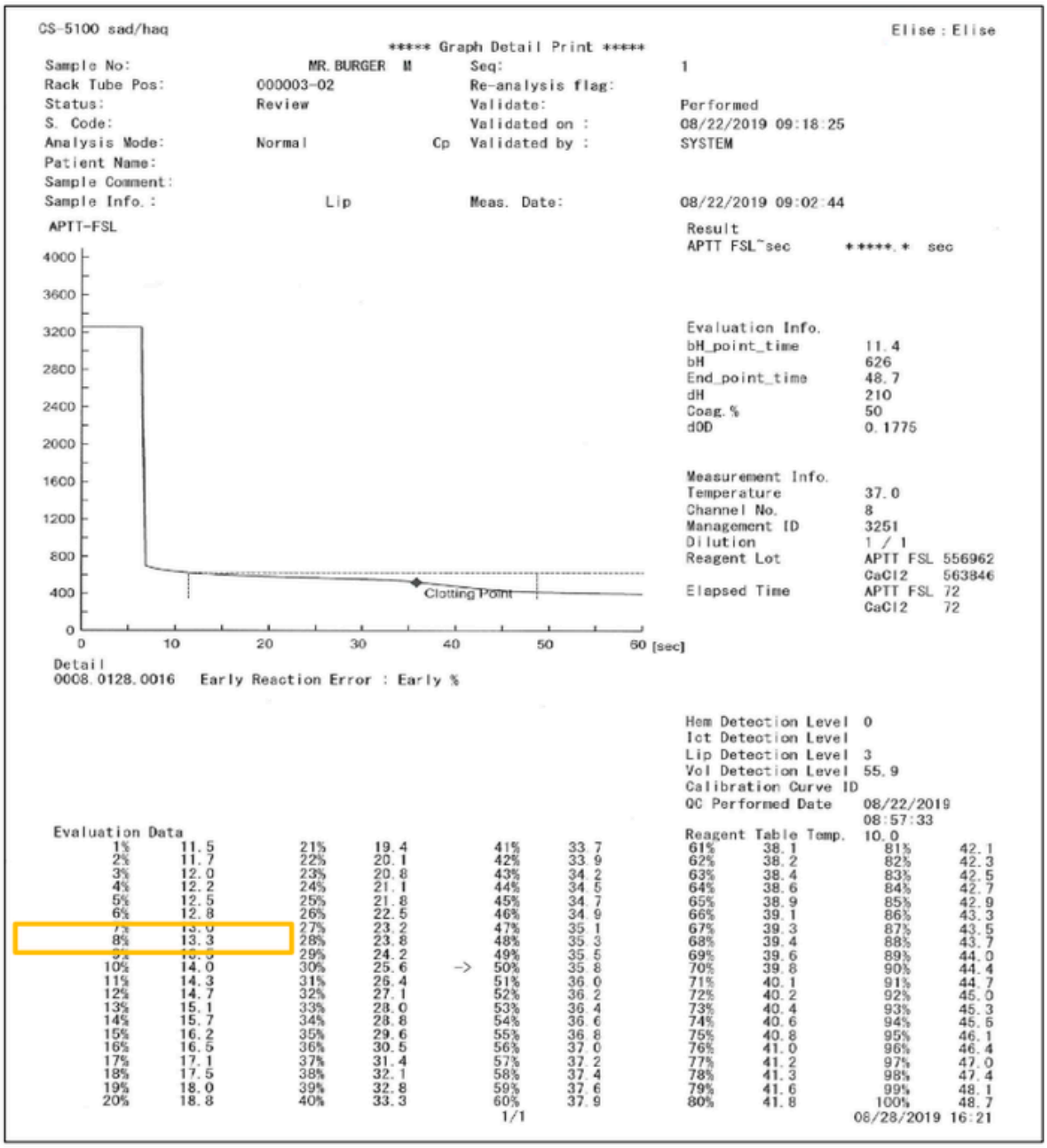


Example #5

Test-PT

Result-***.* No numerical result

Error- Flat Curve

Automatic reanalysis- Yes

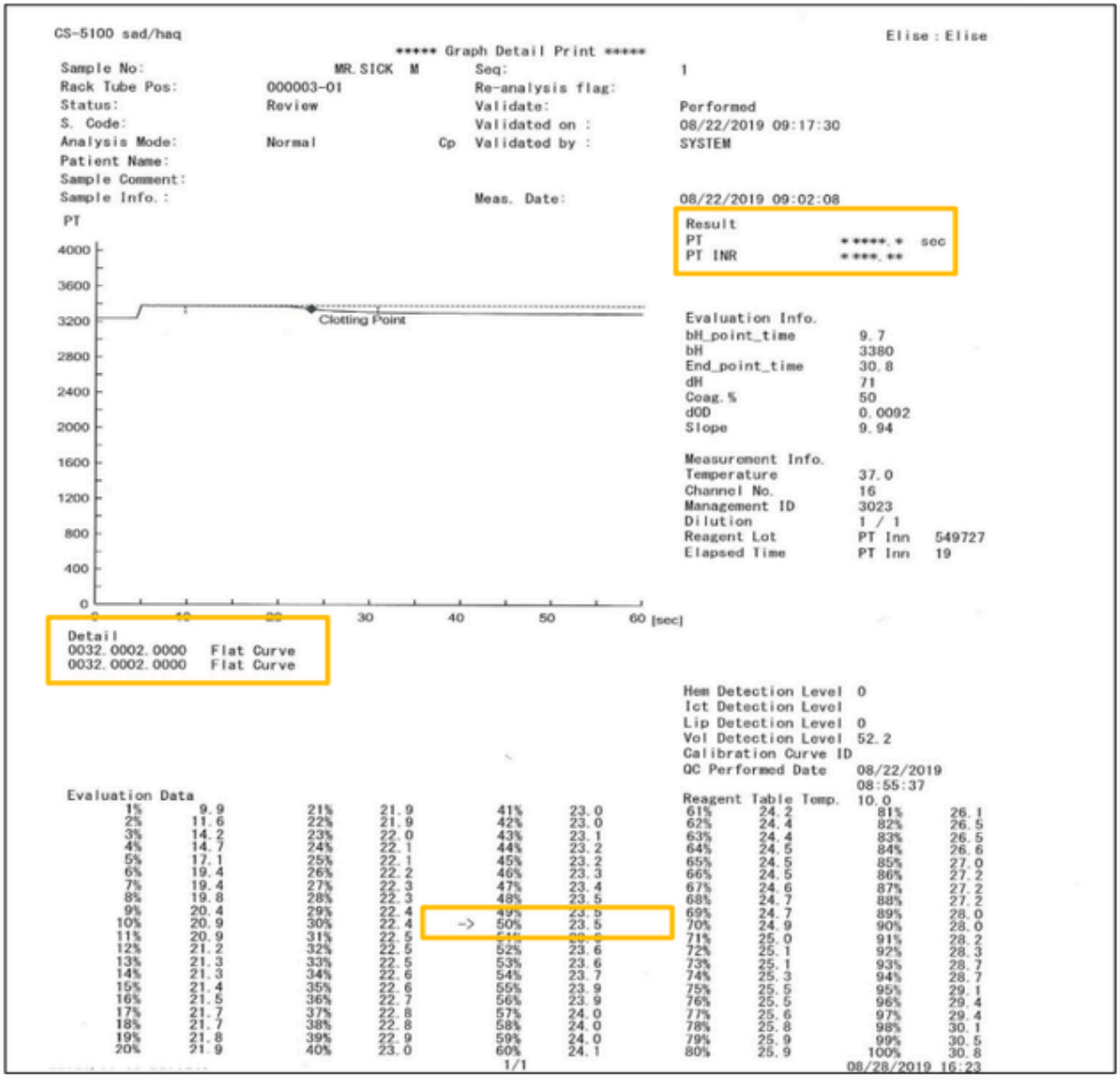
Action steps- Verify reagent and sample integrity. Verify QC.

An automatic reanalysis at a longer measurement time will be performed.

Check the reaction curve for a normal baseline, clot phase, and endpoint. Compare the Evaluation data results at the 50% for both the first run and the reanalysis.

Reportable result-If reanalysis result is without an error, it may be reported. If the reanalysis at the longer measurement time produces Flat Curve again, and the results are comparable, it may be reported.

Use the PT Calib. Curve for the current lot to calculate the INR for the result.



Example #6

Test-PTT

Result- *108.4 sec

Error- Analysis Time Over

Automatic reanalysis- Yes

Action steps- Check sample for possible anticoagulant contamination. Verify reagent and sample integrity.

Check patient history. Verify QC.

An automatic reanalysis at a longer measurement time will be performed.

Test- PTT

Result- *124.9 sec

Error- Coag % Changed: This error occurs on samples that have a biphasic reaction curve. The coagulation time is corrected and the Coagulation detection % is changed.

Action steps- Verify reagent and sample integrity. View the reaction curve. View the Evaluation data to view the detection % used. What % is being used-

70% Can this be reported-Yes, this may be reported.

Initial Run:

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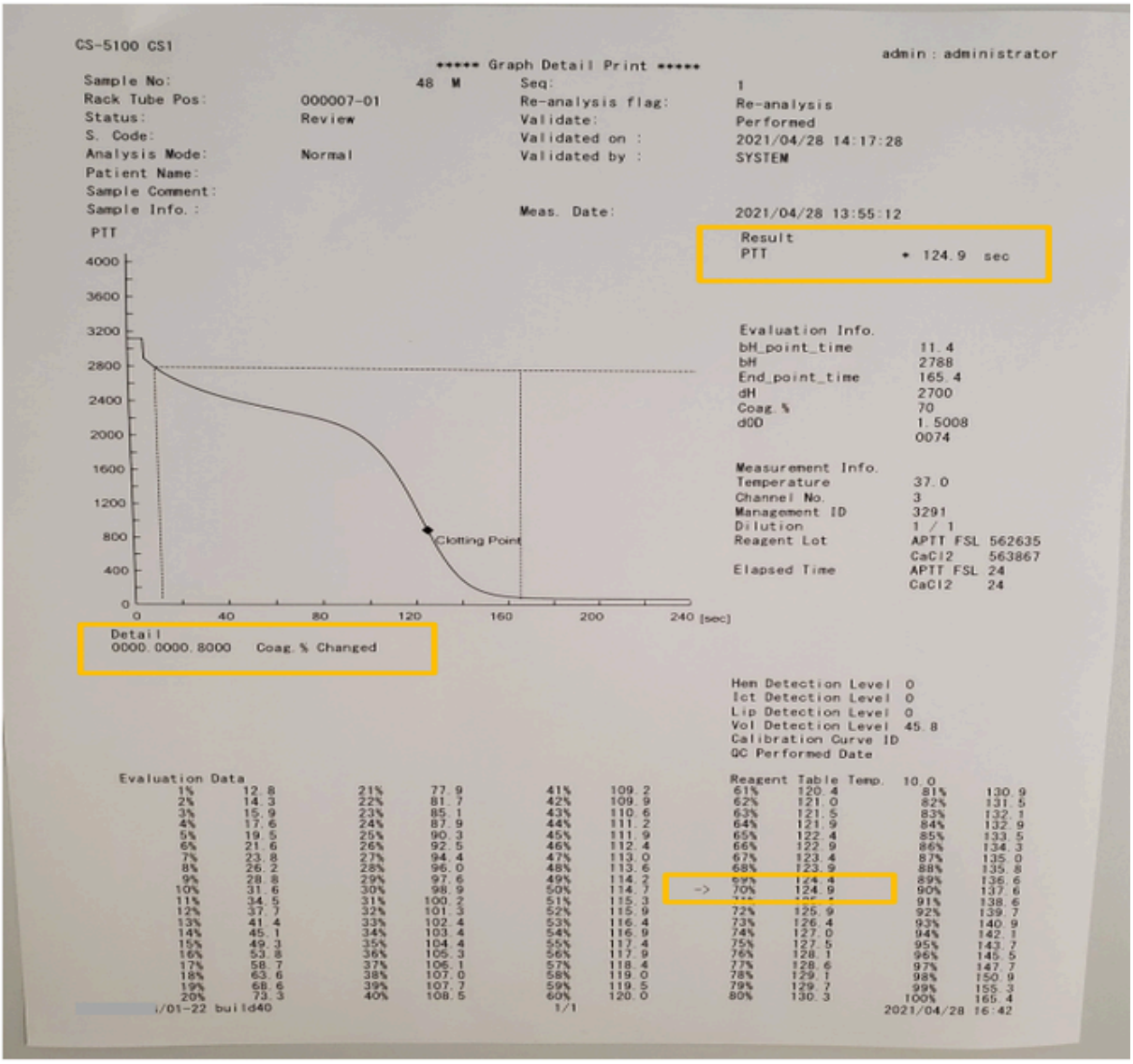
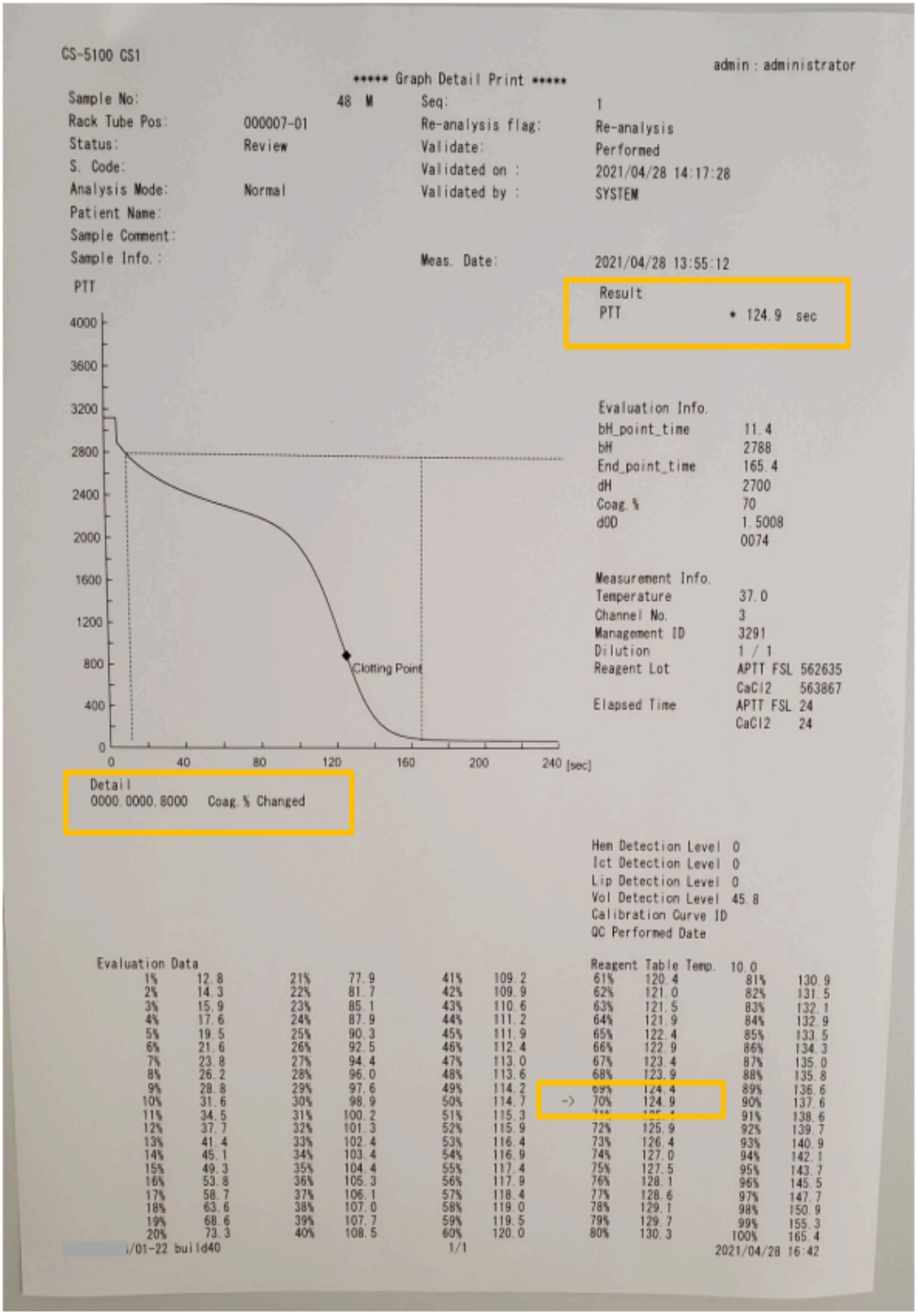


-Reanalysis at longer measurement time:



Example #7

Test-PTT

Result-*152 sec

Error- Early Reaction Error- Slow Reaction

Automatic reanalysis- Yes

Action steps- Result is >100 sec.

An automatic reanalysis at a longer measurement time will be performed. Check the reaction curve. Reaction curve has a normal baseline, clot phase, and endpoint.

Reportable result- Yes, this may be reported.

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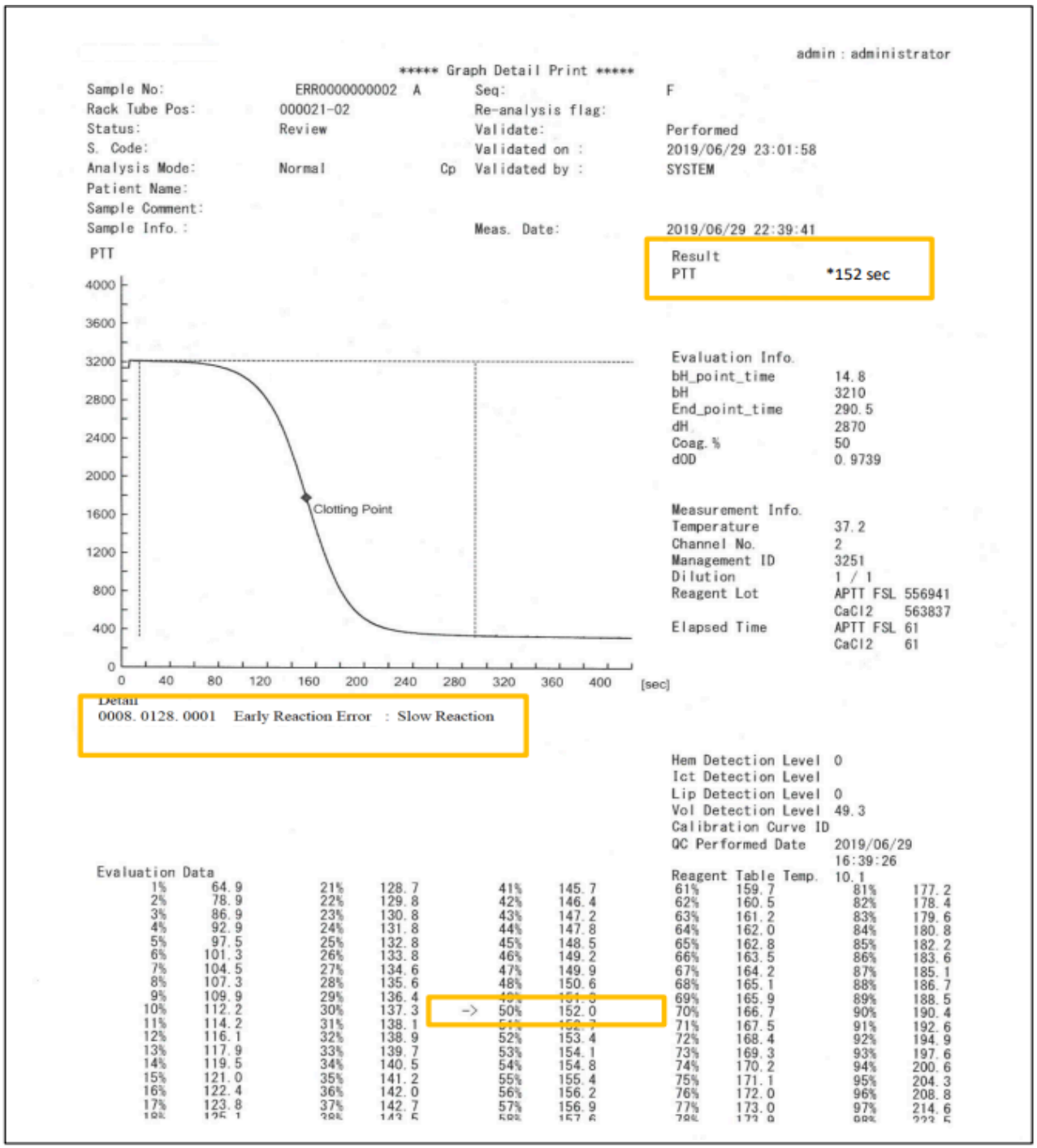

admin : administrator

***** Graph Detail Print *****

Sample No:	ERR0000000002 A		Seq:		F
Rack Tube Pos:	000021-02		Re-analysis flag:		
Status:	Review		Validate:		Performed
S. Code:			Validated on :		2019/06/29 23:01:58
Analysis Mode:	Normal	Cp	Validated by :		SYSTEM
Patient Name:					
Sample Comment:					
Sample Info. :			Meas. Date:		2019/06/29 22:39:41

PTT

Result
PTT *152 sec

Evaluation Info.

bH_point_time	14.8
bH	3210
End_point_time	290.5
dH	2870
Coag.%	50
dOD	0.9739

Measurement Info.

Temperature	37.2
Channel No.	2
Management ID	3251
Dilution	1 / 1
Reagent Lot	APTT FSL 556941
	CaCl2 563837
Elapsed Time	APTT FSL 61
	CaCl2 61

Detail
0008. 0128. 0001 Early Reaction Error : Slow Reaction

Hem Detection Level	0
Ict Detection Level	
Lip Detection Level	0
Vol Detection Level	49.3
Calibration Curve ID	
QC Performed Date	2019/06/29 16:39:26
Reagent Table Temp.	10.1

Evaluation Data

1%	64.9	21%	128.7	41%	145.7	61%	159.7	81%	177.2
2%	78.9	22%	129.8	42%	146.4	62%	160.5	82%	178.4
3%	86.9	23%	130.8	43%	147.2	63%	161.2	83%	179.6
4%	92.9	24%	131.8	44%	147.8	64%	162.0	84%	180.8
5%	97.5	25%	132.8	45%	148.5	65%	162.8	85%	182.2
6%	101.3	26%	133.8	46%	149.2	66%	163.5	86%	183.6
7%	104.5	27%	134.6	47%	149.9	67%	164.2	87%	185.1
8%	107.3	28%	135.6	48%	150.6	68%	165.1	88%	186.7
9%	109.9	29%	136.4	49%	151.3	69%	165.9	89%	188.5
10%	112.2	30%	137.3	-> 50%	152.0	70%	166.7	90%	190.4
11%	114.2	31%	138.1	51%	152.7	71%	167.5	91%	192.6
12%	116.1	32%	138.9	52%	153.4	72%	168.4	92%	194.9
13%	117.9	33%	139.7	53%	154.1	73%	169.3	93%	197.6
14%	119.5	34%	140.5	54%	154.8	74%	170.2	94%	200.6
15%	121.0	35%	141.2	55%	155.4	75%	171.1	95%	204.3
16%	122.4	36%	142.0	56%	156.2	76%	172.0	96%	208.8
17%	123.8	37%	142.7	57%	156.9	77%	173.0	97%	214.6

REFERENCES:

E.M. Keohane, L.J. Smith, J.M. Walenga. *Rodak's Hematology: Clinical Principles and Applications*. 5th ed. St. Louis, Mo.: Elsevier Saunders, 2015.

Sysmex CS2500 Quick Reference Guide – Version01-70

HemosIL® ReadiPlastin, HemosIL® Synthasil, HemosIL® Normal Control 1 & HemosIL® Abnormal Control 3 - package Inserts

CAP Checklist Requirements

HEM.37400Alternative Method Criteria

All Revision Dates

2/24/2026

Approval Signatures

Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator, VCMC & SPH	2/24/2026
Laboratory Service Dept	M. Anwar Molani: Medical Director, Laboratory Services	2/24/2026
Laboratory Service Dept	Samah Meshreky: Supervisor-Hematology, Laboratory Services	2/24/2026
Laboratory Service Dept	Erlinda Roxas: Director, Laboratory Services	2/24/2026

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Owner	Samah Meshreky: Supervisor-Hematology, Laboratory Services
Policy Area	Laboratory Services

L.CGL 4.1 Maintenance Protocol CS2500

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PRINCIPLE:

To ensure that the instrument can function in its optimal state, it is necessary to perform scheduled maintenance. Perform maintenance according to the schedule below and record performance on the Sysmex CS2500 Maintenance Log sheet.

EQUIPMENT:

Sysmex CS2500

REAGENTS

CA Clean I vial.

Deionized water or Reagent Grade water

USE OF INSTRUMENT:

- When performing maintenance work or inspection, use specified tools and parts.
- Do not use substitute parts, or modify the instrument. It is hazardous.
- Do not bring your body or clothes without proper PPE close to the instrument or its reagents.
- Those who have no or only limited experience in using reagents should have guidance or assistance by those with sufficient experience.
- If the instrument has developed a trouble by any chance, take steps within the range specified in the Operator's Manual or (instructions for use) IFU. For extended troubleshooting contact manufacturer's service representative for repair.

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SCHEDULE:

Daily	Rinse Probes
	Discard used Cuvette
	Check and discard trap chamber fluid
	Shut
Weekly	Clean the instrument
Monthly	Clean the filters
As needed	Lamp replacement and calibration
	Air pressure adjustment
	Remove jammed cuvette
	Wipe off piercer
	Clean the racks
	Piercer

DAILY PROCEDURES:

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Shutdown

A. Verify CA Clean I vial is loaded on the Reagent Table.
B. Press Shutdown icon. Select option: Turn the Main Unit OFF.
C. Press OK.
D. Cleaning will take 5 minutes.
E. Wait for IPU computer to automatically shut down.
F. Press analyzer power switch off.
G. Check Trap Chamber for fluid. Remove fluid if present.

Startup

A. Press the Power button on IPU computer.
B. Computer starts up.
C. Press enter on keyboard to select User. (lower left side)
D. Enter User password.
E. Instrument software starts up.
F. Select logon icon, enter password.

Tasks

A. Select Status icon to check rinse, waste, cuvettes.
B. Press Maint. icon.
C. Empty cuvette trash box. Reset trash counter.

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D. Empty Waste Tank: Press Change Waste Tank key Empty waste. Press OK.

E. Check/replace DI water.

F. Add cuvettes to hopper. Do not fill above the red line.

G. Select Manual Maintenance key: check off completed tasks

H. Press the Menu icon to view the Main Menu.

I. Select Operations Log to initial for maintenance tasks.
Enter initials or comment.

   a. Press Menu.

   b. Select Operation Log.

   c. Select the Pencil icon.

   d. Enter initials on the comment line.

   e. Select OK.

   f. Repeat for each maintenance item performed.

   g. Press Close.
   Save file:

      a. Select Operation Log, then select Filter operation key.

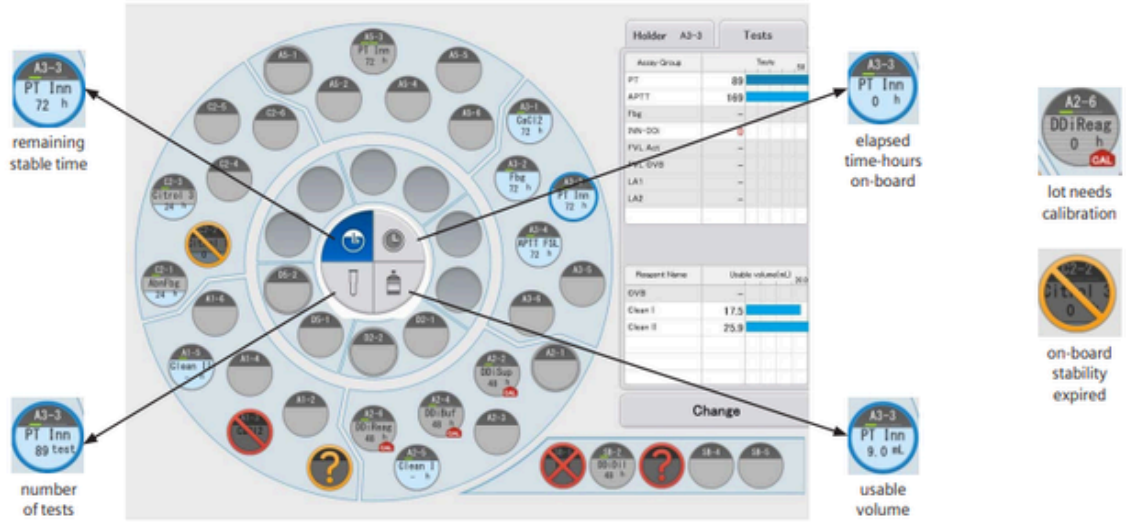
      b. Enter start/end dates using calendar, Select OK.

      c. Select Export operation key and name file and select location, Select Save.

      d. Select Filter, Select Clear, Select OK, and Press Close.

J. Replace reagents and QC as needed.

Reagent Table Features



K. Run QC for assays.

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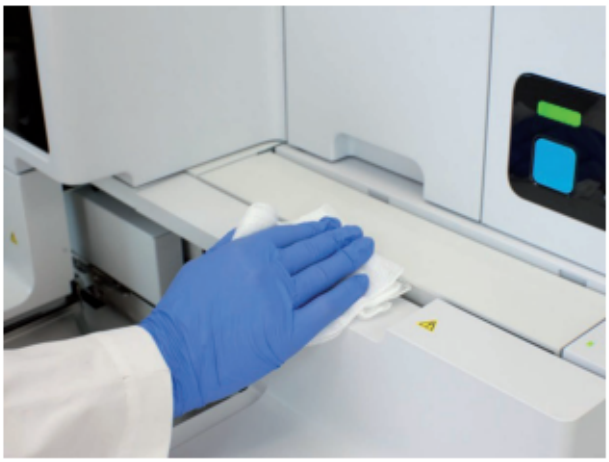
WEEKLY PROCEDURES:

Cleaning the instrument

A. Shut down the main unit and unplug the power cord.
B. Wipe the instrument with a moistened paper towel with water and a neutral detergent

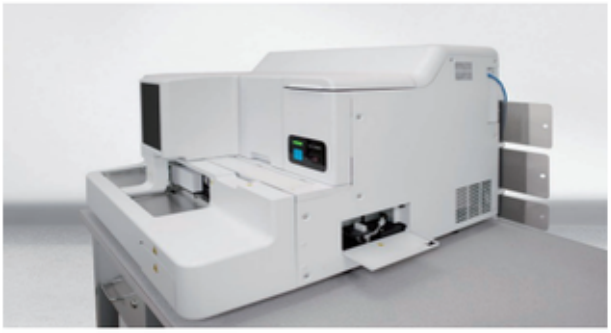


Note: Document manual maintenance in the Maint. screen under Manual Maintenance in the operation panel.

MONTHLY PROCEDURES

Cleaning the filter (rear)

A. Remove filters #514 and #513.
B. Use a vacuum or similar tool to remove dust from the filters.
C. Install the clean filters



Cleaning the filter (left side)

A. Remove filter #16A.
B. Use a vacuum or similar tool to remove dust from the filter.
C. Install the clean filter.
D. Document in the Maint. screen under Manual Maintenance.

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As Needed PROCEDURES:

Lamp replacement

A. Turn OFF the power of the main unit and unplug the power cord. Wait 30 minutes for lamp to cool down.
B. Open the lamp cover located on the right side of the instrument.
C. Disconnect the white connector.
D. Loosen the thumb screw.
E. Remove lamp holder.
F. Squeeze and lift the lamp retainer to remove the lamp.
G. Install a new lamp in reverse order.
H. Reconnect the power cord and turn the power ON.
I. Allow lamp to burn in for 30 minutes before calibration.

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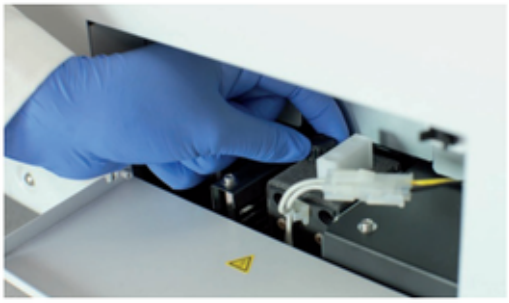
Note: Do not touch the lamp reflector with your fingers, or lamp performance could be affected.



Lamp calibration

A. Press Maint.
B. Press Lamp Calibration.
C. Press Execute.
D. Select the correct option when the lamp confirmation dialog box appears.
    - Reset lamp counter when calibrating a new lamp.

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- Do not reset the lamp counter when calibrating the same lamp.

E. Press OK.

F. Enter initials in Operation Log for calibrating a new lamp.

G. Enter initials/date in Maint. Screen Remarks field next to lamp calibration to record a recalibration of the same lamp.

H. Perform QC on all assays.

Note: Lamp calibration requires a 30-minute warming-up of the lamp to allow light intensity stabilization. Do not start calibration earlier; this will affect patient results.

Pressure adjustment.

Adjusting the 0.10 MPa pressure (range 0.10 to 0.11)

A. Press Maint.

B. Press Pressure Adjustment (press More if not visible).

C. Press Power ON Pressure (if pneumatic unit does not automatically turn on).

D. Open the cover door on the left side of instrument.

E. Pull the 0.10 MPa adjustment knob toward you to unlock.

F. Adjust the pressure slowly.

G. Once adjustment is complete, press the adjustment knob in until it locks.

H. Close the cover door, Press OK.

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0.10 pressure adjustment

Adjusting the 0.22 MPa pressure (range 0.22 to 0.25)

A. Press Maint.

B. Press Pressure Adjustment (press More if not visible).

C. Press Power ON Pressure (if pneumatic unit does not automatically turn on).

D. The 0.22 MPa adjustment knob is located on the pneumatic unit.

E. Loosen the fixing screw on the adjustment knob by turning the screwdriver counterclockwise.

F. Adjust the pressure slowly.

G. Once adjustment is complete, tighten the fixing screw while taking care not to rotate the adjustment knob.

H. Press OK.

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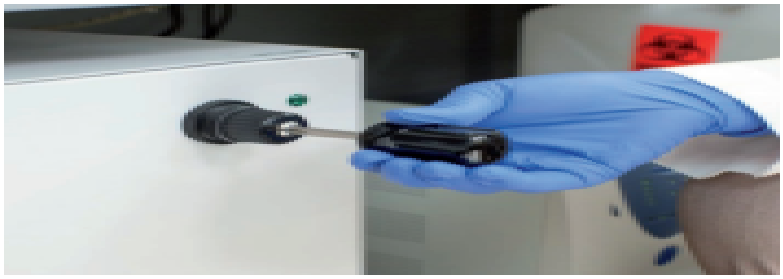

0.22 pressure adjustment

Clean the Sysmex racks.

A. Wipe racks with soft cloth with water or ethanol.
B. Document in Manual Maintenance.

Wipe the piercer clean.

A. Verify light shield is closed
B. Press Maint. on the toolbar.
C. Press Wipe off Piercer operation key
D. Wait for piercer to move to position. Press OK.
E. Power off Main unit.
F. Open the light shield.
G. Set the jig on the piercer.
H. Wipe piercer with gauze moistened with distilled water.
I. Remove the jig.
J. Close the light shield.
K. Power on the Main unit.

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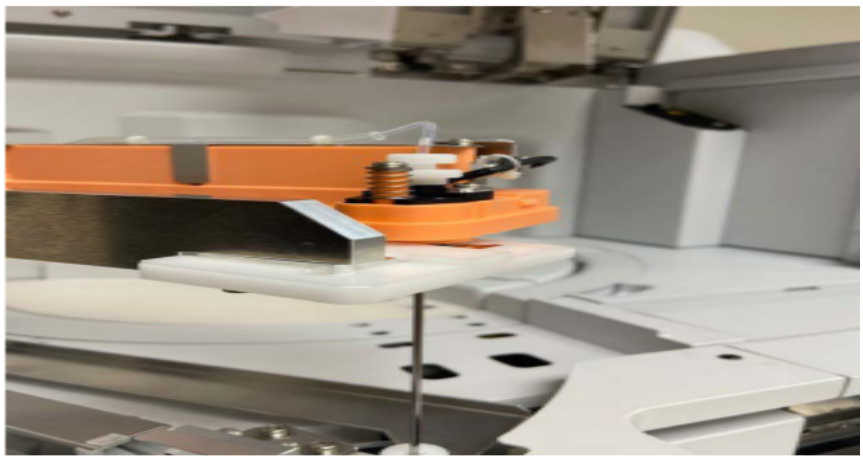

All maintenance logs are reviewed monthly for performance assurance.

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REFERENCES:

Sysmex CS2500 Reference Guide

CAP Accreditation Program – Hematology and Coagulation Checklist 08.24.2023

CAP Checklist Requirements:

COM.30600Maintenance/Function Checks

All Revision Dates

2/24/2026

Attachments

image1.png

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Approval Signatures

Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator, VCMC & SPH	2/24/2026
Laboratory Service Dept	M. Anwar Molani: Medical Director, Laboratory Services	2/24/2026
Laboratory Service Dept	Samah Meshreky: Supervisor-Hematology, Laboratory Services	2/24/2026
Laboratory Service Dept	Erlinda Roxas: Director, Laboratory Services	2/24/2026

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L.CGL 5.1 New Lot Quality Control & Reagents PT, PTT, Fibrinogen - (Lot Rollover) Sysmex CS2500

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PRINCIPLE:

Quality Control (QC) is performed routinely to ensure that an instrument is consistently reporting reliable sample results. Reagents and control lots for PT and aPTT are changed once per year. Lot rollover is performed yearly. This occurs so that you can change lots at the same time as Quality Assurance Program (QAP) peer group to ensure that the laboratory is consistently reporting reliable sample results.

EQUIPMENT:

Sysmex CS2500 1&2

CONTROLS:

Dade®Ci-Trol®1

Dade®Ci-Trol®3

Data-Fi®Abnormal Fibrinogen Control

REAGENTS/MATERIALS:

Dade®Innovin

Dade®Actin®FSL

CaCl2

Dade®Thrombin

Dade® OVB

CA Clean®I

Procedure:

A. RECEIVING AND ENTERING NEW LOT OF QUALITY CONTROLS

1.	When a New Lot of Quality Control& Reagent is received, place ***NEW LOT DO NOT USE*** sticker with received date on boxes.
2.	**To enter the PT & PTT New Lot material on the Sysmex CS2500 analyzer:** Press Menu > Reagent Lot Master a. Verify that New Innovin and New AFSL listed. Scroll down to bottom of the list to view all reagents. b. To add a new QC lot, click in Lot No. field. c. Scan the QC vial barcode with 2D barcode reader or manually enter the 6-digit Siemens lot number. d. Click in the Exp. Date field, enter expiration date on vial using the calendar. NOTE: An incorrect default date is loaded if not entered manually e. Press Add to register the new QC lot number to the list. f. Repeat for each new level of QC. h. Press Save, then press Close
3.	**Register New QC Lots to a chart**: 1.Press QC Chart. Press **Lot Roll** tab. 2. Press on PTN Ci-Trol 1 chart. 3. Select More Operation key until Add Lot is displayed. 4. Select Add Lot. (the software will move through each step). 5. Press down arrow for Lot No. and select lot (see lot just added). 6. Verify Use QC barcode checkbox is enabled, disable Use Preset checkbox 7. Select Next. 8. Assay Parameter Selection- all assays that use Ci-Trol 1 will be selected. Do not make any changes to this screen. 9. Select Next 10. QC Chart Settings- no changes on this screen. The new Ci-Trol 1 is setup for APTT, PT, PTN and PTTN (and Fbg.) No target limits are added at this time. 11. Select Next 12. QC Barcode Settings- Highlight QC11(Ci-Trol 1)

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	13. Select Next 14. Confirmation of the Settings Completion Select OK to save **Repeat to add new lot of Ci-Trol 3 for PTN and PTTN** 15. Select Lot Roll Tab 16. Press on PTN Ci-Trol 3 chart 17. Select Add Lot 18. Press down arrow for Lot No. and select lot 19. Select Next 20. On Assay Parameter Selection, Press Next 21. On QC Chart Settings, press Next 22. On QC Barcode Settings, highlight QC13. 23. Select Next 24. On Confirmation of Settings Completion, select OK
4.	Before using the new reagent with new QC lots it is common practice to perform the following procedures: 1. Establish or verify reference interval/range. 2. Establish a normal PT value (geometric mean) for new PT reagent. 3. Establish QC ranges using new reagent with new control material. . Run QC over 3 shifts with reagent over entire onboard stability time. . Have different techs reconstitute reagents/QC. . Ranges should be established in the same way they will be run daily. . At least 30 points for each level of QC. 4. Perform a lot-to-lot method correlation by running patient samples on both your current reagent lots and the new reagent lots (on both analyzers in VCMC).
5.	**Verification of Reference Interval:** VCMC lab has previously established a reference interval (using 120 samples) for its population, it may verify that reference interval. To verify a reference interval for the new lot a minimum of 20 samples representing the adult reference population (10 males and 10 females). Run samples with the current reagent lot assays, PT and aPTT, and with new reagent lot assays, PTN and aPTTN. This should be conducted simultaneously or within one (1) hour of each other. **Note:** (This data can be used for lot-to-lot correlations). The original study's reference interval may be considered valid if no more than two of the 20 donors' values (or 10% of the results) fall outside of the original study's reference interval. If more than two (2) values exceed the original study reference interval, an additional 20 samples should be assessed. **Notes:** After review of data, medication and patient history may be used for excluding aberrant results. The MNPT for INR calculation must be the geometric mean.
6.	**Fibrinogen Repeat Add Lot for AbnFbg Control (if used)**

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1. Select Tab containing Fibrinogen QC
2. Press on chart for Fibrinogen with AbnFib control
3. Select Add Lot
4. Press down arrow for Lot No. and select lot (see lot just added)
5. Select Next
6. On Assay Parameter Selection, select Next
7. On QC Chart Settings, select Next
8. On QC Barcode Settings, highlight QC14
9. Select Next
10. On Confirmation of Settings Completion, select OK.

7. View charts: Current vs. New

1. Select More Operation key until Switch Display is listed.
2. Select New. All new lots are displayed to the "New" side of the QC chart. Go to Lot Roll tab.
3. To view your current PT and PTT charts, Press Switch Display and select Current. Go to Routine tab. All current lots will be seen in this view.

8. Run New Lots:

1. Reconstitute new QC and reagents lot according to package insert directions.
2. For Fibrinogen: Reconstitute new lot of Dade Thrombin, Dade Data-Fi Abnormal Control, and Standard Human Plasma.
   NOTE: Enter new lots in Reagent Lot Master before loading reagents. Calibrate new lot of Thrombin before running QC **(Refer to Calibration procedure HEM2.5.2)**
3. Load new QC vials.
   a. Select a yellow C rack.
   b. Place QC vials containing SLD minicup with barcodes facing out to be read. c. Load onto the Reagent table. Press OK to barcode read.
4. Order QC
   a. Select Order. Select Switch Order.
   b. Select Holder QC Order.
   c. Select Order Entry.
   d. Select the radio button QC01-QC20 on the left.
   e. Select QC11 from the list, Select PTN, PTTN, (and Fbg) from test

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	list. f. Arrow down. g. Select QC13, order PTN, PTTN, arrow down. h. For Fibrinogen: Select QC 14, order Fbg, press OK.
9.	**Perform a Backup of the database**: 1. Backup system when finished correlations, establishing QC range, and verification of reference interval. 2. Backup Tab to save the settings, calibrations, QC points, Joblist results, Reagent lot information.

B- MOVING NEW LOT TO CURRENT USE

1.	1. **Reagent Lot Master- Enter new PT and PTT lot information** • PT Innovin reagent- Use package insert barcode to enter ISI, lot number and expiration date. a. Select Import. b. Select Barcode. c. Scan barcode on sheet with 2D barcode reader. d. Press Save. e. Press Exit. • Actin FSL- Manually enter lot number and exp. Date. a. Click in Lot No. field. b. Enter 6-digit lot number (or scan vial barcode). c. Place cursor in Exp. Date field. d. Enter expiration date using the calendar. e. Press Add. f. Press Save. • Delete old PT and PTT lot numbers a. Highlight old lot, press Delete.
2.	Remove old lots of reagent and QC from the analyzer Reagent Table and Load new QC.
3.	Load new PT Innovin and new AFSL reagents with barcodes visible. (Must read the barcode. Do NOT call New Inn or New AFSL).
4.	Enter ISI and Normal for new PT lot. Enter ISI and Normal Tab to enter the information.
5.	Print Current QC

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	a. Select QC Chart icon. b. Select Routine tab PT, PTT, and Fbg QC. c. Select Switch Display and choose Current. d. Select Print Report/Select Active Tab/Select Date Range/enter date range/Select List/Select Print. e. Note your Historical SD for your QC.
6.	Print PTN, PTTN, Fbg QC data:
7.	Change Lot for Ci-Trol 1 With PTN Ci-Trol 1 chart highlighted, Select Change Lot. QC lot number is displayed, Select Next.
8.	Assay Parameter Selection Confirm that "Monitoring" is checked, Select Next.
9.	QC Chart Setting is displayed. To calculate PTN and PTTN QC target Limits press Auto Cal NOTE: new lot of Fbg target limits will calculate also. Select 1SD Target Upper/Lower Limit (creates a 2SD range). Warning box appears- press OK. **Enter PT range:** a.place cursor/highlight PT. b. Click on Detailed Settings. c. Enter PTN values including 1 SD into the PT target/limits. d. Press OK on Detailed Settings screen. **Enter the APTT range:** a. Highlight APTT and select Detailed Settings. b. Enter Target/Limits of PTTN including 1SD. c. Press OK on Detailed Settings screen d. Select Next.
10.	QC Barcode Settings: a. Press QC01key This action changes QC01 to your new Ci-Trol 1 lot number. b. Select Next
11.	Confirmation of the Settings Completion: All settings are completed. Press OK or Complete. **NOTE**: Old QC Ci-Trol 1 lot data for PT, PTT, Fbg is stored automatically in a folder on C Drive.
12.	**Change Lot for Ci-Trol 3** 1. Navigate to Lot Roll Tab 2. Highlight PTN Ci-Trol 3 chart, Select Change Lot

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	3. Control Information Registration: Press Next 4. Assay Parameter Selection: Press Next 5. QC Chart Settings: Enter PTN and PTTN target limit values into the PT and APTT settings manually. a. To calculate PTN and PTTN QC target Limits press Auto Calc. b. Select 1SD Target Upper/Lower Limit. c. Press OK on the warning screen. d. Place cursor/highlight PT. e. Click on Detailed Settings. f. Enter PTN Target/Limits including 1SD. g. Press OK. h. Place cursor/highlight APTT. i. Click on Detailed Settings. j. Enter PTTN Target/Limits including 1SD. k. Press OK. l. Press Next. 6. On QC Barcode Settings: highlight QC03. 7. Press Next. 8. Confirmation of the Settings Completion: Press OK/Complete.
13.	**Change lot for AbnFbg Control**: 1. Navigate to tab with AbnFbg control. Highlight chart. 2. Press Change Lot. 3. For Control Information Registration- Select Next. 4. For Assay Parameter Selection- Select Next. 5. For QC chart Settings- Select Auto Calc. a. Select 1SD Target Upper/Lower Limit. b. Select OK. c. Select Next. d. For QC Barcode Settings- Select QC04 e. Select Next. f. For Confirmation of the Setting Completion- Select OK/Complete
14.	**Update QC Barcode Settings** 1. Select More Operation key until Barcode Setting is available. 2. Select 3. Blank out QC11, QC13, and QC14 as desired. Use ↓ down arrow and click on blank

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	space. 4. Select OK
15.	In Cerner, under **QC Maintenance**, enter New Lot number, expiration date and assigned values as New Lot. Activate New Lot of QC in Cerner by expiring the current QC lot.
16.	Place ***THIS LOT IS READY FOR USE*** sticker on all boxes of the newly validated lot.

QC Chart Additional information:

1. QC data points for PTN and PTTN after Change Lot will transfer from New to Current. The Current points will be green. PTN and PTTN data can remain in the QC chart until the next Lot Rollover.
2. PTN and PTTN "New" charts are ready for the next lot rollover.
3. Select Switch Display
4. Select Current
5. Current data points are judged by the Target/Limit settings which indicate your QC is in range or not.
6. Blue Data points are New. There are no Target/Limit settings when establishing a "new" control lot.
1. Different shapes indicate the reagent lot was changed.

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REFERENCES:

Sysmex CS2500 Reference Documents

CLSI -Statistical Quality Control for Quantitative Measurement Procedures: Principle and DefinitionsC24-A3.

CLSI - Laboratory Quality Control Based on Risk Management Approval Guideline. EP23-A

CLSI documents to meet CLIA/CAP requirements for Hemostasis. See CLIA 493.1252(a).

CAP Accreditation Program – Hematology and Coagulation Checklist 08.24.2023

CAP Checklist Requirements

HEM.19380 Control Range Establishment or Verification

HEM.20050 Numeric QC Data

HEM.37300 Coagulation Quality Control

All Revision Dates

2/24/2026

Approval Signatures

Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator, VCMC & SPH	2/24/2026
Laboratory Service Dept	M. Anwar Molani: Medical Director, Laboratory Services	2/24/2026
Laboratory Service Dept	Samah Meshreky: Supervisor-Hematology, Laboratory Services	2/24/2026
Laboratory Service Dept	Erlinda Roxas: Director, Laboratory Services	2/24/2026

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Last Revised	2/24/2026		
Next Review	2/24/2028		

L.CGL 5.2 Calibration and New Lot Change Fibrinogen, D-Dimer & Heparin, Anti-XA Reagent

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PRINCIPLE:

Coagulation results are imperative in monitoring anticoagulant therapy, screening for functional defects or deficiencies, and diagnosing coagulopathies. Differences between reagents and testing systems are known to contribute to result variability, making crossover studies necessary when using new reagents or implementing new testing systems.

VCMC's transition to the use of a New Lot for Fibrinogen, D-Dimer and Heparin, Anti-Xa testing includes the following:

- **Calibrations:** to establish result accuracy
- **Reagent Lot Correlation Studies:** comparing reagent lot results (when feasible)
- **Inter - Instrument Comparisons:** testing any duplicate analyzer platforms within VCMC.

Calibration and calibration verification assures that the instrument's calibration factors output accurately reflects sample results. Calibration Plasma is prepared using citrated plasma pheresed from healthy donors to maintain the characteristics of a normal plasma pool. It is designed for calibration with Sysmex CS2500 in the determination of Innovance® D-Dimer Calibrator is used for calibration of the Innovance® D-Dimer Reagents. Innovance® Heparin Calibrator prepared from human citrated plasma at five different heparin concentrations: 0, 0.38, 0.74, 1.10 and 1.53 IU/mL and are traceable to WHO International Standards are used for the calibration of LMW and UF heparin tests. Calibration verification is done by assaying quality controls that meet manufacturer's recommendations and determining that the correct target values are recovered. Analytical measurement range (AMR) verification validates a linear relationship between the expected and measured analyte values. AMR verification is performed by performing calibration, which includes low, midpoint and high values near the stated AMR.

VCMC hematology department performs calibration on Sysmex CS2500 analyzers:

- With every new Fibrinogen, D-Dimer and Anti-Xa Reagent lot
- Every 6 months
- When quality control values reflect any unusual trend or shift which does not correct
- After the replacement of any major component instrument components
- When advised to do so by an Instrumentation Laboratory representative

Intra-instrument comparisons may be performed post-calibration to ensure the test method is standardized across different platforms for the test method. This comparison is not required for calibration, but helpful for the evaluation of calibration and instrument performance.

EQUIPMENT:

Sysmex CS2500 1&2

CALIBRATORS/CONTROLS:

Standard Human Plasma

Dade®Ci-Trol®1

Data-Fi®Abnormal Fibrinogen Control

Innovance® D-Dimer Calibrator

Innovance® D-Dimer Control1&2

Innovance® Heparin Calibrators 1-5

Innovance® Heparin UF Control 1&2

Innovance® Heparin LMW Control 1&2

REAGENTS/MATERIALS:

Fibrinogen Dade®Thrombin

Innovance® D-Dimer Reagents

Innovance® Heparin Reagents

Dade®OVB

CA Clean®I

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Procedure:

A. RECEIVING AND ENTERING NEW LOT OF TEST REAGENTS

1.	When a New Lot of Reagent is received, place ***NEW LOT DO NOT USE*** sticker with received date on boxes.
2.	**Enter reagent information:** Using 2D barcode on Table of Assigned Values 1. Press Menu from IPU toolbar. 2. Press Reagent Lot Master. 3. Select Import. 4. Select Barcode. 5. Scan assay value sheet CS Systems 2D barcode. 6. Press Save. 7. Press Exit. 8. Press Close. **Note:** 2D barcodes are found on the Table of Assigned Values insert sheet for Siemens PT reagents, calibrators, and all assayed controls.
3.	**Calibration** Identify the reagents: 1. Enter reagent and calibrator lot information in Reagent Lot Master. 2. Load reagents, calibrator, and QC materials **Note:** Calibrator plasma should be transferred into a SLD mini cup and placed in the vial. Place vial in a C-rack.
4.	**Order the calibration:** 3. Select Order. 4. Select Switch Order. 5. Select Holder Calib Curve Order. 6. Select the desired assay to be calibrated. 7. Select Change and select the correct lot number. 8. Select OK. 9. Select the correct calibrator lot number from the list. Assay value automatically displays. 10. For manual entry of assay value: Place the cursor in the

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	Assay Sheet Value field and enter value using keypad. 11. Select OK. 12. Select Start. 13. To view the calibration status and progress, press Joblist
5.	**View new calibration curve:** 1. Select Calib. Curve. 2. Select Change. 3. Select assay. 4. Select lot number.
6.	**Compare new/current calibration curve:** 5. Select Detailed Display. 6. Compared Calib. Curve. 7. Select a calibration curve to compare and press Load. 8. Compare calibration curves. 9. Select Close.
7.	**Validate new calibration curve:** 1. Select Validate to validate the calibration curve. 2. Select OK. 3. Select Print. **Note:**Validate calibration by performing QC.
8.	**Calibration: Restore** Restore Old calibration curves. 1. Display the calibration curve for the selected assay. 2. Select Restore on the operation panel. *If Restore is not displayed, press More. 3. Select the desired calibration curve to restore. 4. Press OK. 5. Select Validate to validate the calibration curve. 6. Select OK.

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B. RECONSTITUTE FIB, D-DIMER and HEPARIN, ANTI-XA CALIBRATORS:

Fibrinogen	**1.**	Remove Calibration Plasma from designated fridge.
	2.	Reconstitute the calibrator with 1mL of Reagent Grade Water or diH_2O. Replace stopper and swirl contents gently.

	3.	Allow calibrator to equilibrate for 15 minutes. Swirl to mix. NOTE: Standard Human Plasma is only used for calibration and does not have on-board stability. Once reconstituted it should stay at room temperature and must be used within 4 hours.
D-Dimer	**1.**	Remove D-Dimer calibrator from D-Dimer box kit.
	2.	Reconstitute the calibrator with 1mL of Reagent Grade Water or diH_2O. Replace stopper and swirl contents gently.
	3.	Allow calibrator to equilibrate for 15 minutes. Swirl to mix. NOTE: Innovance® D-Dimer Calibrator is only used for calibration and does not have on-board stability. Once reconstituted it should stay at room temperature and must be used within 4 hours.
Heparin Anti-Xa	**1.**	Remove the three heparin calibrators from designated fridge.
	2.	Reconstitute each calibrator with 1mL of Reagent Grade Water or diH_2O. Replace stopper and swirl contents gently.
	3.	Allow calibrator to equilibrate for 15 minutes. Swirl to mix. (Calibrator may be stored after reconstitution for 48 hours on board or 48 hours refrigerated at 2-8˚C.)

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PROCEDURE NOTES:

Calibration of Fibrinogen, D-Dimer & Heparin-X_A - Table of Acceptability		
Test	**R^2 Value**	**Criteria**
Fibrinogen	≥ 0.975	N/A
D-Dimer	N/A	Review spline curve fit and recovered values for acceptability.
Heparin-X_A	≥ 0.990	N/A

Evaluation of Fibrinogen, D-Dimer & Heparin-X_a Reagent Lot - Table of Acceptability				
	Reagent Lot Correlation Studies		**Inter - Instrument Comparisons**	
	R Value	**Average % Difference**	**R Value**	**Average % Difference**
Fibrinogen	≥ 0.95	± 20%	≥ 0.95	± 20%
D-Dimer	≥ 0.95	± 20%	≥ 0.95	± 25%
Heparin-XA	≥ 0.95	± 25%	≥ 0.95	± 20%

REFERENCES:

Sysmex CS2500 Reference Guide Version 01-70

Innovance® D-Dimer Reagents, Innovance® D-Dimer Calibrator, Innovance® D-Dimer Control 1&2,

Innovance® Heparin Reagents, Innovance® Heparin Calibrator, Innovance® Heparin UF Control 1&2 , ,Innovance® Heparin LMW Control 1&2 package Inserts

CAP Accreditation Program – Hematology and Coagulation Checklist 08.24.2024

CAP Checklist Requirements

HEM.37360Calibration Procedures

HEM.37363 Calibration and Calibration Verification Materials

HEM.37365Recalibration/Calibration Verification Criteria

HEM.37370Recalibration

HEM.37375AMR Verification

HEM.37940Standard Curve

HEM.37960Standard Curve Verification

COM.30450New Reagent Lot and Shipments Confirmation of Acceptability

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2/24/2026

Approval Signatures

Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator, VCMC & SPH	2/24/2026
Laboratory Service Dept	M. Anwar Molani: Medical Director, Laboratory Services	2/24/2026
Laboratory Service Dept	Samah Meshreky: Supervisor-Hematology, Laboratory Services	2/24/2026
Laboratory Service Dept	Erlinda Roxas: Director, Laboratory Services	2/24/2026

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Effective	1/17/2024	Policy Area	Laboratory Services
Last Revised	2/24/2026		
Next Review	2/24/2028		

L.CGL 5.3 Platelet Poor Plasma Verification - Centrifuges

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PRINCIPLE:

This procedure provides the instructions for evaluating the centrifuges used for separating platelet poor plasma from whole blood for VCMC coagulation testing. The testing is performed:

- Upon installation
- Every six month
- When centrifuge is returned to the laboratory, after taken for repairs

EQUIPMENT:

Centrifuges (used at VCMC to spin coagulation specimens)

Sysmex XN-3100 analyzer

Capless 2.0mL microcentrifuge graduated tubes

Disposable Pipette

REAGENTS/MATERIALS:

1-2 randomly selected coagulation patient samples, per tube volume, per centrifuge

PROCEDURE:

1.	Obtain at least one 3.2% buffered sodium citrate patient sample, per specimen tube volume, per centrifuge.
2.	Mix whole blood patient specimens by inversion, until it is well mixed.

3.	Spin the specimen in the centrifuge being evaluated.
4.	Label a capless microcentrifuge tube with the **Centrifuge ID#** and the specimen's **tube volume** (i.e. 2.0mL or 3.0mL).
5.	After spinning, use a disposable pipette to aspirate a minimum of 300µL of the separated plasma and dispense into the microcentrifuge tube.
6.	On Sysmex XN3100 analyzer switch to manual mode.
7.	Following analyzer screen prompts, run sample as whole blood for the test **Platelets (PLT).**
8.	Use the pipette to mix the plasma in the microcentrifuge container before loading.
9.	Place the microcentrifuge tube in the manual microtainer aliquot slot (GREEN AND BLACK) on the analyzer.
10.	When testing is completed, ensure results are printed. Repeat steps with each centrifuge and sample to be tested.
11.	With each centrifuge tested, record findings. To **PASS** for use for spinning coagulation specimens, plasma must contain **< 10 x 10^3 platelets/µL.** This testing will certify use for this centrifuge for up to one year from the month tested.
12.	Place a sticker on passed centrifuges showing valid approved dates and any necessary coagulation spin requirements.
13.	Failing centrifuges can NOT be used for spinning coagulation specimens.
14.	A printed copy of the documents will be placed in the Hematology Department Intra-Instrument Comparison binder. Results will be stored for a minimum of two years.

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REFERENCES:

CAP Accreditation Program – Hematology and Coagulation Checklist 08.24.2023

CAP Checklist Requirements

HEM.37175Platelet-poor Plasma

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Laboratory Service Dept	M. Anwar Molani: Medical Director, Laboratory Services	2/24/2026
Laboratory Service Dept	Samah Meshreky: Supervisor-Hematology, Laboratory Services	2/24/2026
Laboratory Service Dept	Erlinda Roxas: Director, Laboratory Services	2/24/2026

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Status **Active** PolicyStat ID **19762747**

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Owner	Samah Meshreky: Supervisor-Hematology, Laboratory Services
Policy Area	Laboratory Services

L.CGL 5.4 Intra-Instrument Comparisons – Sysmex CS2500

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PRINCIPLE:

This procedure provides the instructions for inter-instrument comparisons for checking correlation of patient results between analyzers at least quarterly.

EQUIPMENT:

Sysmex CS2500

REAGENTS/MATERIALS:

4 – 10 randomly selected coagulation patient samples

NOTE: For Anti- Xa comparisons, load a minimum of 2 previously tested Hep, Anti-Xa (UFH and/or LMW) samples. This is done to ensure positive samples are included in analyses as patients not receiving heparin would have all negative results, and if evaluated alone, would not produce accurately evaluated comparisons.

PROCEDURE:

1.	Analyze a minimum of 4 randomly selected patient specimens. Avoid running patient samples more than an hour apart between analyzers to minimize testing variabilities.
2.	Load samples the same as when performing routine testing.
3.	Order test(s) to be evaluated. When test(s) are completed, print results.
4.	Run the same specimens on the second analyzer, ordering the same tests per sample. Print tests results upon completion.

5.	Using the patient ID and results, compare each specimen's results from each analyzer and verify that they agree within the acceptability criteria.
6.	If comparison results fail acceptability criteria for any coagulation test, analyze another four to ten specimens for that test and compare those results to the acceptability criteria. • If repeat testing passes above listed criteria, no further action is necessary. • If repeat testing does not pass above listed criteria, institute instrument/analyte troubleshooting. (**If troubleshooting Fibrinogen, D-Dimer, and Anti-Xa tests, calibration is strongly recommended**) After successful troubleshooting, as determined by acceptable quality control results, analyze a minimum of five specimens and compare those results to the acceptability criteria. Ensure acceptability before proceeding with normal patient testing.
8.	Failed comparison studies should be discussed with the Manager/Lab Director.
9.	A printed copy of the documents will be printed and placed in the Hematology Department Intra-Instrument Comparison binder. Results will be stored for a minimum of two years.

PROCEDURE NOTES:

VCMC Coagulation Parallel Intra-Instrument Comparison Limits

Analyte	Parameter	Target	R Value
PT	µ Avg % Difference	± 15%	≥ 0.95
PTT	µ Avg % Difference	± 15%	≥ 0.95
FIB	µ Avg % Difference	± 10%	≥ 0.95
D-DIMER	µ Avg % Difference	± 25%	≥ 0.95
ANTI-Xa	µ SD % Difference	± 20%	≥ 0.95

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REFERENCES:

CAP Accreditation Program – Hematology and Coagulation Checklist 08.24.2023

CAP Checklist Requirements

COM.04250Comparability of Instruments/Methods

COM.04300Comparability Criteria

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Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator, VCMC & SPH	2/24/2026
Laboratory Service Dept	M. Anwar Molani: Medical Director, Laboratory Services	2/24/2026
Laboratory Service Dept	Samah Meshreky: Supervisor-Hematology, Laboratory Services	2/24/2026
Laboratory Service Dept	Erlinda Roxas: Director, Laboratory Services	2/24/2026

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Last Revised	3/3/2026		
Next Review	3/2/2028		

L.MIC 1.14 Disease Reporting to Assess Potential Bioterrorism Events

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EFFECTIVE DATE: 11/11/2005	REVIEW DATES: 6/2006, 10/2007, 4/2008, 7/2009, 3/2010, 3/2011, 5/2013, 7/2015, 12/2015
	REVISION DATES:

DISEASE REPORTING TO ASSESS POTENTIAL BIOTERRORISM EVENTS (R-58-00E)

Laboratory findings indicative/suggestive of following disease/conditions are added to the laboratory reportable list. These diseases are **reportable to the local health officer within one hour** after the laboratory has notified the health care provider who submitted the clinical specimen for analysis.

1. Anthrax (Bacillus anthracis)
2. Botulism (Clostridium botulinum)
3. Brucellosis (Brucella sp.)
4. smallpox (variola)
5. tularemia (Francisella tularensis)
6. viral hemorrhagic fever (Crimean-Congo, Ebola, Lassa, Marburg viruses)
7. plague (Yersinia pestis)

REFERENCE

"Disease Reporting to Assess Potential Bioterrorism Events (R-58-00E), **Title 17: Notice of**

Emergency Rulemaking, California Department of Health Services, 10/17/01.

All Revision Dates

3/3/2026

Attachments

Title 17.Reportables.pdf

Approval Signatures

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Hospital Administration	Jason Arimura: Associate Hospital Administrator, VCMC & SPH	3/3/2026
Policy Owner	Erlinda Roxas: Director, Laboratory Services	3/3/2026
Policy Owner	M. Anwar Molani: Medical Director, Laboratory Services	3/2/2026
Policy Owner	Linda Conboy: Supervisor-Microbiology, Laboratory Services	3/2/2026

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Last Revised	3/3/2026		
Next Review	3/2/2028		

L.MIC 1.15 Bioterrorism Recognition

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EFFECTIVE DATE: 11/11/2005	REVIEW DATES: 6/2006, 10/2007, 4/2008, 7/2009, 3/2010, 3/2011, 5/2013, 7/2015, 12,2015, 12/5/2016, 12/6/2017, 3/20/2019, 12/1/2021, 11/30/2023, 1/2025, 2/2026
	REVISION DATES:

BIOTERRORISM RECOGNITION

GENERAL CONSIDERATIONS

Biological terrorism (bioterrorism) is defined as "the intentional use of microorganisms or toxins derived from living organisms to produce death or disease in humans, animals, or plants." From the public and private health perspective, bioterrorism can be defined as the deliberate release of pathogens or their toxins into a civilian population with the intent to cause illness or death. In addition to humans, agricultural animals and plants must also be considered as potential targets or bioterrorism.
To be effective in preparing for and responding to a suspected or confirmed bioterrorist event, clinical microbiologists should have a general understanding of biological terrorism, including the administrative and technical principles that are necessary for the recognition and management of an event.

The term bio-crime or bio-threat is used when a bioterrorist, which may be one individual who acts alone or a state- or non-state-sponsored group, targets a specific group or individual. A bio-crime is a criminal act involving the use of biological agents as weapons, and a bio-threat is characterized as a suspected but unconfirmed release of a biological agent(s), i.e. microbial pathogens and/or toxins which have been previously considered or used in biological warfare and

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recent terrorist events.

Bioterrorism events are categorized as either overt or covert. The covert pose the greatest challenge to the clinical microbiologist who, along with infectious disease practitioners, in the role as sentinels, will most likely be the first to raise suspicion of a possible event involving a biological agent.

Safe handling practice includes handling suspected organisms under a certified biological safety cabinet and not subjecting the isolates to identification utilizing automated instruments.

Detection and recognition of a possible event will be dependent upon several factors, including an active microbial surveillance and monitoring program, vigilant laboratory staff who are capable or recognizing the unusual or who develop a high index of suspicion, and communication with clinicians (especially emergency medicine personnel), infection control personnel, infectious disease specialists, and other local or regional laboratories. The lack of commercially available diagnostic tests and reagents presents a major obstacle to the clinical microbiologist. As a result, confirmation of these agents will require that the specimen or isolate in question be referred to designated laboratories within the Laboratory Response Network (LRN) that are equipped with the latest diagnostic technologies (state health departments, the CDC, and the U.S. Army Medical Research Institute of Infectious Diseases [USAMRIID]).

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Laboratory and epidemiological features that should alert microbiologists and other health care providers to the possibility of a bioterrorism-related outbreak include the following:

A rapidly increasing disease incidence (e.g., within hours or days) in an otherwise healthy population.

An epidemic curve that rises and falls during a short period.

An unusual increase in the number of people seeking care, especially with fever or respiratory or gastrointestinal complaints.

An endemic disease rapidly emerging at an uncharacteristic time or in an unusual pattern

Any patient presenting with a disease that is relatively uncommon and has bioterrorism potential (e.g., pulmonary anthrax, tularemia or plague) who is without any risk factors for the disease (e.g., travel to the Southwest for plague)

Many rapidly fatal cases

An increase in the number of specimen types submitted for microbiological analysis (e.g., respiratory specimens and blood cultures).

Higher than normal clustering of a specific organism

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Recovery of an unusual or rarely encountered microorganism

A higher-than-normal rate of patient admission to the emergency room or hospital

Receipt of information by the microbiology laboratory that a clinician suspects a specific agent (e.g., "I suspect tularemia in this patient").

INCUBATION PERIODS OF SELECT AGENTS

Disease Time to Disease Onset

Usual Range

- Anthrax 48 h Hours to days
- Botulism 12-36 h Several days
- Brucellosis 5- 60 days Several months
- Plague 2-4 days 1-7 days
- Tularemia 3-5 days 1-14 days

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LABORATORY RESPONSE NETWORK

To facilitate rapid laboratory diagnosis of a bio-crime, the CDC has established a model in which clinical and public health laboratories are linked in a seamless laboratory network based on the role they will play in the ultimate diagnosis of a biological agent used in a terrorist event.

Most of the hospital and commercial reference laboratories have been classified as level A. These laboratories act as sentinels for raising suspicion of a bioterrorist event and rule out or refer suspicious isolates only. Level A laboratories are restricted to testing human specimens only and must forward environmental and animal specimens to a level B (BSL-2) or higher laboratory.

Since level A laboratories are charged with ruling out, not identifying, suspicious isolates, they must immediately recognize when to refer a specimen to the laboratory at the next higher level. Proper packaging and shipping of infectious agents is one of their most important functions. Cultures and clinical specimens known or suspected to contain infectious substances must be packaged according to certain specifications. Refer to procedure for packaging infectious substances.

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Level A laboratories must have a class II certified biological safety cabinet and copies of the level A protocols. Refer to Bio-safety Procedure Manual.

CHAIN-OF-CUSTODY GUIDELINES

Following confirmation by the Federal Bureau of Investigation (FBI), a bio-crime or act of bioterrorism is regarded as criminal offense. The clinical microbiology laboratory may be required to save specimens or isolates suspected of being linked to or associated with the crime under investigation and thus must preserve what is regarded as evidence. Protection of evidence must adhere to the security process known as the chain of custody.

Although level A laboratories will not handle or analyze environmental samples (e.g., soil, bone, hair, surface swabs, water, food, or letters) that are collected in an overt event in which chain of custody is required, it is important for the microbiology staff to be familiar with the process. Unless otherwise specified by the FBI, all environmental specimens must be transported directly to a level B laboratory.

If the laboratory is called upon to handle an environmental sample, all activities, beginning with the receipt and examination of the sample, must be documented using a chain-of-custody form. The key elements of the form include: 1) the document number assigned and the date that the evidence was received, 2) the specimen identification number, 3) a brief description of the evidence (e.g., specimen type and biological agent), 4) the date of final disposition, 5) signatures of all personnel who handled and examined the evidence, and 6) remarks.

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CRITICAL BIOLOGICAL AGENTS FOR BIOTERRORISM AND CIVILIAN PREPAREDNESS

Safe handling of critical agents of bioterrorism ([c]) includes such activities as handling organisms under a certified biological safety cabinet, and not subjecting the isolates to identification utilizing automated instruments.

Organism Disease, common name, Biothreat or toxin level

Bacteria

Bacillus anthracis [c] Anthrax A

Yersinia pestis[c] Plague A

Francisella tularensi s[c] Tularemia A

Brucella specie s[c] Brucellosis B
Burkholderia mallei Glanders B
Salmonella species Salmonellosis B
Shigella dysenteriae Shigellosis B
Escherichia coli O157:H7 Hemorrhagic colitis B

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Vibrio cholerae Cholera B

Coxiella burneti i[c] Q fever B

Mycobacterium tuberculosis[d] Tuberculosis C

Toxin sources

Clostridium botulinum [c] Botulinum toxin A

Ricinus communis[c] Ricin B
(from castor beans)
Clostridium perfringens Epsilon toxin B

Staphylococcus aureus[c] Enterotoxin B B

Protozoa
Cryptosporidium parvum Cryptosporidiosis B

Viruses
Variola major Smallpox A
Ebola Hemorrhagic fever A
Marburg Hemorrhagic fever A
Lassa Lassa fever A
Junin Argentine hemorrhagic fever A

VEE, WEE, EEE[e] Encephalomyelitis B
Nipah Enchalomyelitis C
Hantavirus Hemorrhagic fever, hantavirus C
pulmonary syndrome
Tick-borne viruses Hemorrhagic fever and/or encephalitis C
Yellow fever virus Yellow fever C
Bio-threat level A, agents that pose the greatest threat due to their infectiousness, relative ease of transmission, or high rate of mortality; bio-threat level B, agents having a moderate ease of transmission and morbidity with a low rate of mortality; bio-threat level C, emerging pathogens and potential risks for the future.

[c] Organisms categorized as "critical" agents for bioterrorism or bio-crime.

[d]Multi-drug-resistant strains.

[e]EEE, eastern equine encephalomyelitis; VEE, Venezuelan equine encephalomyelitis; WEE, western equine encephalomyelitis.
RECOGNITION OF BACILLUS ANTHRACIS, BRUCELLA SP. FRANCISELLA TULARENSIS, AND YERSENIA PESTIS

***Bacillus anthracis* Level A Testing**

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Morphology: large aerobic, gram-positive rods (1 to 1.5 by 3 to 5 microns)
Smears/blood/cerebrospinal fluid: short chains of 2 to 4 cells that appear encapsulated.
Sheep blood agar (ambient atmosphere): oval, central-to-subterminal spores which do not cause significant swelling of cell; often in long chains.
Growth on sheep blood agar: 2 to5 mm, tenacious, non-hemolytic colonies after 15 to 24 hours (flat or slightly convex, irregularly round colonies with irregular or wavy border and ground-glass appearance).
Perform all additional work in biosafety cabinet:
Hemolysis: negative
Catalase: positive
Motility: nonmotile
If negative for features in #5, report *Bacillus* species, not *B. anthracis*; continue identification per laboratory protocol.
If positive for features in #5, report *Bacillus* species, sent to reference laboratory to rule out *B. anthracis*.

Brucella species Level A Testing

Safety: as soon as *Brucella* is suspected, perform all further work in a biosafety cabinet (BSL-3).
Major characteristics of Brucella species
Morphology, small (0.4 by 0.8 microns; gram-negative coccobacillus
Visible on Gram stain of positive blood culture broth
Think *Brucella*!
Growth: subculture positive aerobic blood culture bottle to: Sheep blood agar (BAP); chocolate agar (CHOC); incubate in 5 to 10% CO_2 at 35°C.
Spot BAP with *Staph aureus* ATCC 25923 for satellite test.
Note poorly growing colonies after 24-hours incubation on BAP and CHOC. Incubate plates for at least 2 additional days if no growth in 24 hours. Organism does not grow on MacConkey agar.
Is the organism satelliting the *Staph aureus* at 24 to 48 hours? Consider *Haemophilus*.
Is the organism oxidase positive and catalase positive? If no, consider *Francisella*. See *Francisella* procedure.
Is the organism oxidase positive, catalase positive, and urea positive? If yes, send to Ventura County Public Health Lab; inform physician that we need to rule out *Brucella sp.*

Francisella tularensis Level A Testing

Morphology: aerobic, pleomorphic, minute (0.2 to 0.5 by 0.7 to 1.0 microns), faintly staining, gram-negative coccobacillus.
Growth: scant to no growth on sheep blood agar after more than 48 hours. Produces 1- to 3-mm gray to grayish white colonies on chocolate agar after more than 48 hours.

Perform all additional work in biosafety cabinet.

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Oxidase: negative; catalase: weak positive; beta-lactamase: positive; satellite: negative; urease: negative.

CAUTION: Automated identification systems may key our as non-*F. tularensis* (e.g., *Haemophilus influenzae* and *Actinobacillus* spp.

If the key results in step 4 are not present, report: *Francisella tularensis* is ruled out. Continue identification per laboratory protocol.

If the key results in step 4 are present, report: Suspect *Francisella tularensis*, could not rule out; referred to Ventura County Public Health Laboratory for identification.

***Yersinia pestis* Level A Testing**

Morphology: facultative, bipolar, 0.5 by 1.0 to 2.0 microns, gram-negative rods. Growth: slow-growing, pinpoint (1 to 2 mm), gray-white to opaque colonies on sheep blood agar after 24 hours. Non-lactose fermenter, +/- growth on MacConkey agar or EMB at 24 hours.

Features: oxidase negative, catalase positive, urea negative, indole negative.

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CAUTION: Automated identification systems often key out as non-*Yersinia pestis* (e.g., *Shigella* spp., H_2S-negative *Salmonella* sp., *Acinetobacter* spp., and *Yersinia pseudotuberculosis*).

If the features in step 2 are not present, report: *Yersinia pestis* is ruled out. Continue identification as per laboratory protocol.

If the features in step 2 are present, report: Suspect *Yersinia pestis*, could not rule out; referred to Ventura County Public Health Laboratory for identification.

REFERENCES

Leber, Amy L. et al, **Clinical Microbiology Procedures Handbook**, ASM, Washington, D.C., 4rd edition, Vol. 3, 2016, pages 16.1.1- 16.14.6.

Versalovic, James, et al, **Manual of Clinical Microbiology**, ASM, Washington, D.C., 10th edition, Vol. 1, 2011, pages 174-187.

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Approval Signatures

Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator, VCMC & SPH	3/3/2026
Policy Owner	Erlinda Roxas: Director, Laboratory Services	3/3/2026
Policy Owner	M. Anwar Molani: Medical Director, Laboratory Services	3/2/2026
Policy Owner	Linda Conboy: Supervisor-Microbiology, Laboratory Services	3/2/2026

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Owner	Linda Conboy: Supervisor-Microbiology, Laboratory Services
Policy Area	Laboratory Services - Microbiology

L.MIC 1.16 Brucellosis in the Context of Bioterrorism

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	REVISION DATES:

BRUCELLOSIS IN THE CONTEXT OF BIOTERRORISM

GENERAL CONSIDERATIONS

Brucellosis is an extremely debilitating zoonotic systemic bacterial disease which may last months to years if not properly treated with antibiotics. The case fatality rate is 3% to 5% in inadequately treated cases. The U.S. bioweaponized Brucella suis in the 1940s to 1950s, and other countries also have weaponized Brucellae. The organism can be delivered as a slurry in bomblets, or a dry aerosol by the airborne route.

To meet the threats of bioterrorism it is imperative that the reporting time frame for brucellosis be advanced from with 7 days of diagnosis to immediately by phone after the diagnosis is made by a health care provider, or a labortory finding suggestive of brucellosis is made by a laboratory.

SPECIMEN

Types

Blood placed in blood culture bottles and incubation time extended to 21 days.

Bone marrow placed in blood culture bottles and incubation time extended to 21 days.

Biopsy of spleen and liver: Place in sterile container with sterile saline to keep moist.

Abscesses: Place in sterile tube or swab transport system.

Transport as soon as possible to lab.

SAFETY PRECAUTIONS

Observe Biosafety Level 3 (includes using biological safety cabinet (BSC), gloves, and mask)

Most commonly reported bacterial infection in the lab.

Aerosolization is primary mechanism of transmission.

Suspicious colonies must be worked up in BSC.

Gram stain will show very small gram negative coccobacilli, faintly-staining sppearing like "fine sand."

Urea hydrolysis positive on heavily inoculated Christenson's urea agar within 1 hour.

LAB HANDLING

Culture and Isolation

Blood and bone marrow : Place in blood culture bottles and extend incubation for 21 days.

Biopsy material: Inoculate BAP, CHOC, MAC. Incubate CHOC at 35 degrees Celsius in CO2 incubator.

Growth on Media

Will grow on brucella agar, BAP, and CHOC at 35 degrees Celsius in 5-10% CO2.

Some may grow on MAC.

Slow-growing. May take 48 hours to show visible colonies.

Will grow on MTM, which may be useful for isolation in mixed flora sites; e.g., surface wounds or the lungs.

IDENTIFICATION

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Presumptive Identification
. Gram stain shows tiny, fine, faintly staining, sand-like, gram negative coccobacilli.

Takes about 48 hours to show colonial growth on plated media.

Urea positive

Refer to Ventura County Public Health Lab for definitive identification.

REFERENCE

"Disease Reporting to Assess Potential Bioterrorism Events (R-58-00E), **Title 17: Notice of Emergency Rulemaking**, California Department of Health Services, 10/17/01.

Murray, Patrick et al, **Manual of Clinical Microbiology**, 7th edition, ASM, Washington, D.C., 1999, pages 626-628.

COPY

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3/3/2026

Approval Signatures

Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator, VCMC & SPH	3/3/2026
Policy Owner	M. Anwar Molani: Medical Director, Laboratory Services	3/3/2026
Policy Owner	Linda Conboy: Supervisor-Microbiology, Laboratory Services	3/3/2026
Policy Owner	Erlinda Roxas: Director, Laboratory Services	3/3/2026

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Owner	Linda Conboy: Supervisor-Microbiology, Laboratory Services
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L.MIC 1.17 Clinical Laboratory Bioterrorism Readiness Plan

COPY

EFFECTIVE DATE: 6/15/2010	REVIEW DATES: 9/2011, 2/2014, 7/2015, 12/2015, 12/5/2016, 3/20/2019, 12/1/2021, 11/30/2023, 1/2025, 2/2026
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PRINCIPLE:

The laboratory BT (Bioterrorism) preparedness plan should be integrated into the institutional BT preparedness plan.

NOTE: It is quite possible that the laboratory will not be contacted in advance and informed that one of the potential agents of BT is suspected. As a result, it is essential that appropriate safeguards be taken, including subculture of all blood cultures in a biosafety cabinet or behind a safety shield, and always considering the possibility of BT agents.

BT PREPAREDNESS PLAN:

Purpose

The purpose of this protocol is to provide a formal description of the laboratory will respond to a suspected or confirmed BT event. The laboratory needs to promptly assist in the diagnosis and management of patients by providing physicians with accurate information on selection, collection and transport of specimens.

In a suspected or confirmed BT event, immediate and effective communication with all

appropriate institutional, medical and public health officials is imperative.

Contact protocol and chain of command

If a possible BT agent is grown in the laboratory or detected by other means, place phone calls to the responsible physician and the following individuals immediately. Contacting these individuals is not a one-person task.

Place phone calls to the following individuals immediately: microbiology laboratory supervisor, laboratory director, infection control officer, clinical pathologist on call

Laboratory Response Network

Introduction to the LRN: The Laboratory Response Network is a partnership of laboratories that provide immediate and sustained laboratory testing and communication in support of public health emergencies, particularly in response to acts of BT. All laboratories are considered partners, and in some cases, registered members of the LRN.

a. LRN structure for BT agent testing. LRN laboratories are designated as sentinel, reference, and national laboratories.

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Basic sentinel laboratory is certified by the Centers for Medicare & Medicaid Services for general laboratory testing, including microbiology.

The laboratory is inspected successfully in accordance with the CLIA or by an agency that has been given deemed status by the CMS.
The laboratory has policies and procedures for referral of diagnostic specimens to an advanced sentinel laboratory.

Advanced sentinel laboratory has been certified by the CMS as a high complexity laboratory performing the specialty of microbiology and has been inspected successfully in accordance with CLIA or by an agency that has been given deemed status by the CMS.

Advanced sentinel laboratories shall meet the following:

Have a class II or higher certified biological safety cabinet

Comply with BSL-2 practices

Have policies and procedures for use of additional
respiratory protection (e.g. N-95 fit testing)

Responsibility of the clinical laboratory

As members of the LRN, sentinel laboratories have access to the network and serve as "sentinels" for the early detection of and raising suspicion regarding a suspicious agent that cannot be ruled out as a possible BT associated organism.

Sentinel level clinical microbiology laboratory guidelines for BT agents.

Packing and shipping instruction

U.S., international and commercial regulations mandate the proper packing, documentation and safe shipment of dangerous goods in order to protect the public, airline workers, couriers and other persons who work for commercial shippers and who handle the dangerous goods during many segments of the shipping process.

Information checklist

Appendix 16.12-1 shows a checklist that may help in the gathering of information in a suspected BT event. The checklist is to be filled out by shift operations manager or other designated personnel.

REFERENCES:

COPY

Garcia, Lynn S. ed., **Clinical Microbiology Procedures Handbook**,2nd ed, ASM Press, Washington D.C. 2007, Volume 3, pp16.12.1-16.12.27

www.asm.org. , Sentinel Level Clinical Microbiology Laboratory Guidelines, 1/04/2010

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Policy Owner	M. Anwar Molani: Medical Director, Laboratory Services	3/2/2026

Policy Owner	Linda Conboy: Supervisor-Microbiology, Laboratory Services	3/2/2026

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L.MIC 1.18 Safe Work Practices

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12/2016,12/2017, 3/2019, 12/2021, 11/2023, 1/2025, 2/2026

SAFE WORK PRACTICES

PRINCIPLE

All laboratory personnel must follow standard precautions guidelines. Specimens received in the laboratory cannot be distinguished between containing potentially infectious and noninfectious material. The implementation of safe work practices is essential for the prevention of laboratory-associated infections.

HANDLING OF SPECIMENS

A. Gloves and gowns

1. Always wear gloves and gowns (impervious to liquids) when handling and processing patient specimens, decontaminating instruments and countertops, and cleaning spills. Coats with snug-fitted sleeves and aprons are optional.
2. Bandage open cuts and scratches on hands and then wear gloves.
3. Wear gloves (e.g., latex free or vinyl) when performing phlebotomy and when handling actual blood specimens.
4. Wash hands immediately after gloves are removed, after a task that involves heavily contaminated matter, and before leaving the laboratory.

B. Specimen transport

1. Place specimens in plastic bags and transport in leak-proof containers with the

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biohazard symbol affixed.

2. DO NOT accept grossly soiled or contaminated specimens. Notify the individual responsible for submitting such a specimen immediately and follow the Laboratory's specimen rejection policy.

C. Needles and syringes

1. Use needle-locking syringes or plastic disposable syringe-needle units.
2. Never recap or bend needles or remove them from syringes.
3. DO NOT accept specimens received in syringes with needles attached. Notify the individual responsible for submitting such a specimen immediately and follow the laboratory's specimen rejection policy.
4. Discard in a puncture-resistant container that has the biohazard symbol affixed.
5. Use needle-less systems for blood samples if available.
6. Use mechanical devices or one-handed techniques when handling sharp objects.
7. Secure blood culture bottles before inserting needles into the bottles (e.g., place bottles in support racks).

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D. Tubes

1. Carry tubes in racks.
2. Use plastic tubes when possible.
3. Uncap tubes behind a clear plastic shield to contain splashes or sprays (e.g., when removing tops from vacuum tubes).

E. Centrifuges

1. Centrifuge tubes must be intact and properly balanced when centrifuged.
2. Centrifuge tubes used in mycobacteriology areas must be enclosed in sealed safety cups.
3. Use aerosol-free centrifuges when possible (e.g., in the mycobacteriology laboratory).
4. Centrifuge safety cups must be opened in a biological safety cabinet (BSC) after centrifugation.
5. DO NOT place tabletop centrifuges in a BSC because air turbulence within the cabinet can allow aerosols to escape.

F. Hand washing

1. Perform frequent hand washing after removing gloves, before leaving the laboratory, and before eating, drinking, or applying cosmetics.
2. Use nonirritating soap for routine washing.

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3. Use antiseptic soap or an alcohol wipe followed by thorough hand washing for accidental skin contamination.

PROCESSING OF SPECIMENS

1. Process all specimens in a Biological Safety Cabinet.
2. Mix or transfer liquids by using disposable sterile plastic pipettes..
   Alternatively, use mechanical pipetting devices.
3. Cover tubes when mixing, blending, vertexing, etc. (e.g., cap tubes or cover them with parafilm).
4. Work over an absorbent covering
5. Use appropriate safety precautions when working with colonies that exhibit mycelial growth such as taping of culture plates and performing transfers within a biological safety cabinet.
6. Hazardous waste must be disposed of in a manner to minimize hazards to all personnel handling the material. This includes the use of red biohazard containers, bleach solutions, and sharps containers.
7. Plan tasks to minimize exposure to known hazards.
8. Follow standard precautions when performing non-culture techniques such as molecular detection methods.

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HOUSEKEEPING AND MISCELLANEOUS SAFE PRACTICES

A. General Considerations.

1. Avoid or minimize activities associated with the transmission of infectious agents.
2. Designate clean and contaminated work areas.
3. Wear gloves in contaminated areas.
4. Clean and disinfect all surfaces after spills and at the beginning and end of each work shift.
5. Keep all work areas neat and uncluttered.
6. DO NOT store personal items in the work areas.
7. DO NOT store large quantities of disposable items in the work areas.
8. Remove coats and gowns before leaving the laboratory. Place contaminated laundry (e.g., reusable lab coats and gowns) in designated bag for cleaning by the laundry.
9. Dispose of all contaminated material in containers for treatment
10. Samples placed in storage will go into racks, bins, or clear bags. For disposal, they will be transferred to a red biohazard waste container for proper hazardous waste disposal.

B. Compresses gasses (Handling by the maintenance department)

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1. Secure cylinders in an upright position with wall mounts.
2. Store cylinders away from open flames and sources of heat.
3. Use the correct pressure regulators.
4. Verify contents of the cylinder before gas is used.
5. Transport cylinders in secured hand trucks or carts.

C. Chemicals

1. Wear appropriate PPE when handling hazardous chemicals.
2. Label all reagents with their chemical names and appropriate hazard warnings provided from the MSDS information.
3. Keep MSDSs for all chemicals in MSDS Manual in overhead cabinet near blood bank
4. Store flammable and combustible liquids in fire-rated storage cabinets and explosion-proof refrigerators.
5. Store all hazardous chemicals, including reagents and dyes, below eye level.
6. Use plastic bottles when appropriate.
7. Store on the bench volumes necessary for daily work.
8. Gram stain and methanol waste container to be replaced when 1/3 full. Container must be labeled with a biohazard sticker, and a green chemical waste sticker. It must be taken to the locked chemical waste area outside the EVS department for proper disposal. Key is on a lanyard in the supervisor area.

COPY

REFERENCE

Isenberg, Henry D. et al, **Clinical Microbiology Procedures Handbook**, Volume 3, ASM Press, Washington, D.C., 2004, pages 15.2.2.1 to 15.2.2.3.

California Code of Regulations Title 22, Biohazardous Waste Control Procedures and Regulation

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Hospital Administration	Jason Arimura: Associate Hospital Administrator, VCMC & SPH	3/3/2026
Policy Owner	Erlinda Roxas: Director, Laboratory Services	3/3/2026
Policy Owner	M. Anwar Molani: Medical Director, Laboratory Services	3/2/2026
Policy Owner	Linda Conboy: Supervisor-Microbiology, Laboratory Services	3/2/2026

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L.MIC 1.19 Microbiology Safety

COPY

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		REVISION DATES: 12/2013

MICROBIOLOGY SAFETY

GENERAL CONSIDERATIONS

All fresh specimens should be handled carefully, since each specimen represents a potential source of infectious material (bacteria, viruses, fungi, and parasites).

Safety precautions should include awareness of the following.

- Proper labeling of fixatives when used
- Specific areas designated for specimen handling (biological safety cabinets may be necessary under certain circumstances)
- Proper containers for centrifugation
- Acceptable discard polices

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- Appropriate policies for no eating, drinking, or smoking, etc., within the working areas
- If applicable, correct techniques for organism cultures and/or animal inoculation.

GENERAL PRECAUTIONS

BE CAREFUL! All material to be received or discarded from the laboratory must be considered potentially pathogenic.
Smoking, eating, or drinking in the laboratory is not permitted.

Do not work with uncovered open cuts or broken skin. Cover them with a Band-Aid, finger cot, or other suitable means, such as nitrile or vinyl gloves.

Mouth pipetting of specimens is not permitted.

Do not create aerosols. Remember, infectious diseases, such as infectious hepatitis, may be transmitted by aerosols produced by centrifuges, stirrers, pipettors, etc. Please use extreme care when using such equipment. Cool inoculating loops or needles before touching colonies on plates or going into liquid material.

Develop the habit of keeping your hands away from your mouth, nose, eyes, and face. Wash hands well with soap and water after de-gloving and before leaving the laboratory.

Do not lay personal articles, such as eyeglasses, on the bench in your work area.

Laboratory coats or gowns are not to be worn outside the laboratory, particularly not to the employee lounge or cafeteria, or out of the building.

Wipe benches in your work area with bleach or disinfectant wipes before and after each day's work. Keep your area clean at all times.

In case of injury or unusual incident, however slight, notify the supervisor in charge immediately, and consult the **Laboratory Safety Manual** for course of action. T
he report may include cause of accident, type of contamination or hazard, list of personnel possibly exposed and amount of exposure to possible pathogenic material, decontamination procedures taken if pathogenic material was involved, actions taken to prevent reoccurrence, actions taken to safeguard or monitor employees.

Infections can be spread by a number of routes in the laboratory.
The actual occurrence of an infection depends on the virulence of the infecting agent, susceptibility of the hosts, route of entry, inoculating does, etc.

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Airborne. Droplets and aerosols may be formed by simply removing caps, cotton plugs or swabs from tubes. Heating liquids on needles too rapidly may also create an aerosol. Breakages in centrifuges are considered serious accidents.
Ingestion. Ingestion can occur through mouth pipetting, failure to wash hands after handling specimens or cultures, or smoking, eating, and drinking in the laboratory.

Direct inoculation. Scratches, needle sticks, cuts from broken glass, or animal bites can permit direct inoculation.

Skin contact. Some very virulent organisms, and others not so virulent, can enter through small cuts or scratches or through the conjunctiva of the eye.
Vector. Flies, mosquitoes, ticks, fleas, and other ectoparasites can be potential sources of infection in the laboratory, especially if animal work is performed.

HANDLING SPECIMENS

Specimens must be placed in biohazard labeled plastic specimen bags. Specimens with **gross external** contamination must not be accepted. Place the specimen in another plastic bag to protect subsequent handlers. The test requisition should be bagged separately from the specimen (keep paperwork clean and uncontaminated). Use gloves when handling the specimen and wash your hands thoroughly when you finish handling the specimen. Notify the supervisor immediately about a contaminated specimen so that further corrective action can be taken.

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Centrifuge. Specimens to be centrifuged MUST be placed in a sealed container to prevent aerosols.

Biological safety cabinets. All specimens must be processed in a biological safety cabinet on an absorbent surface (disposable mats), using appropriate protective technique. Disposable mats must be changed daily or when visibly soiled. The immediate work area of the mat should be dampened with 0.5% bleach solution (made fresh daily) or any suitable disinfectant to handle small spills.

PROCESSING SPECIMENS

All specimens are potentially pathogenic—always use careful techniques.

All discarded material used in processing of specimens is considered contaminated.

Disposable specimen containers and centrifuge tubes should be placed in biohazardous disposal container (stericycler). Be sure to secure lid.

Discard glass slides in stericycler.

Pipettes may be placed in biohazardous discard bucket lined with biohazard labeled red bag to be

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discarded ultimately in stericycler.

HANDLING CULTURES

All cultures from sterile body sites with growth only on the chocolate plate should be handled, observed and manipulated in the biological safety cabinet.

Do not open the lid to plated media without checking to see if fungal growth is present. If fungus is evident, tape the lid shut to prevent accidental opening of the plate.

All transfer involving mycology cultures and mycobacteriology (AFB) cultures must be handled in the Biological Safety Cabinet.
Wear gown with opening in back and gloves when making smears from AFB cultures.

Discard used pipettes, swabs, sticks, glass slides, coverglass, and loops into the red-lined biohazard labeled bucket on the bench top. When bucket is full, remove and discard red bag into the stericycler.

Handle highly infectious, contagious isolates in the Biological Safety Cabinet with gloves and gown in place.

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BIOLOGICAL SPILLS

Disinfectants in Current Use

0.5% bleach (sodium hypochlorite) is virucidal against 25 viruses tested (including enteroviruses) and is effective against anthrax spores. Is corrosive to stainless steel.
70% alcohol to clean the biological safety cabinets.

Immediate Actions
Clear the area at once.
Notify the supervisor in charge.
Assess the type of spill and degree of hazard involved.
Determine the most effective and least hazardous approach to clean up and decontaminate.

"Dry Spills" With No Significant Aerosol Formation
Flood the area with bleach solution.
Soak up disinfectant and contaminated material with absorbent material (paper towels) and dispose of it in a plastic red biohazard bag or sealed container (stericycler). Be sure to wear gloves for cleanup.
If routine cleanup is not possible, the unit may have to be decontaminated by means of a sterilizing gas such as paraformaldehyde.
Thoroughly was the unit (if possible) after decontamination.

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Liquid Spills on Bench or Floor
If significant aerosols were formed, the area must be evacuated and not re-entered for at least one hour.
Flood the area with disinfectant and cover the spill with absorbent material (paper towels). Be sure to wear gloves during cleanup.
Dispose of absorbent and contaminated material in plastic bags (red bag, if material is biohazardous) and place in stericycler.
Thoroughly wash the area after cleanup.

Centrifuge Spills
Shut off the instrument and evacuate the area at once.
Do not re-enter the area for at least one hour, or until aerosols have settled.
Person entering the area to clean up must wear protective clothing, gloves, and mask.
If liquids are present, soak up in absorbent material and handle as specified above. If liquids are not present, clean the instrument and room thoroughly before resuming work.
Wipe all surfaces with 10 % bleach, 70% alcohol, or Sani Cloths.

Spills in Incubators or Other Closed Areas
Flood the area with 0.5 % bleach or 70% alcohol and soak up liquids with absorbent material (paper towels).
Dispose of material as specified above, if possible.
If routine cleanup is not possible, the unit may have to be decontaminated by means of a sterilizing gas such as paraformaldehyde.
Thoroughly was the unit (if possible after decontamination).

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Chemical Spill
Minor chemical spill Involving 100 ml or less, can be cleaned-up by Lab personnel
Access Safety Data Sheet (SDS) for the chemical from the Safety Cabinet for directions regarding appropriate cleanup of material
If fumes are present, personnel must leave the area. Close doors and restrict access.
Notify supervisor. PM and Grave Shift notify Nursing Supervisor
Liquids will be treated with the appropriate absorbent. Solids (powders, granules, crystals) should be swept up and placed in a plastic bag.

Contain the spill using adsorbent socks to surround the spill and/or dike drains. Use appropriate spill kit to absorb minor spill.
Follow directions with spill kit. Dispose appropriately; do not place in biohazardous trash receptacle. Confirm: Hazardous Waste or sanitary landfill.

In case of splashing of corrosive liquids on the body or clothing, it is urgent that the employee be placed under the emergency shower and sprayed with large amounts of water for at least 20 minutes, or until emergency response personnel direct otherwise.
If the eyes are contaminated, turn on the eye wash fountain, hold the lids of the eyes open and place the face into the full stream of water to flush with large amounts of water for 20 minutes or

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until otherwise directed.
Chemical exposures will be reported on GSA-75, and the employee will be seen in ER

DISPOSAL OF CONTAMINATED MATERIALS

Discard specimens and cultures into stericycler container with double plastic red liners. Be sure to close lid.
Place culture plates into stericycler container as above.
Report any breakage of glass or leakage of contaminated materials to the supervisor in charge at once for instructions on procedures for safe cleanup.

UNIVERSAL PRECAUTIONS OR STANDARD PRECAUTIONS

Universal or Standard Precautions is defined as a method of infection control in which all human blood and certain body fluids are treated as if known to be infectious for HIV, HBV, and other blood borne pathogens. Usually involves wearing gloves, protective gown, and protective eyewear.

HEPATITIS EXPOSURE PROTOCOL

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Laboratory personnel have a high risk of contracting hepatitis for the following reasons:

- Frequent close personal contact with patients with hepatitis
- Direct and frequent contact with biological specimens containing the virus
- Frequent opportunity for accidental puncture wounds with contaminated needles and sharp objects
- Carelessness in handling specimens
- Inadequate or unsafe disposal of contaminated needles, specimens, or other objects.
- Carelessness in proper and frequent hand washing technique

The prevention of hepatitis is the primary reason for emphasis on infection control precautionary measures found in any safety manual. These procedures also apply to HIV (AIDS).

All known hepatitis specimens must be so labeled; however, to minimize exposure to the virus, every specimen must be handles as though it would transmit hepatitis. Hepatitis may be transmitted to laboratory personnel in several ways:

- Puncture or other wounds (HIV)

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- Abrasions of the skin (HIV)
- Aerosols (inhaled into the respiratory tract)
- By mouth (oral route)
- Direct contact with the patient
- Splashing material into the eyes

The following protocol is to be followed in the event of an exposure:

Immediately wash the exposed area with soap and water.

Report the incident to the supervisor and laboratory personnel office.

Consult **Laboratory Safety Manual**.

COPY

REFERENCE

Garcia, Lynne et al, **Diagnostic Medical Parasitology,** 2nd edition, ASM, Wahington, D.C., 1993, pages 487, 643-649.

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Hospital Administration	Jason Arimura: Associate Hospital Administrator, VCMC & SPH	3/3/2026
Policy Owner	Erlinda Roxas: Director, Laboratory Services	3/3/2026
Policy Owner	M. Anwar Molani: Medical Director, Laboratory Services	3/2/2026

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Policy Owner	Linda Conboy: Supervisor-Microbiology, Laboratory Services	3/2/2026

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L.MIC 1.20 Biosafety Levels

COPY

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		REVISION DATES:

PRINCIPLE:

Biosafety levels are guidelines that describe appropriate containment equipment, facilities, and procedures for use by laboratory workers. The BSLs range from BSL 1 to BSL 4. Each BSL is based on increased risk associated with the pathogenicity of the microorganisms encountered. Most clinical microbiology laboratories follow BSL 2 practices.

When working with highly infectious agents for which the risk of aerosol transmission is greater (eg. Brucella sp, Francisella sp, Mycobacterium tuberculosis, and systemic fungi) , clinical microbiology laboratories should follow BSL 3 practices. Because of the new threat of bioterrorism, new facility designs for public health laboratories are conforming to BSL 3 requirements. Information on BSL recommendations for specific organisms can be found on the website http://www.cdc.gov/od/ohs/biosfty/bmbl/bmbl

BIOSAFETY LEVEL 1: Is recommended for work with microorganisms not known to cause disease in healthy adults (eg., Bacillus subtilis).

- Restrict access to authorized personnel.
-

Make sinks for hand washing readily accessible.

- Make eyewash stations readily accessible.
- Make appropriate PPE available and ensure use.
- Ensure that laboratory bench tops are impervious to liquids and resistant to chemicals.
- Ensure that laboratory surfaces and equipment are easily cleaned and disinfected and that these procedures are done on a regular basis or whenever the surfaces or equipment is contaminated.
- Decontaminate solid waste within the laboratory (eg by autoclaving), or package the waste to be transported off site.

BIOSAFETY LEVEL 2: Is recommended for microorganisms associated with human disease but not transmitted by aerosol (e.g., Salmonella sp)
Follow BSL 1 practices plus the following.

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- Display universal biohazard signs outside of the laboratory
- Perform specimen processing in a biological safety cabinet (BSC)
- Perform centrifugation of mycobacteriology specimens by using centrifuge safety cups.
- Ensure that decontamination equipment is available and used for treatment of infectious waste
- Use the appropriate PPE (e.g., gowns, gloves, and facial barriers)
- Place all sharps carefully in conveniently located, puncture resistant containers.
- Trained personnel must observe good microbiological practices and techniques.

BIOSAFETY LEVEL 3: Is recommended for hazardous microorganisms primarily Transmitted by aerosols (e.g., M. tuberculosis)
Follow BSL 1 and BSL 2 practices plus the following.

- Control access to the laboratory.
-

Perform all manipulations of cultures and clinical material in a BSC (class II)

- Maintain a negative pressure airflow in the laboratory
- Include double doors and an anteroom in the laboratory design
- Discharge HEPA filtered exhaust air from BSC outside the facility
- Use all appropriate PPE and containment devices.
- Use HEPA filtered respirators or masks when aerosols may be generated.
- Collect baseline serum samples from all personnel for serological determinations of immune status.

BIOSAFETY LEVEL 4: Is recommended for agents causing life-threatening or untreatable diseases by aerosols or unknown transmission by aerosols (eg., Ebola virus)

- Follow BSL 3 practices plus the following.
- Change to protective clothing before entering, and shower on exit.
- Decontaminate all waste on exit.
- Use a BSC (class III) and full-body, air supplied, positive pressure suit for all procedures.
- Locate facility with specialized ventilation and waste management systems separately from other laboratories.

COPY

REFERENCES:

Denys, Gerald A. and Gray, Larry D., eds., **Clinical Microbiology Handbook**, 2nd ed., 2007 update, ASM Press, Washington D.C., pp. 15.3.3.1-2 and 15.3.2.2-3.

U. S. Department of Health and Human Services, CDC and NIH, **Biosafety in Microbiological and Biomedical Laboratories**, 5th ed. 2007

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L.MIC 1.21 Biological Safety Cabinet

COPY

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		REVISION DATES:12/2016

BIOLOGICAL SAFETY CABINET

PRINCIPLE

The biological safety cabinet (BSC) is the most important primary containment equipment in the clinical microbiology laboratory.
Class IIA laminar-flow cabinets are the most commonly used for BSL 2 and 3 practices. Air is drawn into the cabinet by negative air pressure and passes through a HEPA filter. The air flows in a vertical sheet that serves as a barrier between the outside and the inside of the cabinet. The cabinet exhaust air is also passed through HEPA filters. Aerosols are contained within the BSC, and the work area is protected from outside contamination when the cabinet is operating under the manufacturer's recommended conditions.
The class III BSC is completely enclosed, ventilated cabinet of airtight construction and provides the highest level of protection of laboratory workers and the environment. Class III cabinets are used for working with agents that require BSL 3 or 4 containment.
The biological safety cabinet located must be cleaned daily and must be certified at least annually to ensure filters are functioning properly and that airflow rates meet specifications.(*Records maintained in Biomed Department*)

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MATERIALS

Disinfectants

10% Household bleach solution (0.5% sodium hypochlorite). Metal surfaces must be rinsed to avoid corrosion.
70% Ethanol. Store outside of the cabinet.

Supplies

Supplies to stock area: sterile disposable loops, sterile swabs, sterile disposable pipettes, forceps, and glass slides with frosted end.
Absorbent paper mat
Beaker with bleach solution prepared daily or more frequently as needed.
Biohazard waste container

Equipment

Vortex
Test tube rack
Slide warmer

PROCEDURES

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Start-up

Turn on blowers for at least 10 minutes before QC checks and specimen processing.
Open the viewscreen to operating height (8 inches).
Turn off UV lights (if present).
Turn on fluorescent light.
Remove items in biological safety cabinet (BSC).
Clean the cabinet working surfaces with 70% Ethanol. Wipe down and dry with paper towels.
Replace and restock items in BSC as needed.
Remove red specimen bag from specimen bucket. Close off the bag and place in plastic drawer file. The bag should be marked with the date when specimens were set up. Bags are to be held for 3 days.

Operation

Avoid outside sources of air currents (e.g., personnel walking by, doors being opened or closed, etc.)
Wear long-sleeved coats or cuffed gowns and gloves during specimen processing.
Place all items that will be used in a planned activity inside the cabinet prior to starting work.
Segregate clean from contaminated materials.
Place the minimum number of large devices and supplies inside the cabinet.
Do NOT block intake or rear grills.
Do NOT place sterile material or specimens near the sides, front, or back of the cabinet.
Do NOT place or tape paper notes or procedures on the window.
Do NOT use a flame in the cabinet.
Do NOT operate centrifuges in the cabinet.

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Plan workflow to minimize movements.
Work at least 6 inches inside the front grill intake.
Avoid rapid arm movement in and out of the cabinet while a procedure is in progress.
If necessary, slowly move arms in and out of the cabinet.

Shutdown
Daily
Disinfect all cabinet surfaces while cabinet is running, and document daily cleaning performed.
Check the blower function.
Monthly
Clean the gutter area with disinfectant
Annually
Certify BSCs annually for proper function by certified personnel
Have certified personnel measure UV light output (if present).

LIMITATIONS OF THE PROCEDURES

BSCs should not be used as fume hoods.
Toxic, radioactive, or flammable vapors or gases are not removed by HEPA filters.
Potentially hazardous amounts of volatile material may build up in class II-type cabinets.
Exhausted vapors can be vented into the laboratory air.
The use of gloves when performing routine manipulations should not substitute for proper hand washing practices. Wash hands with soap and water between tasks and when heavily soiled with clinical material.

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REFERENCE

Isenberg, Henry D. et al, Clinical Microbiology Procedures Handbook, Volume 3, ASM, Washington, D.C., 2004, pages 15.3.4.1 to 15.3.4.3.

NuAire Operation & Maintenance Manual, Labgard ES Energy Saver Class II, Type A2 Laminar Flow Biological Safety Cabinet, December 2010

All Revision Dates

3/3/2026

Approval Signatures

Step Description	Approver	Date

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Hospital Administration	Jason Arimura: Associate Hospital Administrator, VCMC & SPH	3/3/2026
Policy Owner	Erlinda Roxas: Director, Laboratory Services	3/3/2026
Policy Owner	M. Anwar Molani: Medical Director, Laboratory Services	3/2/2026
Policy Owner	Linda Conboy: Supervisor-Microbiology, Laboratory Services	3/2/2026

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Status **Active** PolicyStat ID **20032102**

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Last Approved	3/3/2026		
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L.MIC 1.22 Taxonomic Changes of Microorganisms

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EFFECTIVE DATE 2/2/2016	REVIEW DATES: 12/2017,3/2019, 12/2021,11/20231/2025,2/2026
	REVISION DATES:

PRINCIPLE:

The genus and/or species names of microorganisms may change as new methods are applied to their taxonomy. This change can affect the choice of appropriate antimicrobials to report and/or the interpretive breakpoints to use for reporting. The laboratory should ensure that clinically relevant taxonomic changes are incorporated into reporting patient and proficiency testing results even when commercial identification systems have not been updated.

Taxonomic changes are often incorporated into the educational challenges through CAP's proficiency program. The Participant Summary Report Final Critique is a good source of information.

Additional information for specific specialties may be found on-line using web sites, such as:

For bacteriology

- www.bacterio.net/-classification.html
- www.dsmz.de/bacterial-diversity/prokaryotic-nomenclature-up-to-date.html
- http://zipcodezero.com
- CAP proficiency testing program, Participant Summary Report Final Critique

For mycology

- http://mycobank.org
- http://mycology.adelaide.edu.au
- http://fungaltaxonomy.org

For parasitology

- http://www.cdc.gov/dpdx

All taxonomic changes are to be added to the taxonomy binder in the department. Complete the review chart by filling in the current name of the genera and species, the previous name of the genera species, the LIS update information and current source of information change.

Taxonomic changes are reviewed at least annually by the laboratory in collaboration with physicians, antimicrobial stewardship, and infection control committees, as appropriate, and incorporated into the report as "New Name; previously known as Old Name" until commercial systems are updated.

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REFERENCES

Tille, Patricia M., PhD, Bailey & Scott's Diagnostic Microbiology, 13th ed., Elsevier Mosby, St. Louis, Mo., 2014, pp.2-3,193-196

All Revision Dates

3/3/2026

Attachments

Micro 1.22a TAXONOMY CHANGES OF MICROORGANISMS.xls

Approval Signatures

Step Description	Approver	Date

Hospital Administration	Jason Arimura: Associate Hospital Administrator, VCMC & SPH	3/3/2026
Policy Owner	Erlinda Roxas: Director, Laboratory Services	3/3/2026
Policy Owner	M. Anwar Molani: Medical Director, Laboratory Services	3/2/2026
Policy Owner	Linda Conboy: Supervisor-Microbiology, Laboratory Services	3/2/2026

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VENTURA COUNTY HEALTH CARE AGENCY

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Last Revised	3/3/2026
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Owner	Linda Conboy: Supervisor-Microbiology, Laboratory Services
Policy Area	Laboratory Services - Microbiology

L.MIC 1.23 Miscellaneous Antimicrobial Susceptibility Testing and Unusual Organism Isolation

COPY

EFFECTIVE DATE 11/15/2010	REVIEW DATES: 9/2011,2/2014,1/2016, 12/2017, 3/2019, 12/2021, 11/2023, 1/2025, 2/2026
	REVISION DATES: 2/2014

Unusual Organism Isolation

Isolates that are unable to be identified at VCMC are to be submitted to the appropriate testing facility for final identification. Referral of isolate is to be noted on report.

Supplemental susceptibilities that are unable to be performed at VCMC or require confirmation, are to be submitted to the appropriate testing facility for final testing. Referral for susceptibilities is to be noted on patient report.
Refer to reference laboratory testing manual (or online) for the test number,
CPT code, specimen requirement, and transport temperature

Filamentous Fungi

If growth resembles the possibility of Coccidiodes immitis, do not open outside of Biological safety cabinet.
All isolates recovered from routine culture are re-plated for isolation to a SabDex bottle for safe transport..

All fungal isolates are submitted to Ventura County Public Health Department for fungal identification.

Ordering for referral in LIS

Complete the appropriate Department order entry fields in LIS.
Include the following information in the order entry fields:

- Organism submitted (if appropriate)
- CPT code
- Test ordered
- Microbiology accession number referred to
- Source

Send Out Department

Communicate needs with the Send Out Department for proper transport and submission requirements to outside testing entity.

Document the referral testing in the electronic work card of the culture referred for further work. Document the isolate referred for identification or susceptibilities in the isolate referral notebook. Keep a hard copy of the work card to retain at the workstation so that Microbiology can monitor the progress of the send out test.
When the result is available, document result, for our records only, in the isolate logbook.

COPY

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3/3/2026

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Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator, VCMC & SPH	3/3/2026

Policy Owner	Erlinda Roxas: Director, Laboratory Services	3/3/2026
Policy Owner	M. Anwar Molani: Medical Director, Laboratory Services	3/2/2026
Policy Owner	Linda Conboy: Supervisor-Microbiology, Laboratory Services	3/2/2026

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VENTURA COUNTY HEALTH CARE AGENCY

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Next Review	3/1/2028
Owner	Linda Conboy: Supervisor-Microbiology, Laboratory Services
Policy Area	Laboratory Services - Microbiology

L.MIC 10.1 VITEK® 2 Identification Card Systems

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PRINCIPLE

VITEK® 2 Systems identify an organism by using a methodology based on the characteristics of the data and knowledge about the organism and reactions being analyzed. Sufficient data have been collected from known strains to estimate the typical reactions of the claimed species to a set of discriminating biochemicals. If a unique identification pattern is not recognized, a list of possible organisms is given, or the strain is determined to be outside the scope of the database. Certain species may belong to a slash line (mixed) taxa identification. This occurs when the biopattern is the same for the taxa listed. Supplemental tests may be used to separate slash line taxa.

Card Types

The VITEK® 2 **Gram-Negative identification card (GN)** is intended for use with VITEK® 2 Systems for the automated identification of most clinically significant fermenting and non-fermenting Gram-negative bacilli. The GN card is based on established biochemical methods and newly developed substrates measuring carbon source utilization, enzymatic activities, and resistance. There are 47 biochemical tests and one negative control well. The Decarboxylase Negative Control Well (well 52) is used as a baseline reference for the Decarboxylase test well. Final results are available in approximately 10 hours or less

The VITEK® 2 **Gram-Positive identification card (GP)** is intended for use with VITEK® 2 Systems for the automated identification of most significant Gram positive organisms. There are 43 biochemical tests measuring carbon source utilization, enzymatic activities and resistance. Final identification results are available in approximately eight hours or less

The VITEK® 2 **Anaerobic and Corynebacteria identification card (ANC)** is intended for use with VITEK® 2 Systems for the automated identification of most clinically significant anaerobic organisms and *Corynebacterium* species. The ANC card is based on established biochemical methods and newly developed substrates. There are 36 biochemical tests measuring carbon source utilization and enzymatic activities. Final results are available in approximately six hours.

The VITEK® 2 **Neisseria-Haemophilus identification card (NH)** is intended for use with the VITEK® 2 Systems for the automated identification of most clinically significant fastidious organisms. The NH Card is based on established biochemical methods and newly developed substrates measuring carbon source utilization and enzymatic activities. There are 30 biochemical tests. Final identification results are available in approximately 6 hours.

The VITEK® 2 **Yeast identification card (YST)** is intended for use with VITEK® 2 Systems for the automated identification of most clinically significant yeasts and yeast-like organisms. The YST card is based on established biochemical methods and newly developed substrates. There are 46 biochemical tests measuring carbon source utilization, nitrogen source utilization, and enzymatic activities. Final results are available in approximately 18 hours.

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When used with the VITEK® 2 instrumentation, the identification cards are a complete system for routine identification testing of most clinically significant organisms.

MATERIALS AND SUPPLIES

Required materials:

- VITEK® 2 Identification Card (GN, GP, ANC, NH, and YST)
- VITEK® 2 DensiCHEK™ Plus (*refer to DensiCHEK™ Plus Users Guide on instrument desktop)*
- DensiCHEK™ Plus Standards Kit
- VITEK® 2 Cassette
- Sterile Saline (aqueous 0.45% to 0.50% NaCl, pH 4.5 to 7.0)
- 12 mm x 75 mm clear plastic (polystyrene) disposable test tubes
- Sterile sticks or swabs
- VITEK® FLEXPREP Software (*Refer to VITEK® 2XL Instrument User Manual, Section 2-1 for detailed information.)*

STORAGE AND HANDLING

Store the unopened cards in their original package liner at 2C to 8C.

PROCEDURE

The inoculum should be prepared from a pure culture. In case of mixed cultures, a re-isolation step is required. It is recommended that a purity check plate be done to ensure that a pure culture was used for testing.

Precautions

Check the expiration date shown on package liner to ensure the card has not expired. Do not use card after the expiration date.
Allow the card to come to room temperature before opening the package liner.
Inspect cards for tape tears or damage to the tape prior to use and discard any that are suspect.
Check the saline level in the tubes after the cassette had been processed to ensure proper filling of card.
Do not use glass tubes. Use clear plastic (polystyrene) tubes only. Variation exists among test tubes of standard diameter. Carefully place the tube in the cassette. If resistance is encountered, discard and try another tube that does not require pressure to insert.
A Gram Stain should be performed to determine an organism's gram reaction and morphology prior to selecting which identification card to inoculate.

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Inoculum Preparation

Select isolated colonies from a primary plate
Aseptically transfer 3.0 mL of sterile saline into a clear plastic polystyrene test tube.
Use a sterile stick or swab to transfer a sufficient number of morphologically similar colonies to the saline tube prepared in step 2.

Zeroing on Saline Filled Test Tube

This procedure must be performed whenever a new type of test tube (such as a new manufacturer or part number) is used to ensure proper accuracy.

Select a clean test tube and visually confirm that it is free from scratches.

Fill the test tube with sterile saline.

With the DensiCHEK™ Plus powered off, insert the saline filled test tube into the instrument.

Press the **Power** key to turn the DensiCHEK™ Plus on.

Ensure the correct tube type setting for plastic or glass is selected.

Press the **Zero/Scroll** key and slowly rotate the test tube. Ensure one full

rotation is completed before the reading is displayed. The instrument will display a series of dashes followed by 0.00.

Preparing Inoculum Suspensions

Press the Power key to turn the DensiCHEK™ Plus on.

Place the well-mixed organism suspension into the instrument and slowly rotate the test tube. Ensure one full rotation is completed before the reading is displayed.
The DensiCHEK™ Plus will display a series of dashes followed by a reading.

Check that the displayed McFarland value is within the card limits.

Card	McFarland Units
GN	0.5-0.63
GP	0.5-0.63
YST	1.8-2.2
NH	2.7-3.3
ANC	2.7-3.3

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The Cassettes

The cassette is the main component of the test card transport system. It can hold up to 15 test cards
with their inoculum test tubes.

Test Card Slots. The top portion of a cassette is divided into 15 test card slots that can hold various
combinations of VITEK® 2 Systems test cards.

Test Tube Holders. The cassette has 15 wells that hold test tubes for inoculum.

Cassette Base. The base of a cassette is custom shaped to fit into the Filler and the Cassette Load/Unload stations and is designed with a hand grip located on the end of the cassette opposite the bar code.

Note: The age of the suspension before loading the instrument for AST testing must be less than one hour when using VITEK® 2 XL.

FlexPrep Software System

The VITEK® FLEXPREP™ is accessed and used by trained laboratory to define VITEK® 2 cassettes allowing the linking of VITEK® 2 test cards to accession numbers
Computer terminals are networked with the VITEK® 2 PC and are used as additional systems to prepare test cards/run VITEK® Solutions FLEXPREP™. *Refer to FlexPrep Software User's Manual installed on instrument desktop.*

Cassette Identification

From the main Cassette Identification screen, users can navigate to instrument- or isolate specific information.

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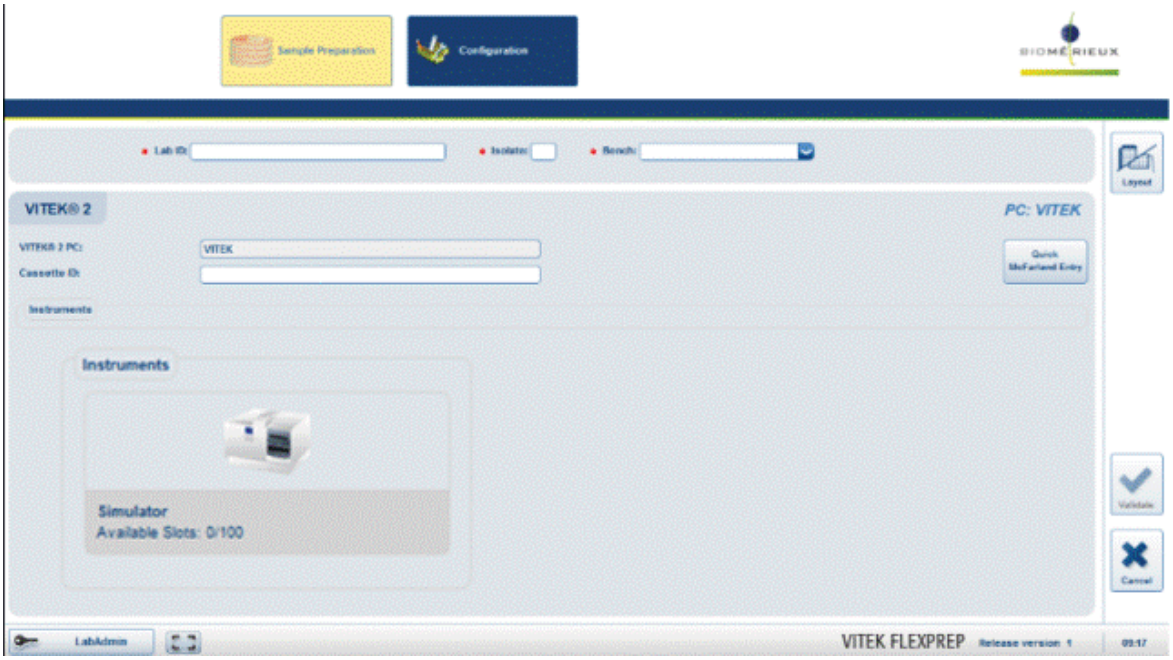

• **Lab ID**: Field where the user can enter or scan the laboratory identification number.
• **Isolate Number**: Field where the user can enter or scan the isolate number, with respect to lab ID.
• **VITEK 2 PC**: The PC to which the FLEXPREP™ cassette will be sent.
• **Cassette ID**: The identifier used to represent the cassette being used in the current cassette preparation.
• VITEK® 2 instrument: Graphic that displays the instruments connected to the VITEK® 2 PC. We The FLEXPREP™ cassette being created can be loaded on any instrument displayed if there is available capacity.
• **Full Screen** button: Expands the window to take up the entire computer screen.
• **Logoff** button: Logs the current user out of the software.
• **Help** button: Accesses the *VITEK® FLEXPREP™ Software User Manual*

Cassette Definition

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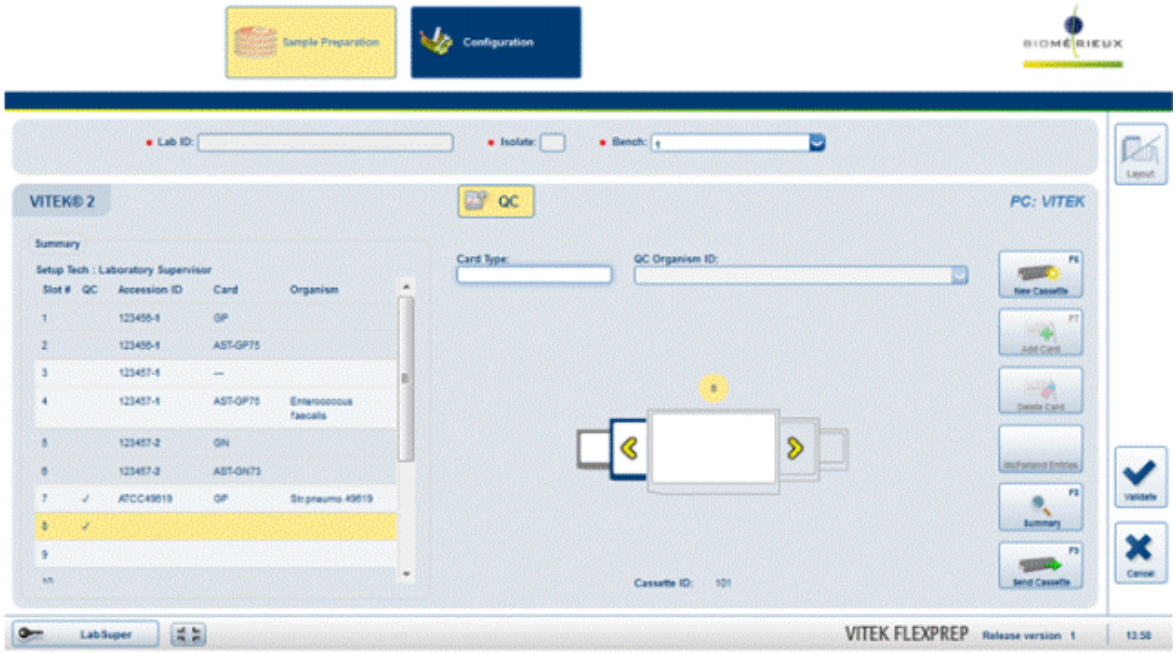

From the Cassette Definition screen, users can enter information regarding cassettes to be sent to the VITEK® 2 instrument.

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Cassette Definition Screen

The Cassette Identification screen allows access to, or entry of, the following information:
• **Lab ID**: Field where the user can enter or scan the laboratory identification number.
• **Isolate Number**: Field where the user can enter or scan the isolate number, with respect to lab ID.
• **QC**: When selected, indicates the card being defined is a quality control test.
• **Card Type**: Indicates the name of the VITEK® 2 test card being used.
• **New Cassette**: Allows the user to start a new cassette definition.
• **Add Card**: Allows the user to pair ID and AST cards.
• **Delete Card**: Allows the user to remove the card defined in a cassette.
• **Summary**: Displays the cassette definition, which allows the user to confirm entries.
• **Send Cassette**: Sends the cassette to the VITEK® 2 instrument
• **Current Selected Card**: Displays the position in the cassette and any cards defined on the isolate.
• **Read Only Preview Summary**: Displays an abbreviated summary screen, which helps the user create and review the cassette as defined in the VITEK® FLEXPREP™ software.
• **Validate** button: Saves the isolate.
• **Cancel** button: Erases the current information

Entering Cassette Information

Starting at the **Cassette Identification** screen, click the **Lab ID** field and enter the Lab

ID.

Lab ID and Isolate Number Fields

This can be done either by scanning the barcode or manually entering the barcode number.

The isolate number will automatically populate. Check the isolate number to confirm it is the isolate desired.

Single ID Card

The **Lab ID**, **Isolate** number, and **Bench** (if enabled) are entered in the Cassette Identification screen.
If the information does not auto-populate, it may be entered or edited by clicking the field and keying the information directly into the field.

Click the **Card Type** field and enter the barcode number.

This can be done either by scanning the barcode or manually entering the barcode number.

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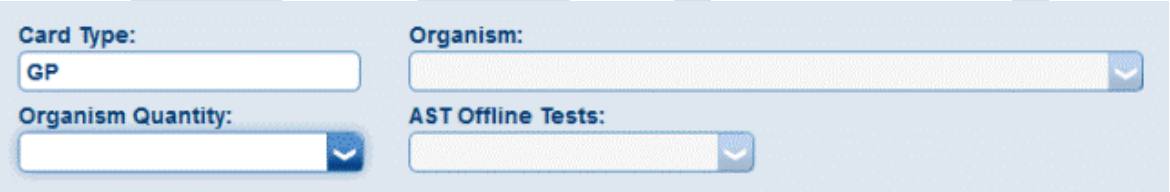
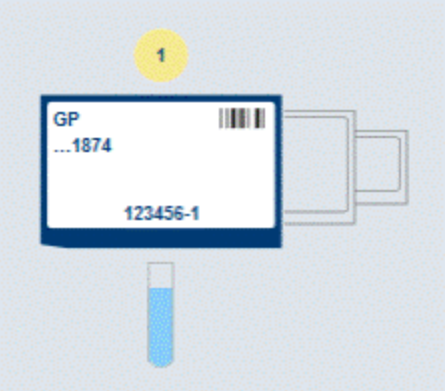
Card Type Field



The card type should auto-populate in the **Card Type** field when the barcode is recognized. Once the card type is entered, a graphic of the isolate will be displayed.
The graphic includes both a card and test tube
Card Graphic



The **Organism** and **AST Offline Tests** fields will be unavailable for entry on an ID card.

Click **Validate** to save the information and advance to defining the next isolate.

Sending a Cassette to VITEK® 2

Once each isolate has been defined in the cassette in VITEK® FLEXPREP™ and the user has confirmed that the software matches the physical cassette, the cassette is ready to be sent to the VITEK® 2 Systems instrument.

Click the **Summary** button to access the Cassette Summary screen.

Review the details of each card slot and ensure the software matches the physical cassette.

Click **Back** to return to the Cassette Definition screen

IMPORTANT: If any cards need to be edited, delete the isolate and re-enter the correct card information.
Click the **Send Cassette** button.

RESULTS/INTERPRETATION

MYLA®* software provides real-time instrument and sample information. Though the Technologist Dashboard, one can review VITEK2 Results and MDRO isolated, enter a manual ID and AST result, and Fix Patient Inconsistencies and Unknown Codes. Refer to the *Myla Customer Training Manual, Section 4, Managing Test Information, pages 4.18 through 4.60.*

Information regarding testing, managing, and viewing QC reports can be found in the VITEK 2 60/ XL Customer Training Manual, Sections 9.11 through 9.31
Quality Control Cards
Click the **QC** button.

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Click the **Card Type** field and enter the barcode.
This can be done by scanning the barcode or entering it manually.

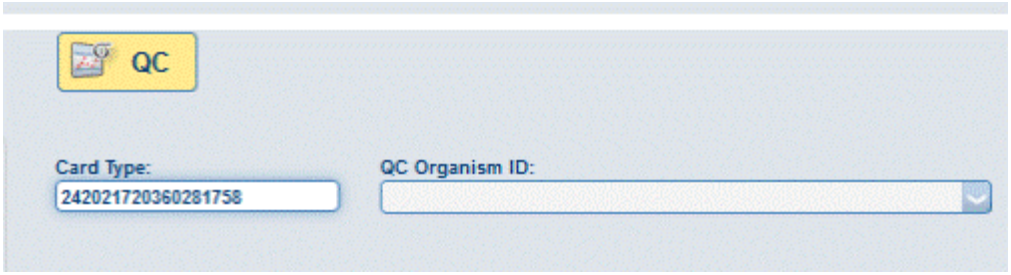

Figure 32: Card Type Field with Barcode

The **Card Type** field will auto-populate with the card type when the barcode is recognized. The **Shipment Date**, **Lot Number**, and **Expiration Date** fields will populate if the user entered a shipment in the VITEK® 2 Systems software.
If the user has not entered the shipment information, the system will prompt the user to enter the shipment information before proceeding.

Figure 33: Card Type Field with Card Type

Quality control organisms and their expected results are listed in the VITEK® 2 Identification Quality Control Tables found in the *VITEK® 2 Systems Product Information Manual, Comprehensive Quality Control, Chapter 9*
The QC organisms should be processed according to the procedure for test isolates. If the reactions do not meet the expected results, subculture for purity, and repeat the test.

TROUBLESHOOTING

An abbreviated instrument trouble shooting guide can be found in the
To resolve card handling and processing messages refer to VITEK® 2 Instrument User Manual, *Section 8, Troubleshooting the VITEK2® Instrument, Section 8.1-8.29*
If you have attempted to troubleshoot using the available information and the system continues to be down, you must call the Technical Support Center.
If you need to call for technical support, please have the following information available:

- Instrument Functional Location 522051
- Customer Number 1010426
- Software version 9.01

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- The function you were performing when the problem occurred
- Any messages that appeared when the problem occurred.
- From the United States or Canada, call 1-800-682-2666

MAINTENANCE

Refer to the *VITEK® 2 Instrument User Manual, Section 7, Maintaining the VITEK® 2 Instrument, 7.1-7.30* for Daily, Weekly, and Monthly maintenance information.

Shut down and Startup of the VITEK® 2 can be found in the *VITEK® 2 Instrument User Manual, Section 7.25, Shutting Down the Instrument*

LIMITATIONS

Use of powdered gloves may interfere with the optics.

Suspensions not within the appropriate zone on the VITEK® 2 DensiCHEK™ Plus may compromise card performance.

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The VITEK® 2 GN and GP Identification cards cannot be used with direct clinical samples or other sources containing mixed flora. Any change or modification in the procedure may affect the results.

Newly described or rare species may not be included in the GN or GP database. Selected species will be added as strains become available. Testing of unclaimed species may result in an unidentified result or a misidentification.

REFERENCE

VITEK® 2 Systems Product Information Manual, Reference Number 410791, bioMérieux, Inc., Durham, North Carolina, September 2010.

VITEK® 2XL Instrument User Manual

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REVIEW DATE: 12/2016
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REVISION DATES:
1/2018, 12/2018, 12/2019, 7/16/21, 9/2023,4/25,2/2026
```

All Revision Dates

3/2/2026

Approval Signatures

Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator, VCMC & SPH	3/2/2026
Policy Owner	Linda Conboy: Supervisor-Microbiology, Laboratory Services	3/1/2026
Policy Owner	M. Anwar Molani: Medical Director, Laboratory Services	3/1/2026
Policy Owner	Erlinda Roxas: Director, Laboratory Services	2/28/2026

COPY

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Last Revised	3/2/2026
Next Review	3/1/2028
Owner	Linda Conboy: Supervisor-Microbiology, Laboratory Services
Policy Area	Laboratory Services - Microbiology

L.MIC 10.2 VITEK® 2 Antimicrobial Susceptibility Tests (AST)

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The VITEK® Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an *in vitro* test to determine the susceptibility of clinically significant aerobic Gram-negative and Gram-positive organisms to antimicrobial agents when used as instructed.

SUMMARY AND EXPLANATION

Susceptibility testing is indicated for any organism that contributes to an infectious process warranting antimicrobial chemotherapy. Susceptibility tests are most often indicated when the causative organism is thought to belong to a species capable of exhibiting resistance to commonly used agents. Isolated colonies of each type of organism that may play a pathogenic role are selected from an agar plate and tested for susceptibility. These tests are then examined, and the Minimum Inhibitory Concentration (MIC) is determined. The MIC obtained using a dilution test may tell the physician the concentration of an antimicrobial agent needed at the site of infection to inhibit the infecting organism.

MICs have traditionally been determined using antimicrobial concentrations derived from serial twofold dilutions. The MIC is then determined from the lowest concentration that exhibits inhibition of growth. An interpretive criterion (Susceptible, Intermediate, or Resistant) can then be assigned to MIC results to aid in the direction of therapy.

For some antimicrobials (e.g., high-level gentamicin, high-level streptomycin) a qualitative result is generated.

The standard and reference procedures are based on susceptibility tests requiring 16 to 24 hours of incubation for bacteria.

Extended-Spectrum Beta Lactamases (ESBLs)

ESBLs are enzymes that arise by mutations in genes for common plasmid-mediated beta-lactamases. Strains of *Klebsiella* spp. and *E. coli* that produce ESBLs may be clinically resistant to therapy with penicillins, cephalosporins, or aztreonam despite apparent *in vitro* susceptibility to some of these agents. Some of these strains will show MICs above the normal susceptible population but below the standard breakpoints for certain extended spectrum cephalosporins or aztreonam. The VITEK® 2 ESBL Test is a confirmatory test for those ESBLs inhibited by clavulanic acid, and it utilizes cefepime, cefotaxime, and ceftazidime, with and without clavulanic acid, to determine a positive or negative result.

PRINCIPLE

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The AST card for VITEK® 2 Systems is an automated test methodology based on the MIC technique reported by MacLowry and Marsh and Gerlach. The AST card is essentially a miniaturized and abbreviated version of the doubling dilution technique for MICs determined by the microdilution method.

Each AST card contains a control well containing only microbiological culture medium. The remaining microwells contain premeasured amounts of specific antimicrobials combined with culture medium.

The organism suspension to be tested must be diluted to a standardized concentration in 0.45% saline before being used to rehydrate the antimicrobial medium within the card. The card is then filled, sealed, and placed into the instrument incubator/reader, either automatically (as with VITEK® 2 60 or VITEK® 2 XL) or manually (as with VITEK® 2 Compact). The instrument monitors the growth of each well in the card over a defined period (up to 18 hours for Gram-negatives). At the completion of the incubation cycle, MIC values (or test results, as appropriate) are determined for each antimicrobial contained on the card.

STORAGE AND HANDLING

Upon receipt, store VITEK® 2 AST cards unopened in their original package liner at 2°C to 8°C.

Check the expiration date shown on package liner to ensure the card has not expired. Do not use card after the expiration date.

Allow the card to come to room temperature before opening the package liner.

Inspect cards for tape tears or damage to the tape prior to use and discard any that are suspect.

REAGENTS

When used with VITEK® 2 instrumentation, the AST card is a complete system for routine susceptibility testing. Each AST card contains selected antimicrobials in varying concentrations, dried with a microbiological culture medium.

Refer to Package Inserts on computer desktop for detailed list of antimicrobials available.

MATERIAL AND SUPPLIES

COPY

• VITEK® 2 DensiCHEK™ Plus and DensiCHEK™ Plus Standards
• VITEK® 2 Cassette
• Adjustable volume saline dispenser
• 12 mm x 75 mm clear plastic (polystyrene) disposable test tubes
• VITEK® 2 Pipettor/Diluter Accessory Kit (containing instrument pipette tips and saline hookup) and 0.45% saline bag

Materials required, but not provided are:

• Sterile saline (aqueous 0.45% to 0.50% NaCl, pH 4.5 to 7.0)
• Loops, sterile sticks, or swabs
• Appropriate agar medium
• QC isolates
• VITEK® 2 AST Cards

PROCEDURE

Test Card Set Up

The following procedure contains general information applicable to all susceptibility products. The inoculum used for antimicrobial susceptibility testing is controlled using a turbidity standard.

Zeroing on Saline Filled Test Tube

This procedure must be performed whenever a new type of test tube (such as a new manufacturer or part number) is used to ensure proper accuracy.
Select a clean test tube and visually confirm that it is free from scratches.
Fill the test tube with sterile saline.

With the instrument powered off, insert the saline filled test tube into the instrument.

Press the **Power** key to turn the instrument on.

Ensure the correct tube type setting for plastic or glass is selected.

Press the **Zero/Scroll** key and slowly rotate the test tube. Ensure one full rotation is completed before the reading is displayed. The instrument will display a series of dashes followed by 0.00 +/- 0.01.

Note: The DensiCHEK Plus measurement performance is verified using one or more of the McFarland standards (0.5, 2.0 or 3.0) after zeroing the instrument with the 0.0 McFarland Standard (blank). This is performed monthly in tandem with instrument monthly maintenance.

COPY

Preparing Inoculum Suspensions

Label the tubes.

Apply all labels or markings from the middle of the test tube to the top of the tube (SafeZone).

Do not place any labels or markings from the center to the bottom of the tube as readings occur in this area.

Aseptically transfer 3.0 mL of sterile saline into a labeled clear plastic (polystyrene) test tube (12 mm x 75 mm). **Do not use glass tubes**.

Prepare the inoculum from a pure culture, according to good laboratory practices. In case of mixed cultures, a re-isolation step is required.

A purity check plate must be performed to ensure that a pure culture was used for testing.

Press the **Power** key to turn the *DensiCHEK™ Plus* on
Place the well-mixed organism suspension into the instrument and slowly rotate the test tube. Ensure one full rotation is completed before the reading is displayed. The instrument will display a series of dashes followed by a reading.

Check that the displayed McFarland value is within the acceptable range for the organism tested.

McFarland Equivalence turbidity standards are available for comparison of bacterial suspensions.

If the displayed value is not within an acceptable range, adjust the suspension by

adding organism or saline to achieve a suspension that falls within the range.

AST Cards GN-95, GP-75, XN09, ST-02	*GNI and GPI*	*YST ID*	*NH ID*	*ANC ID*
0.5-0.63 McFarland Unit	*0.5-0.63 McFarland Unit*	*1.8-2.2 McFarland Unit*	*2.7-3.3 McFarland Unit*	*2.7-3.3 McFarland Unit*

Refer to DensiCHEK™ Plus User's Manual , Troubleshooting, installed on instrument desktop for detailed information regarding the use of the DensiCHEK Plus.

The Cassettes

The cassette is the main component of the test card transport system. It can hold up to 15 test cards
with their inoculum test tubes.

Test Card Slots. The top portion of a cassette is divided into 15 test card slots that can hold various
combinations of VITEK® 2 Systems test cards.

Test Tube Holders. The cassette has 15 wells that hold test tubes for inoculum.

Cassette Base. The base of a cassette is custom shaped to fit into the Filler and the Cassette Load/Unload stations and is designed with a hand grip located on the end of the cassette opposite the bar code.

COPY

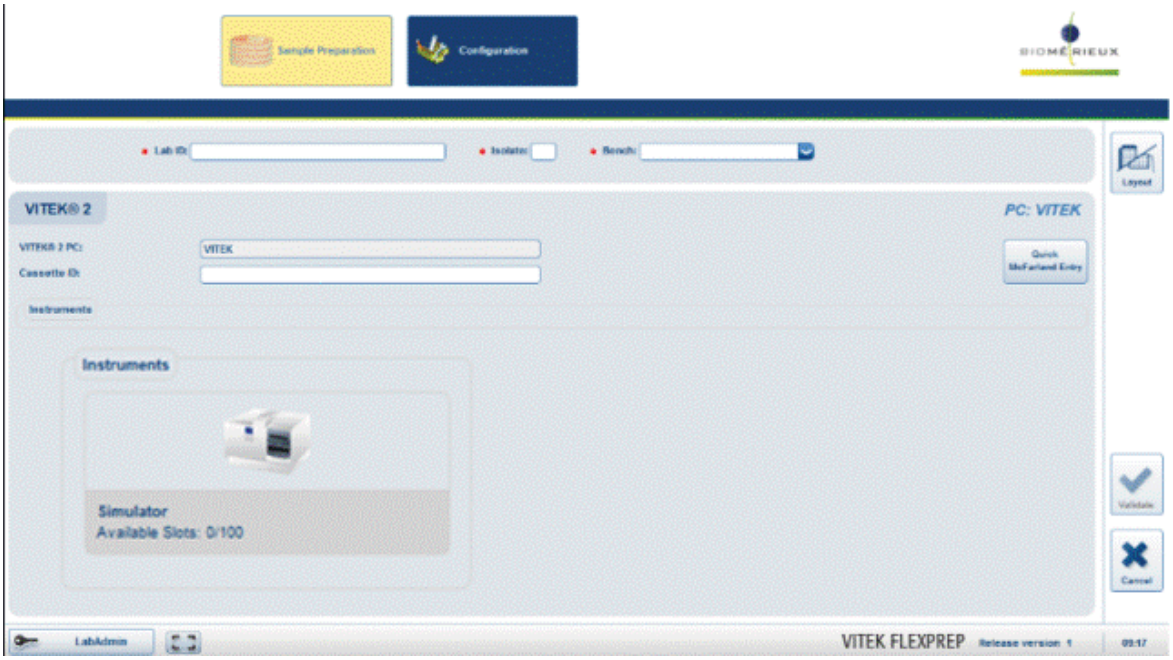
Note: The age of the suspension before loading the instrument for AST testing must be less than one hour when using VITEK® 2 XL.
FlexPrep Software System

The VITEK® FLEXPREP™ is accessed and used by trained laboratory to define VITEK® 2 cassettes allowing the linking of VITEK® 2 test cards to accession numbers

Computer terminals are networked with the VITEK® 2 PC and are used as additional systems to prepare test cards/run VITEK® Solutions FLEXPREP™. *Refer to FlexPrep Software User's Manual installed on instrument desktop.*

Cassette Identification

COPY



From the main Cassette Identification screen, users can navigate to instrument- or isolate specific information.

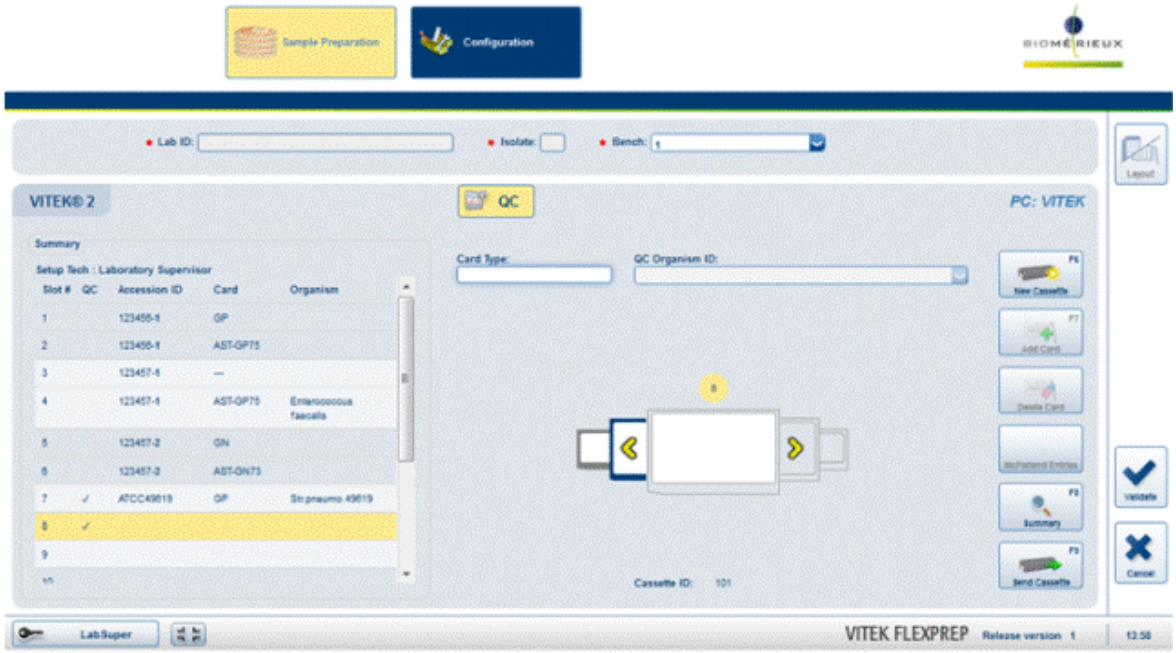
COPY

• **Lab ID**: Field where the user can enter or scan the laboratory identification number.
• **Isolate Number**: Field where the user can enter or scan the isolate number, with respect to lab ID.
• **VITEK 2 PC**: The PC to which the FLEXPREP™ cassette will be sent.
• **Cassette ID**: The identifier used to represent the cassette being used in the current cassette preparation.
• VITEK® 2 instrument: Graphic that displays the instruments connected to the VITEK® 2 PC. We The FLEXPREP™ cassette being created can be loaded on any instrument displayed if there is available capacity.
• **Full Screen** button: Expands the window to take up the entire computer screen.
• **Logoff** button: Logs the current user out of the software.
• **Help** button: Accesses the *VITEK® FLEXPREP™ Software User Manual*

Cassette Definition

From the Cassette Definition screen, users can enter information regarding cassettes to be sent to the VITEK® 2 instrument or VITEK® 2 Compact instrument.

Cassette Definition Screen



The Cassette Identification screen allows access to, or entry of, the following information:

- **Lab ID**: Field where the user can enter or scan the laboratory identification number.
- **Isolate Number**: Field where the user can enter or scan the isolate number, with respect to lab ID.
- **QC**: When selected, indicates the card being defined is a quality control test.
- **Card Type**: Indicates the name of the VITEK® 2 test card being used.
- **Organism:** Allows selection of genus and species of a particular microbe when an AST card is used.
- **AST Offline Test** (if enabled): Selects tests that are performed outside of the VITEK® 2 system and may be required to obtain a susceptibility result.
- **New Cassette**: Allows the user to start a new cassette definition.
- **Add Card**: Allows the user to pair ID and AST cards.
- **Delete Card**: Allows the user to remove the card defined in a cassette.
- **Summary**: Displays the cassette definition, which allows the user to confirm entries.
- **Send Cassette**: Sends the cassette to the VITEK® 2 instrument
- **Current Selected Card**: Displays the position in the cassette and any cards defined on the isolate.
- **Read Only Preview Summary**: Displays an abbreviated summary screen, which helps the user create and review the cassette as defined in the VITEK® FLEXPREP™ software.
- **Validate** button: Saves the isolate.
- **Cancel** button: Erases the current information

COPY

Entering Cassette Information

Starting at the **Cassette Identification** screen, click the **Lab ID** field and enter the Lab ID.

Lab ID and Isolate Number Fields

This can be done either by scanning the barcode or manually entering the barcode number.

The isolate number will automatically populate. Check the isolate number to confirm it is the isolate desired.

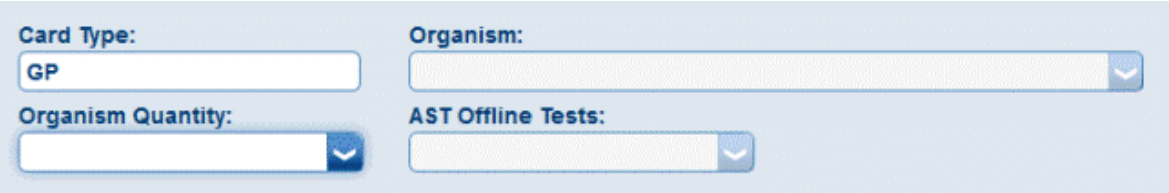
Defining Card Types

There are four possible scenarios for defining card types in a cassette:
Single ID Card
ID Card with AST Card(s)
Single AST Card
Quality Control Cards
Each scenario involves a slightly different method of data entry. All scenarios require the user to validate the isolate before defining the next isolate or sending the cassette.

COPY

Single ID Card
The **Lab ID**, **Isolate** number, and **Bench** (if enabled) are entered in the Cassette Identification screen.
If the information does not auto-populate, it may be entered or edited by clicking the field and keying the information directly into the field.
Click the **Card Type** field and enter the barcode number.
This can be done either by scanning the barcode or manually entering the barcode number.

Card Type Field

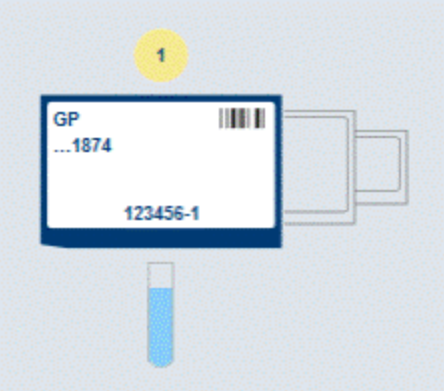


The card type should auto-populate in the **Card Type** field when the barcode is recognized. Once the card type is entered, a graphic of the isolate will be displayed.
The graphic includes both a card and test tube

Card Graphic
The **Organism** and **AST Offline Tests** fields will be unavailable for entry on an ID card.

Click **Validate** to save the information and advance to defining the next isolate.

ID Card with AST Card(s)

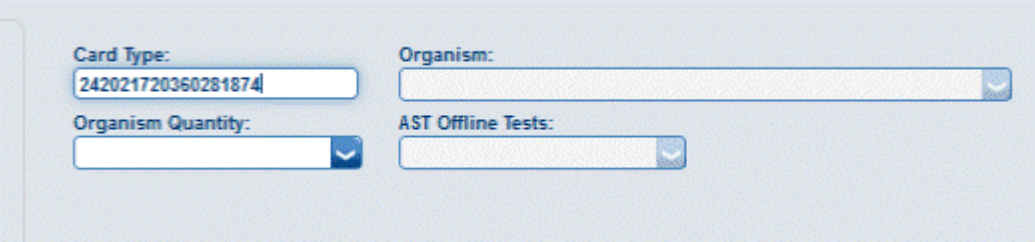


For the first care in the isolate, the **Lab ID**, **Isolate** number, and **Bench** (if enabled) selection are entered in the Cassette Identification screen. This information may be edited prior to validation by clicking the field and manually entering the correction. If the information does not auto-populate, it may be entered or edited by clicking the field and keying the information directly into the field.

Lab ID, Isolate, and Bench Fields

Click the **Card Type** field and enter the barcode number for the ID card. This can be done by scanning the barcode or entering it manually.

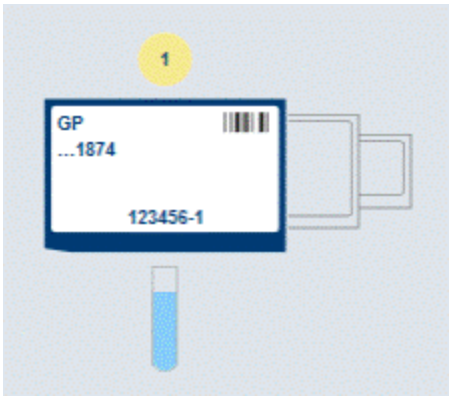
Card Type Field with Barcode



The **Card Type** field will auto-populate with the card type when the barcode is recognized. Once the card type is entered, a graphic of the isolate will be displayed. The graphic includes both a card and a test tube.

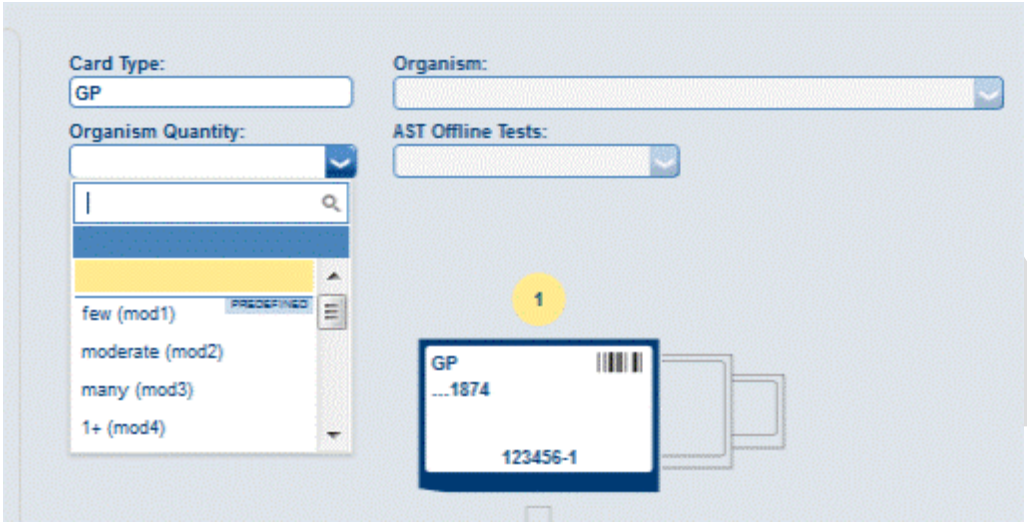
Card Graphic

COPY



The **Organism Quantity** field is not required, but users can select from the drop-down menu if desired.

Organism Quantity Drop-down Menu



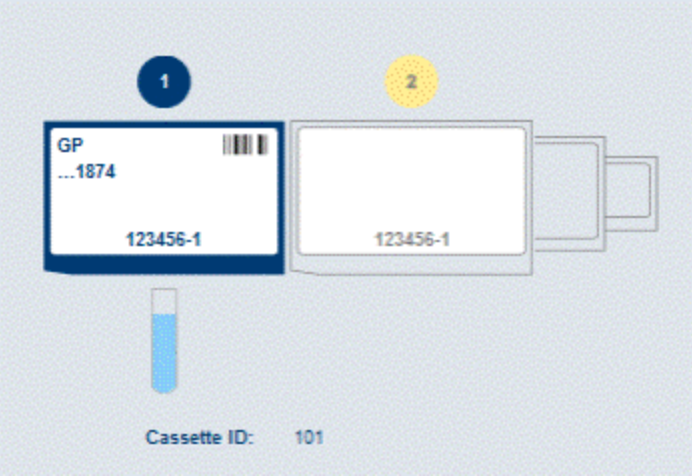
The **Organism** and **AST Offline Tests** will be unavailable for entry on an ID card.
IMPORTANT: Do not click Validate. If Validate is clicked, the ID card will validate as a single card and cannot be paired with an AST card.

Click **Add Card** (**F8**) to add an AST card to the ID card.

Add Card Button

After the AST card is added, a second empty card graphic will appear beside the ID card graphic.

AST Card with ID Card



Click the **Card Type** field and enter the barcode number.
This can be done either by scanning the barcode or manually entering the barcode number.

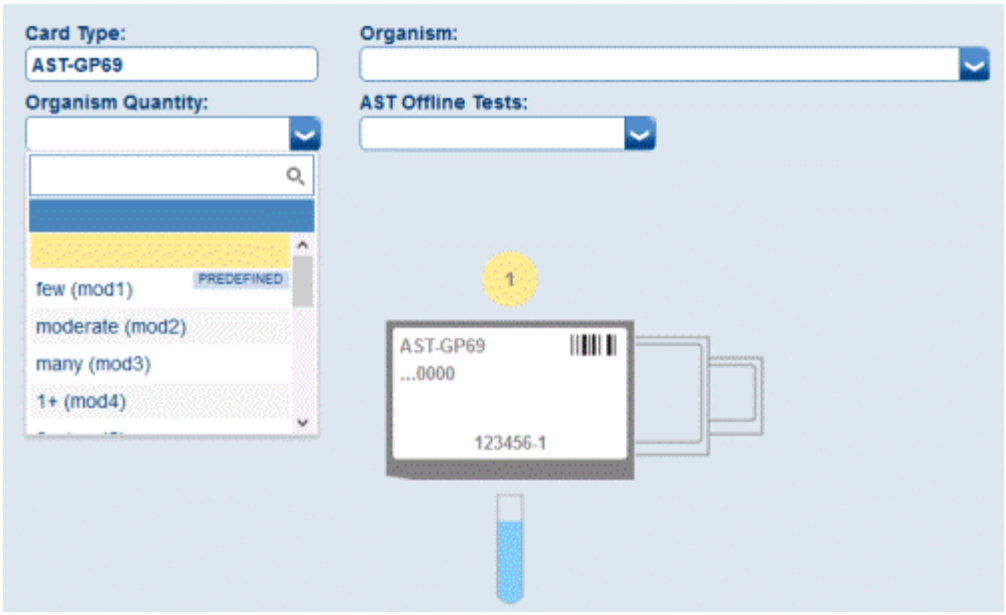
Card Type with Barcode

The **Card Type** field will auto-populate with the card type when the barcode is recognized.
Note: *If the card type is not recognized, it must be defined in the VITEK® 2 Systems software before the card can be added to the cassette. Refer to the VITEK® 2 Systems Software User Manual.*

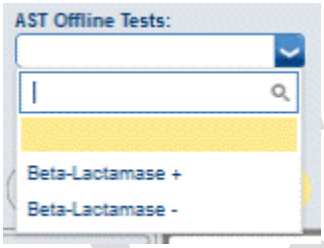
The **Organism Quantity** and **AST Offline Tests** fields are not required, but users can select from the drop-down menu if desired.

Organism Quantity Drop-down Menu

COPY



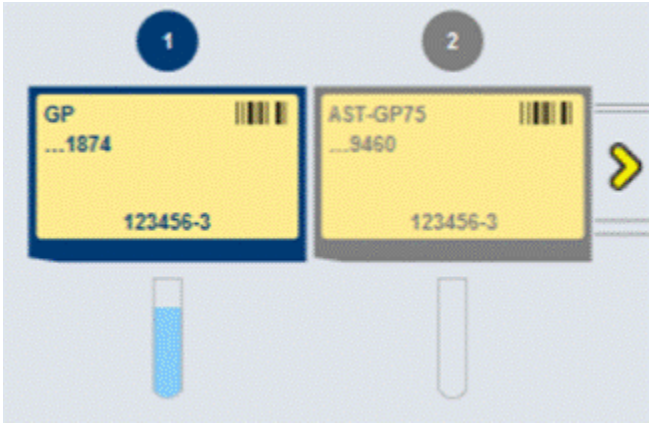
AST Offline Tests Drop-down Menu



COPY

The **Organism** field will be unavailable for entry, since an ID card is paired with the AST card.
Once the card type is entered, a graphic of the isolate will be displayed. The graphic includes both a card and test tube.

Card Graphic



Note: *Additional extension AST cards may be entered in addition to paired ID and AST cards. To add an extension card to an ID/AST pair, repeat steps 3 and 4.*

Click **Validate** to save the information and advance to the next isolate.

Single AST Card

The **Lab ID**, **Isolate** number, and **Bench** selection are entered in the Cassette Identification screeen. This information may be edited by clicking the field and manually entering the correction.

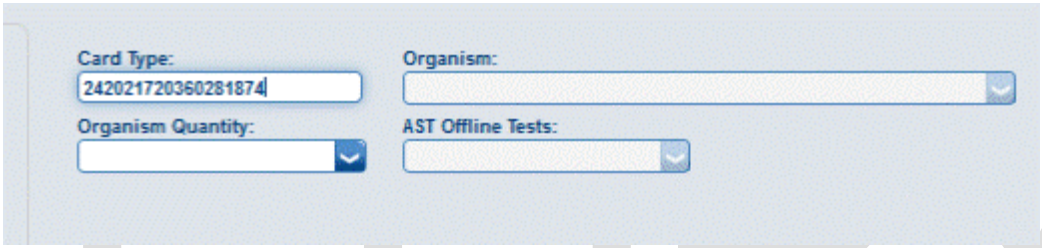
If the information does not auto-populate, it may be entered or edited by clicking the field and keying the information directly into the field.

Lab ID, Isolate, and Bench Fields

Click the **Card Type** field and enter the barcode number.

This can be done by scanning the barcode or entering it manually.

Card Type Field with Barcode



The **Card Type** field will auto-populate with the card type when the barcode is recognized.

Note: *If the card type is not recognized, it must be defined in the VITEK® 2 Systems software before the card can be added to the cassette. Refer to the VITEK® 2 Systems Software User Manual.*

Once the card type is entered, a graphic of the isolate will be displayed.

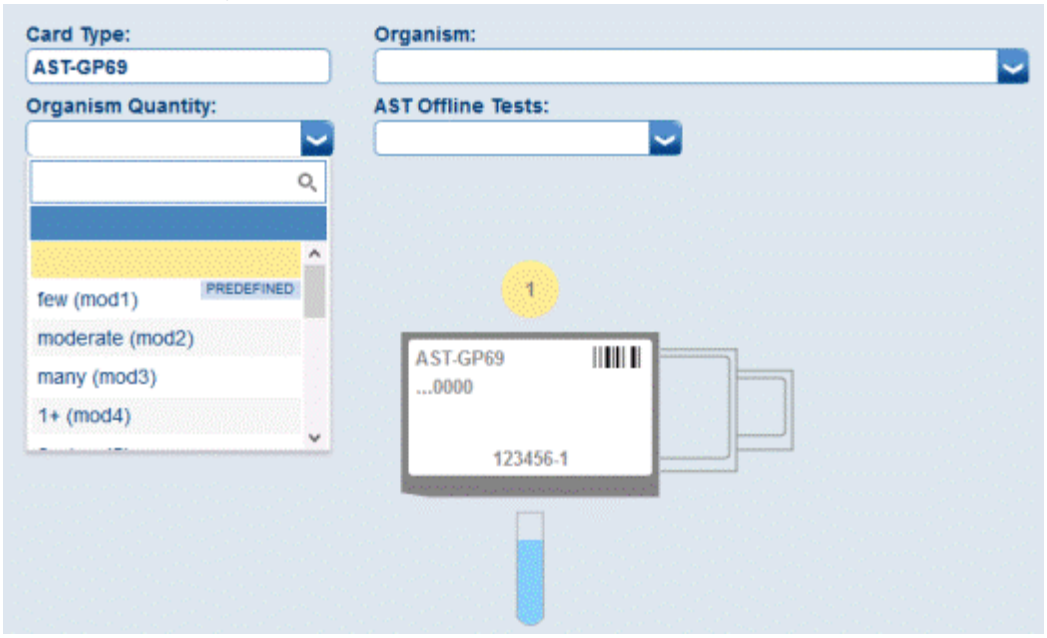
The first slot shows a test tube filled with saline (no card), and the second slot shows the AST card and an empty test tube.

Card Graphic (with Auto Dilute Enabled)

The **Organism Quantity**, **Organism**, and **AST Offline Tests** fields may not be required, but users can select from the drop-down menu if desired.

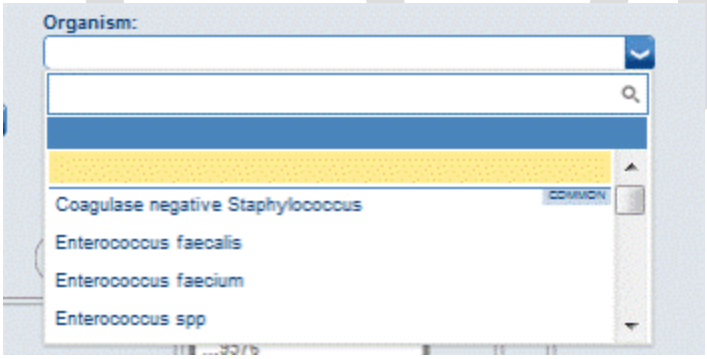
COPY

Organism Quantity Drop-down Menu

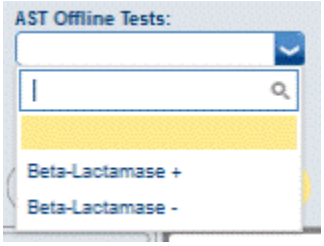


Start typing any portion of an organism name and the drop-down menu will filter to the best matches available.

Organism Drop-down Menu



AST Offline Tests Drop-down Menu



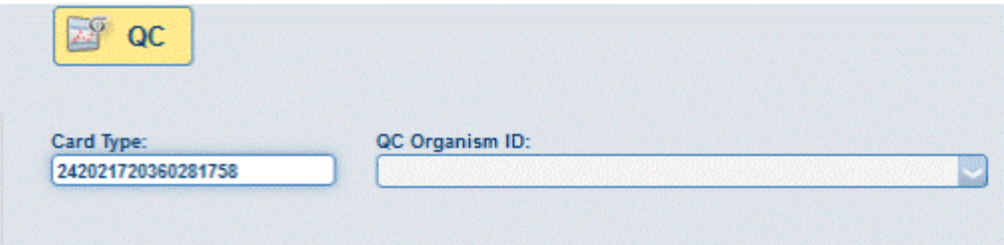
Click **Validate** to save the information and enter the next isolate.

Quality Control Cards

COPY

Click the **QC** button.
Click the **Card Type** field and enter the barcode.
This can be done by scanning the barcode or entering it manually.

Card Type Field with Barcode

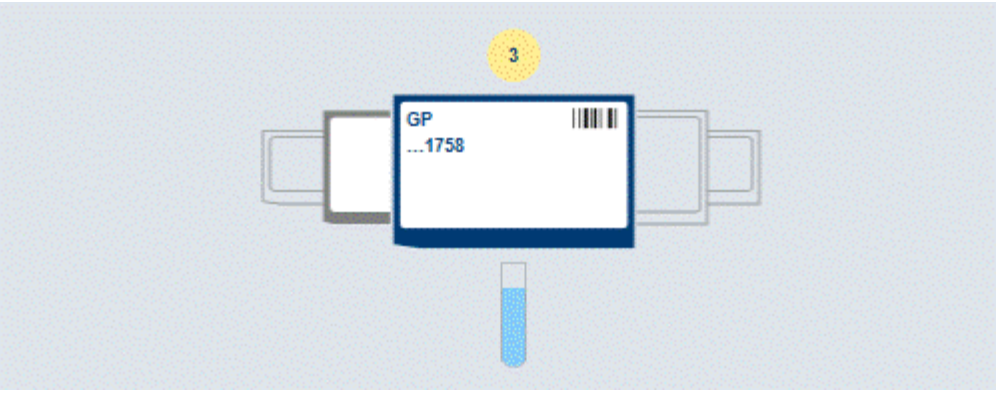


The **Card Type** field will auto-populate with the card type when the barcode is recognized. The **Shipment Date**, **Lot Number**, and **Expiration Date** fields will populate if the user entered a shipment in the VITEK® 2 Systems software.
If the user has not entered the shipment information, the system will prompt the user to enter the shipment information before proceeding.

Card Type Field with Card Type

Note: *If the card is an AST card and the card type is not recognized, it must be defined in the VITEK® 2 Systems software before the card can be added to the cassette. Refer to the VITEK® 2 Systems Software User Manual.*
The next two graphics show the proper setup for ID and AST cards used for QC

ID Card for QC



COPY

AST Card for QC

Start typing any portion of an organism name and the drop-down menu will filter to the best matches available. Select the correct **QC Organism ID** for the AST card from the **Organism** drop-down field.
Click **Validate** to save the information and advance to the next card entry.
Note: *QC and patient samples may be defined in the same cassette. To define QC, click the* ***QC*** *button, then click the* ***QC*** *button again to turn off QC for patient sample definition.*

COPY

Entering Data for ANC Offline Tests

When an ANC card is scanned into the ID Card field, VITEK® FLEXPREP™ will automatically display ANC Offline Tests which may be entered.

ANC Offline Tests

Offline Test	Description
Gram Stain	Positive, Negative, Variable
Morphology	Cocci, Bacilli, Coccobacilli
Aerotolerance	Aerobe, Anaerobe, Facultative

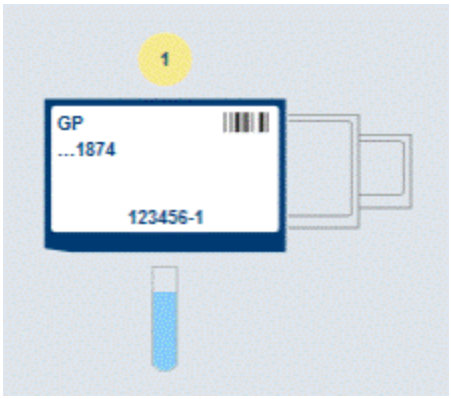
If ANC tests are not entered, the system will display "missing" in the offline test field. Once all offline tests have been entered, a summary of the tests and results are displayed. A cassette can be saved with ANC offline tests missing. The isolate will be qualified until offline tests are entered.

Working with Cards

Selecting a Card

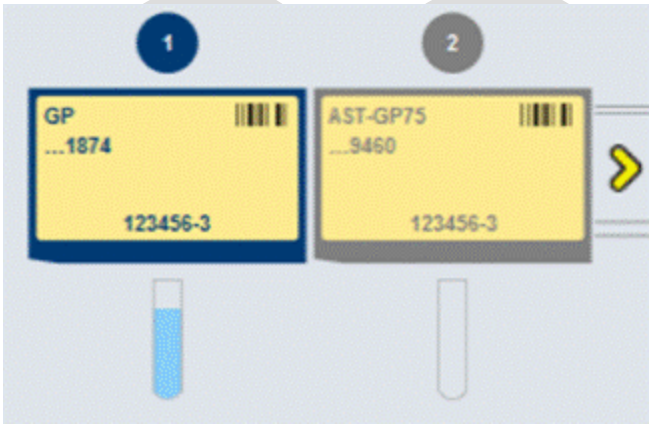
Cards are selected by clicking the card graphic. There are three scenarios for selecting a card:
Single ID card: When there is a single ID card, click the card to select it.

Selecting a Single ID Card



ID Card paired with AST card(s): When there is an ID card paired with AST cards, the user may want to select a single card or both cards.
Because the AST card is paired with the ID card, when the user clicks the ID card (on the left), both cards will be selected.

Selecting Both ID and AST Card



When the AST card (on the right) is clicked, only the AST card will be selected.

Selecting Only the AST Card

COPY

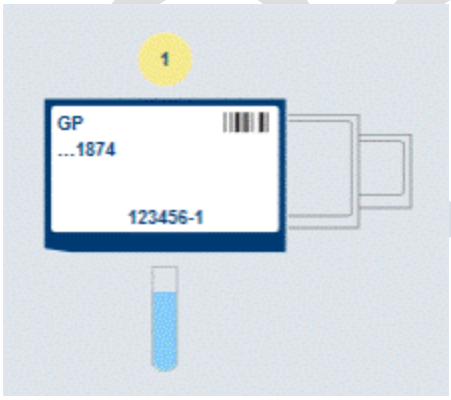
No ID cards: When only AST cards are entered, and the system is configured for automatic dilution, there will be a graphic with an empty slot for a filled test tube on the left and the AST card on the right. Because the slots are paired, any cassette slot may be clicked to select both.

Selecting with No ID Cards

Card Graphics

Once a card barcode is entered, graphics showing the entered card as well as the test tube will appear. The figure below shows an example of a single ID card with a filled sample test tube.

Single ID Card



The figure below shows an example of an ID card paired with an AST card when automatic dilution is enabled. Notice the ID card has organism suspension in the test tube and the AST card does not. If pre dilute is enabled, the AST card will also have organism suspension shown in the test tube.

ID Card Paired with AST Card

COPY

The figure below shows an example of a single AST card showing the first slot with a filled organism suspension test tube and the second slot with an empty test tube for the AST card when the system is configured for auto dilution. If configured for pre-diluted, the first slot will contain the filled organism suspension test tube and the AST card.

Single AST Card

COPY

Navigating with Multiple Cards

When several card types have been entered, the user may need to go back to a previous card slot. The **yellow left** and **right arrows** can be used to move between cards.

Using Arrows for Navigation

As the user navigates through the cards, the summary preview (**F9**) will show the specifics of the current card in the highlighted row. The summary preview is read-only and cannot be used to navigate through the cards.

Current Card Seen on Summary Screen

Changing a Card Type in the Cassette

Card types may not be modified once they have been validated. To change card type information, the card must be deleted and a new card with the correct information must be created.

If an AST card that was paired with an ID card is deleted, both cards will be deleted and must be recreated.

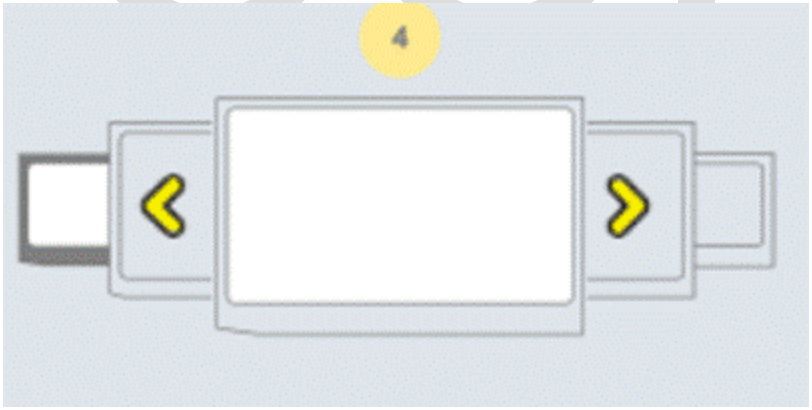
COPY

Deleting a Card

Click a slot associated with the desired isolate group.

. User the **Left** and **Right Arrow** buttons to navigate to the correct car

Navigate to the Card

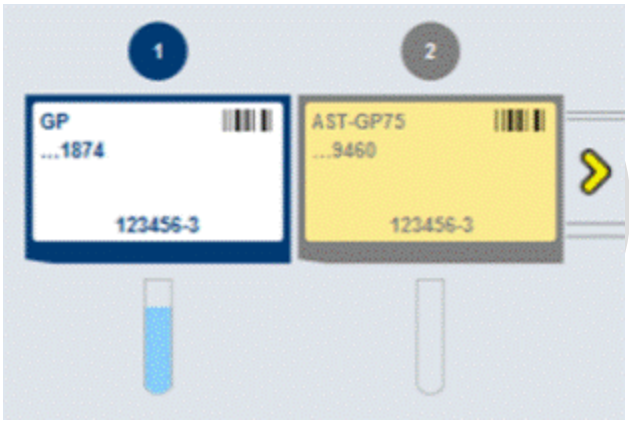


1. Click the card to be deleted.

Select the Card to Be Deleted

Note: *To delete an AST card paired to an ID card, select only the AST card.*

Select AST Card



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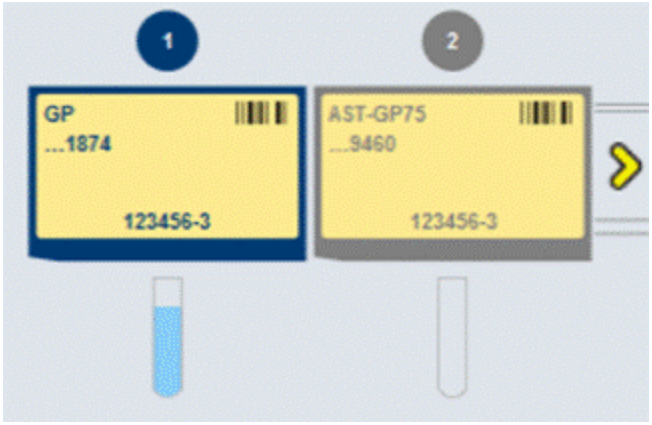
Note: *To delete an ID card that is paired with an AST card, select the ID card on the left. Doing so will select both cards. Both cards must be deleted.*

Select Both Cards



Click the **Delete Card** button.
Click **OK** on the **Confirmation** dialog.
The **Please confirm** dialog will appear. This dialog shows the available instruments. attached to the VITEK® 2 PC.

Please Confirm Dialog

IMPORTANT: The cassette must be loaded on one of the instruments shown in the Please confirm dialog. Loading it on an instrument not shown in the dialog will result in errors. Our system has only one instrument so this is not applicable at this time.
Click **OK** to send the cassette.

Load cassette into the instrument.

The VITEK® 2 Systems instrument reads the card barcode in the physical cassette loaded and the system compares it to the FLEXPREP™ definition in the software. When the VITEK® 2 card barcode matches what was expected in the respective cassette slot, the link between sample information and test card is made and is visible in the VITEK® 2 Systems Web Software. For additional information, refer to the *VITEK® 2 Networking Configuration User Guide*.

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RESULTS / INTERPRETATION

VITEK® 2 Systems evaluates each organism's growth pattern in the presence of the antimicrobial in relation to the growth control well. Several parameters based on the growth characteristics are used to determine the MIC or qualitative result (for example, ESBL POS/NEG). The MIC result must be linked to an organism identification to determine a category interpretation. Accurate identification is critical, especially with certain organism/antimicrobial combinations (e.g., Staphylococcus aureus/oxacillin).
In cases where the identification of an organism is in question, confirmatory testing is necessary to ensure correct interpretation of susceptibility results.

A category interpretation will be reported along with a MIC, according to the interpretations defined by the Food and Drug Administration (FDA), CLSI®, MYLA®* software provides real-time instrument and sample information.

Though the Technologist Dashboard, one can review VITEK2 Results and MDRO isolated, enter a manual ID and AST result, and Fix Patient Inconsistencies and Unknown Codes. Refer to the *Myla Customer Training Manual, Section 4, Managing Test Information, pages 4.18 through 4.60.*

Selection of Antimicrobial Agents to report is based on specific organisms isolated from various body sites. This list is based on the CLSI recommendations provided in the M100 Table 1, which suggests those agents that might be reported routinely (groupA0, and that might be reported selectively (Group B). Refer to the Micro 9.11 *Selection, Testing, and Recording of Antimicrobial Agents.*

QUALITY CONTROL

Information regarding testing, managing, and viewing QC reports can be found in the VITEK 2 60/ XL Customer Training Manual, Sections 9.11 through 9.31

The acceptability of the antimicrobial agents are checked by testing organisms with known reactions and MIC ranges weekly using CLSI criteria.

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Organisms are as follows:

Quality control organisms for Gram Negative Susceptibility Card

- *E. coli* ATCC® 25922™
- *P. aeruginosa* ATCC® 27853™
- *E. coli* ATCC® 35218™
- *K. pneumoniae* ssp *pneumoniae* ATCC® 700603™

Quality Control organisms for Gram positive Susceptibility Card

- *E. faecalis* ATCC®29212™
- *S. aureus* ATCC® 29213™
- *E. faecalis* ATCC®51299™
- *S. aureus* ATCC® BAA-1026™
- *S. aureus* ATCC® BAA-976™
- *S. aureus* ATCC® BAA-977™

Quality Control organisms for Streptococcus susceptibility Card (ST-02)

- *S. pneumoniae* ATCC® 49619™
- *S. aureus* ATCC® 29213™

- *S. aureus* ATCC® BAA-977™

Quality Control Card Set up

From the Cassette Definition screen, users can click the QC button to set up Quality Control (QC) tests to check that the reagent is giving accurate results.

Quality Control Screen

The Quality Control screen allows access to, or entry of, the following information:

Read Only Preview Summary mode: Displays an abbreviated summary screen to help the user create and review the cassette as defined in the FLEXPREP™ software.

QC button: When selected, indicates the card being defined is a quality control test.

Card Type: Indicates the name of the VITEK® 2 test card being used.

QC Organism ID: Allows selection of genus, species, and ATCC number of a particular microbe.

When a card barcode is entered, the Shipment Date, Lot Number, and Expiration Date fields will auto-populate based on the card lot number. These fields cannot be edited. If the shipment has not been entered on the lot number, the system prompts the user to enter the shipment information. If there are multiple shipment dates for the card lot, a shipment date is selected from the drop-down list.

The results for the recommended American Type Culture Collection (ATCC**) control organisms are listed in the susceptibility package inserts installed on the computer.

This testing is governed by the laboratory's IQCP plan which includes:

Testing of appropriate QC strains on each new lot/shipment of panels before of concurrently with placing these materials into use for testing patient isolates.

Testing of appropriate QC strains on each panel weekly

Testing of appropriate QC strains on each panel types after major system maintenance or software upgrade before or concurrently with placing the equipment back into service.

Testing of appropriate QC strains against any new antimicrobial agent added to the panel at least 15 times (over a minimum of 5 days) prior to resuming weekly WC testing of panel.

Any out-of-range results are to be immediately investigated and corrective action performed prior to releasing any patient results.

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TROUBLESHOOTING

To resolve card handling and processing messages refer to VITEK® 2 Instrument User Manual, *Section 8, Troubleshooting the VITEK2® Instrument, Section 8.1-8.29*

If you have attempted to troubleshoot using the available information and the system continues to be down, you must call the Technical Support Center.

If you need to call for technical support, please have the following information available:

- Instrument Functional Location 522051
- Customer Number 1010426
- Software version 9.01
- The function you were performing when the problem occurred
- Any messages that appeared when the problem occurred.
- From the United States or Canada, call 1-800-682-2666

MAINTENANCE

Refer to the *VITEK® 2 Instrument User Manual, Section 7, Maintaining the VITEK® 2 Instrument,*

7.1-7.30 for Daily, Weekly, and Monthly maintenance information.

Shut down and Startup of the VITEK® 2 can be found in the *VITEK® 2 Instrument User Manual, Section 7.25, Shutting Down the Instrument.*

LIMITATIONS OF TESTING

Use of powdered gloves may interfere with the optics.

Suspensions not within the appropriate zone on the VITEK® 2 DensiCHEK™ Plus may compromise card performance.

The VITEK® 2 AST cards cannot be used with direct clinical samples or other sources containing mixed flora. Any change or modification in the procedure may affect the results.

Give special consideration to specimen source and patient therapy regimen. AST cards may contain some antimicrobials that are not proven to be effective for treatment of infections due to all organisms that may be tested. For interpreting and reporting of antimicrobial results that have been shown to be active against organism groups both in vitro and in clinical infections, refer to the individual pharmaceutical antimicrobial labeling, or local therapy guidelines.

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Panel Specific Limitations

GN75 (Aerobic gram-negative bacilli)

A negative ESBL test result does not rule out the presence of an ESBL masked by an AmpC beta-lactamase.
Perform an alternative method of testing prior to reporting of results for the following antibiotic/organism combination(s):

- Amikacin: *Acinetobacter baumannii*
- Ampicillin: *Citrobacter* spp., *Enterobacter* spp., *Pantoea* spp., *Serratia* spp., *Cronobacter sakazakii*
- Ampicillin/Sulbactam: *Citrobacter* spp., *Enterobacter* spp., *Pantoea* spp., *Serratia* spp., *Cronobacter sakazakii*
  Perform an alternative method of testing prior to reporting results when a resistant result is obtained with the following antibiotic/organism combination(s):
- Meropenem: *Aeromonas* spp.
  The ability of the AST card to detect resistance with the following combination(s) is

unknown because resistant strains were not available at the time of comparative testing:

- Ertapenem: *E. coli, K. pneumoniae, C. freundii, C. koseri, E. aerogenes, E. cloacae, K. oxytoca* (excluding ESBL producing strains), *M. morganii, P. mirabilis, P. vulgaris, S. marcescens*

NOTE: A result for an antibiotic/organism combination which may have a limitation may be suppressed from reporting.

GP-75 (*Staphylococcus* spp., *Enterococcus* spp., and *S. agalactiae*)

Perform an alternative method of testing prior to reporting of results for the following antibiotic/organism combination(s):

- Daptomycin: *Streptococcus agalactiae*
- Erythromycin: *Streptococcus agalactiae*
  Perform an alternative method of testing prior to reporting of results when a Positive (+) result is obtained with the following antibiotic/organism combination(s):
- Cefoxitin Screen: *Staphylococcus saprophyticus*
  The ability of the AST card to detect resistance with the following combination(s) is unknown because resistant strains were not available at the time of comparative testing:
- Ampicillin: *Streptococcus agalactiae*
- Linezolid: *Enterococcus* spp., *Staphylococcus* spp., *Streptococcus agalactiae*
- Tigecycline: *Enterococcus* spp., *Staphylococcus* spp., *Streptococcus* spp.

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NOTE: A result for an antibiotic/organism combination which may have a limitation may be suppressed from reporting.

XN30 (Aerobic gram negative bacilli)

Ticarcillin/Clavulanic Acid (tcc01n) has been approved for use only with *Pseudomonas aeruginosa*. An alternative method of testing must be performed prior to reporting of results for all other organisms.

Perform an alternative method of testing prior to reporting of results for the following antibiotic/organism combination(s):

- Amikacin (an01n): *Acinetobacter baumannii*
- Aztreonam (atm01n): *Pseudomonas* spp.
- Ceftolozane/Tazobactam (ct01n): *Morganella morganii*, *Providencia rettgeri*, *Serratia marcescens*
- Cefotaxime (ctx02n): *Pseudomonas fluorescens*, *Alcaligenes faecalis*, *Achromobacter denitrificans*, *Hafnia alvei*, *Shigella* spp.
- Cefpodoxime (cpd01n): *Morganella morganii, Serratia* spp.

- Ceftazidime/Avibactam (cza02n): *Providencia rettgeri*

Perform an alternative method of testing prior to reporting results when a resistant result is obtained with the following antibiotic/organism combination(s):

- Meropenem (mem02n): *Aeromonas* spp.
  The ability of the AST card to detect resistance with the following combination(s) is unknown because resistant strains were not available at the time of comparative testing:
- Tigecycline (tgc02n): *C. freundii*, *E. cloacae*, *E. coli*, *K. oxytoca*, *K. pneumoniae*, *C. koseri*, *E. aerogenes*, *S. marcescens*
  The ability of the AST card to detect resistance with the following combination(s) is unknown because an insufficient number of resistant strains were available at the time of comparative testing: If such a strain is observed, it should be submitted to a reference laboratory for further testing.
- Ceftolozane/Tazobactam (ct01n): *Citrobacter koseri*, *Proteus mirabilis*, *Proteus vulgaris*, *Serratia liquefacians*
  Due to an insufficient number of on-scale isolates available for comparative testing, the performance of VITEK® 2 Gram-negative Cefotaxime is unknown for this species with MICs in the range of 1 to 4 µ g/mL. Isolates with MICs of 1 to 4 µ g/mL should be tested using another method.
- Cefotaxime (ctx02n): *Proteus vulgaris*

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Although within Essential Agreement when compared to the reference method, errors (major and/or very major) were observed due to the lack of intermediate category. Testing should be repeated using an alternative testing/reference method prior to reporting results for the following antibiotic/organism(s):
Ceftazidime/Avibactam (cza02n): *Pseudomonas aeruginosa* when the VITEK® 2 MIC is ≥ 16µg/mL due to observed major errors (4.1%), with an adjusted categorical major error rate of 1.2%

ST-02 (S. pneumoniae, beta-hemolytic Streptococcus, and Viridans Streptococcus)

Perform an alternative method of testing prior to reporting of results for the following antibiotic/organism combination(s):

- Erythromycin: *Streptococcus mitis*, *S. oralis*, *S.parasanguinis*

The ability of the AST card to detect resistance with the following combination(s) is unknown because resistant strains were not available at the time of comparative testing:

- Benzylpenicillin: *S. pneumoniae* (based on the breakpoints for pneumonia)
- Linezolid: *S. pneumoniae*, *S. agalactiae*, *S. pyogenes*
- Tigecycline: *S. pneumoniae* (penicillin-susceptible strains), *S. anginosus*, *S. intermedius*, *S. constellatus*, *S. agalactiae*, *S. pyogenes*

- Vancomycin: *Streptococcus agalactiae*, *Streptococcus pyogenes*, *Viridans* group *Streptococcus*

REFERENCE

VITEK® Systems User Manual, Reference Number 510731-10EN1, BioMerieux Inc. Durham, North Carolina, June 2008.

VITEK® FLEXPREP™ Software Core Functionality, Reference Number 048984 – 01, BioMerieux Inc. Durham, North Carolina, February 2018

VITEK® 2 Systems Product Information Manual, Reference Number 410791, BioMerieux, Inc., Durham, North Carolina, September 2010.

VITEK® 2 AST-N806, Reference Number 424709, BioMerieux Inc., Durham, North Carolina, 10/2024

VITEK® 2 AST-GP75, Reference Number 415670, BioMerieux Inc., Durham, North Carolina, 10/2015.

VITEK® 2 AST-XN30, Reference Number 424639, BioMerieux Inc., Durham, North Carolina, 10/2024

VITEK® 2 AST-ST02, Reference Number 420915, BioMerieux Inc., Durham, North Carolina, 03/2016.

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REVIEW DATES: 9/2023, 4/2025
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REVISION DATES: 10/6/2021
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All Revision Dates

3/2/2026

Approval Signatures

Step Description	Approver	Date

Hospital Administration	Jason Arimura: Associate Hospital Administrator, VCMC & SPH	3/2/2026
Policy Owner	Linda Conboy: Supervisor-Microbiology, Laboratory Services	3/1/2026
Policy Owner	M. Anwar Molani: Medical Director, Laboratory Services	3/1/2026
Policy Owner	Erlinda Roxas: Director, Laboratory Services	2/28/2026

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Next Review	3/1/2028
Owner	Linda Conboy: Supervisor-Microbiology, Laboratory Services
Policy Area	Laboratory Services - Microbiology

L.MIC 10.3 VITEK MS PRIME

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PURPOSE

This procedure will provide the instructions to properly use the VITEK MS instrumentation for microbial identification of clinical isolates within a laboratory setting.

PRINCIPAL

The VITEK MS PRIME uses MALDI-TOF (Matrix Assisted Laser Desorption Ionization – Time of Flight) principles. Once the sample slide has been prepared, it is introduced into a high vacuum environment. The sample is ionized with multiple laser shots inside the instrument, which utilizes the laser energy for the ionization process. Electric fields then guide the ions into the drift tube which separates them according to their mass (small molecules fly faster than large molecules). This "time of flight" creates a series of peaks (spectrum) which correspond to molecules within the organism sample. The resulting spectrum is compared to the BioMerieux Knowledge Base with the use of bioMerieux's proprietary algorithm generating an organism identification.

The VITEK MS PRIME system utilizes the following components & applications through the use of internal instrumentation PC(s),Virtual Machine/Server or PC(s) (VITEK MS Results Management platform (RM), and bioMérieux middleware solutions), and local laboratory remote computer(s) connected to the lab network:
VITEK MS PRIME instrument & Internal PC: MALDI-TOF mass spectrometers controlled by an internal PC

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Acquisition Software: Software used for controlling the instrument and acquiring specimens. bioMérieux Portal page (also known as: VMS portal): Provides access to the following applications which are hosted on the VITEK MS Results Management (RM) Virtual Machine/Server or PC.

- VITEK® FLEXPREP™ Software: a web application used to enter VITEK® MS-DS target slide data.
- VITEK® MS Software: a web application used to review the identification results. bioMérieux MYLA®: Transfers the identification results to the VITEK® 2 system and the LIS (when applicable).

STORAGE AND HANDLING

VITEK® MS-DS Target Slides (410893): The Target slides should be stored inside the plastic cartridges or cartons at 15 – 25°C and may be used until the expiration date.

VITEK® MS-CHCA (411071): Before use, store tubes at 2–8°C protected from light. The VITEK MS-CHCA matrix may be used for up to 1 week after the tube has been opened.

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NOTE: Yellow crystals may form in the liquid and do not affect performance, but only clear liquid should be applied to spots.

VITEK® MS-FA (411072): Before use, store the tubes at 2-8°C. VITEK MS-FA may be used for up to 2 weeks after the tube has been opened.

QUALITY CONTROL

Internal Quality Control:

A daily calibrator will be performed in the center well with each VITEK® MS run on each Acquisition group (group of 16). Patient results are not available for viewing unless the calibrator passes. E. coli ATCC® 8739™ will be maintained for this purpose.

Calibration Strain

- A fresh 18 – 24-hour subculture of E. coli ATCC® 8739™ calibration strain is required for each day of testing on the VITEK MS
- The calibration strain is required for every acquisition group on every target slide.
- Media: Trypticase Soy Agar + 5% sheep blood (TSAB) or Columbia Agar + 5% sheep blood (CBA)
- Incubate at 35°C +/- 2°C.

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NOTE: Follow the directions for E. coli ATCC® 8739™ concerning the number of passages that can be made from the stock strain. In general, the organism should have less than or equal to 3 passages when received from the manufacturer. Testing should be performed from a strain with no more than five passages.

External Quality Control:

Follow the recommended test procedure using the following strains:
Klebsiella aerogenes ATCC® 13048™ – Bacteria positive control
Matrix Only – Bacteria negative control
Candida glabrata ATCC® MYA-2950™– Yeast positive control
Formic Acid and Matrix – Yeast negative control
Acceptable criteria are identifications to species level with high level of confidence for the QC strains and no identification for negative tests.

SPECIMEN REQUIREMENTS

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For measurement in the VITEK® MS instrument, isolates must be tested from a fresh culture incubated as indicated below:

Organism Type	Incubation Time
Bacteria	18 – 72 Hours
Yeast	18 – 72 Hours

MATERIALS AND SUPPLIES

Reagents

IMPORTANT: Before use, check that the packaging and components are intact.
E. coli ATCC® 8739™ calibration strain , VITEK® MS-CHCA matrix, VITEK® MS-FA
Daily Quality control, if indicated:
Klebsiella aerogenes ATCC® 13048™
Candida glabrata ATCC® MYA 2950™

List of Consumables
VITEK® MS-DS target slides
1 ul calibrated sterile inoculating loops or VITEK® PICKME™ pen and nibs
Precision pipettes (0.5 – 2 ul)

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Sterile colorless pipette tips
Powderless gloves
Bacterial or Yeast Test Isolates (Fresh 18 – 72-hour culture on a validated media)
Columbia blood agar with 5% sheep blood
Trypticase soy agar with 5% sheep blood
Trypticase soy agar
Chocolate polyvitex agar
MacConkey agar
CHROMID® CPS
Sabouraud dextrose agar (Glucose 40g/l pH 5.6) – Yeast
Modified Sabouraud dextrose agar (Glucose 20g/l pH 6.1) - Yeast

PROCEDURE

VITEK® FLEXPREP™ SOFTWARE

Click on the VITEK FLEXPREP icon once logged onto the bioMérieux portal (web browser) with a user account with VITEK® MS Tech privileges created in User Management

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The Sample Preparation screen displays

Click on the Layout icon to display VITEK MS only or both VITEK MS and VITEK® 2 (layout displayed depends on your available instrument type(s))

NOTE: This procedure describes spotting VITEK® MS-DS target slides only and does not include set up of VITEK 2 cards.

Scan or type the VITEK MS-DS target slide barcode. Keep the default IVD Preparation mode. Click Ok

Scan or enter the Matrix lot number and expiration date. Enter the lot number and expiration date for other reagents, if applicable.

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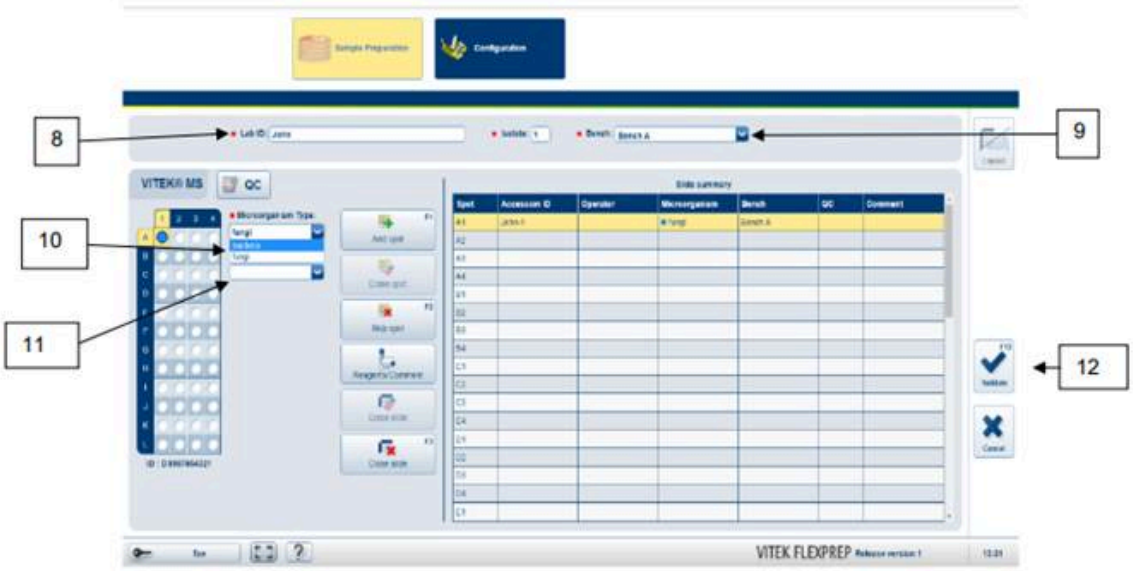
Click Continue



Scan or type in the Lab ID and change the Isolate number, if necessary.

Select the Bench (Urine or Wound)

Microorganism Type: Verify the correct option is selected for Bacteria or Fungi

Bacteria: Bacteria, Mycobacteria, Nocardia

Yeast: Yeast, Mold

NOTE: You will receive a reminder to add Formic Acid to yeast spots when running Fungi

Select Setup Operator

Click Validate (or F12).

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Repeat steps 8 – 12 for all isolates to be tested.

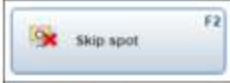
When all spots are linked to a LabID, click Close Slide (or F3) to exit. It is possible to reopen the slide for later completion of the acquisition group, providing it has not been acquired. Perform the acquisition within 72 hours of sample prep.

NOTE: VITEK® MS spots can be deposited after information for each accession number is entered or at the end of data entry for all accession numbers,

This procedure outlines depositing spots at the end of data entry for all accession numbers.

Additional buttons:

BACTERIA/YEAST SAMPLE PREP

Button	Function
	Adding a Spot
	Erasing a Spot
	Skipping a Spot
	Editing Reagent Information (if **Reagent Traceability** is enabled) Adding or Editing Spot Comments
	Erasing a Slide
	Closing a Slide

Wearing powder-free gloves, place the VITEK® MS-DS target slide on a flat surface.

Using a 1ul loop or VITEK® PICKME™ pen with nib, pick up part of a suitable bacterial or yeast colony.

Apply the colony material to the center of the sample spot.

Use the loop or pen with nib to smear the sample(s) in a thin homogenous layer on the spot(s).

Bacterial Isolates

Open the VITEK® MS-CHCA vial. Using a pipette, add 1ul to the center of each bacterial spot

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before it dries. (Make no more than two spots before adding matrix)

Yeast Isolates

Open the VITEK® MS-FA vial. Using a pipette, add 0.5 ul to the center of the yeast spot. Allow to dry completely, 1 – 3 minutes.

Add 1 ul of VITEK MS-CHCA to the center of each yeast spot.

NOTE: Use a new pipette tip each time pipetting VITEK® MS-CHCA and/or VITEK® MS–FA

Recap the vial. Click Validate (F12)

Repeat Step 4 for all isolates to be tested.

Prepare Calibrant spot for each used acquisition group

Using a 1 µl loop or VITEK® PICKME™ pen and nib, pick up part of a suitable colony.

Apply the sample to the center of the calibrator spot for the first acquisition group to be tested.

Dab, dab with the loop or VITEK PICKME pen and nib

Smear the sample in a thin layer on the spot

Flip the loop and prepare the thin film or with VITEK PICKME pen and nib, completely fill the spot.

Open the VITEK MS-CHCA matrix vial.

Add 1.0 µl of matrix to the center of the spot.

Repeat steps 1 – 5 for the Calibrant spot of each acquisition group that was used.

Allow the matrix/suspension to dry completely.

After about 5 minutes, verify crystal formation on the spots (visible as a yellow film)

Test or store prepared slides at room temperature for up to 72 hours.

Note: Depending on the configuration, user may have to be logged into the software to load a slide.

Note: Slides are Loaded and Unloaded one at a time through the slide slot. The instrument will

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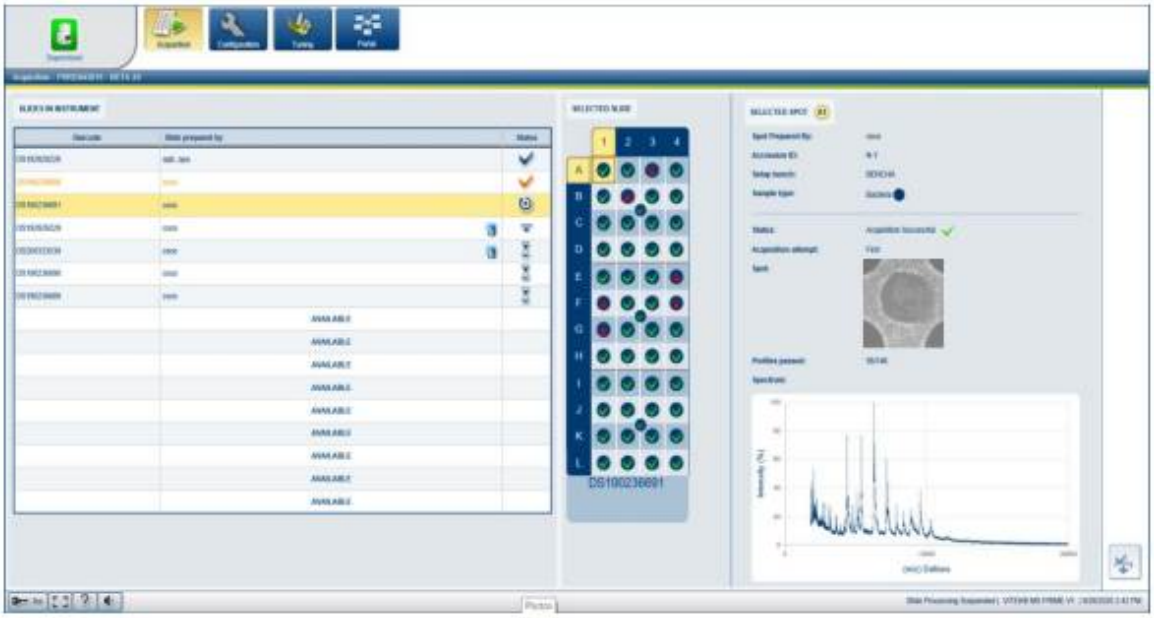
hold up to 16 slides.

Verify all target slides are dry.

Launch and Log into the VITEK MS PRIME Software by click on the bottom left part of the screen:



Make sure the slot status indicator is green. See Fromt Panel Slot Status Indicator.

Indicator	Color	Status
	Steady Green	Ready to accept a slide
	Steady Blue	Slide to be removed from the slot
	Steady Red	Instrument full (16 slides maximum)
	Flashing Red	Slot in error: • Slide loading issue • Barcode not recognized • Camera issue • Communication issue with VITEK® MS Software • No new acquisition group • All spots have expired

Insert the slide into the slot.

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Slide information is retrieved. Then the slide(s) are displayed and process in the order that they were loaded. The oldest slide being located at the top of the list.

Urgent Slides.

Marking a Slide as Urgent

Select a slide with an Awaiting Acquisition status in the **Slides in Instrument** list.

Click Urgent in the **Selected Slide** Panel

Click **Add Priority** to confirm. The slide is moved to the position immediately after the slide being acquired and is flagged with the Urgent icon.

Unmarking a Slide as Urgent

Select a slide marked with the Urgent icon in the **Slides in Instrument** list.

Click **Urgent** in the **Selected Slide** mapping panel.

Click **Remove** to confirm.

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Slide	Status
	Completed with every new acquisition group successfully acquired
	Completed with at least one spot of the new acquisition groups which has failed
	Completed with at least a whole acquisition group which has failed
	User test
	Awaiting acquisition
	Urgent

Spot	Status
	Empty (available for deposit)
	Bacterial specimen deposited, awaiting acquisition
	Fungal specimen deposited, awaiting acquisition
	Specimen being acquired
	Specimen acquired successfully
	Specimen not acquired successfully

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UNLOADING SLIDES FROM THE VITEK MS PRIME INSTRUMENT

If configured, login to the application

Select a slide in the Slides in instrument list.

Click the button associated to the slide in the list

Click YES to confirm. The slide is ejected out of the slot.

Remove the slide from the slot.

UNLOADING ALL COMPLETED SLIDES FROM THE VITEK MS PRIME INSTRUMENT

Log into the application.

Click on the location on the bottom right of the Acquisition screen. A window displays

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the list of all the completed slides selected to be ejected.

If needed, unselect the slides not to be ejected.

Click Yes to confirm. All the completed slides are ejected one after the other into the slot.

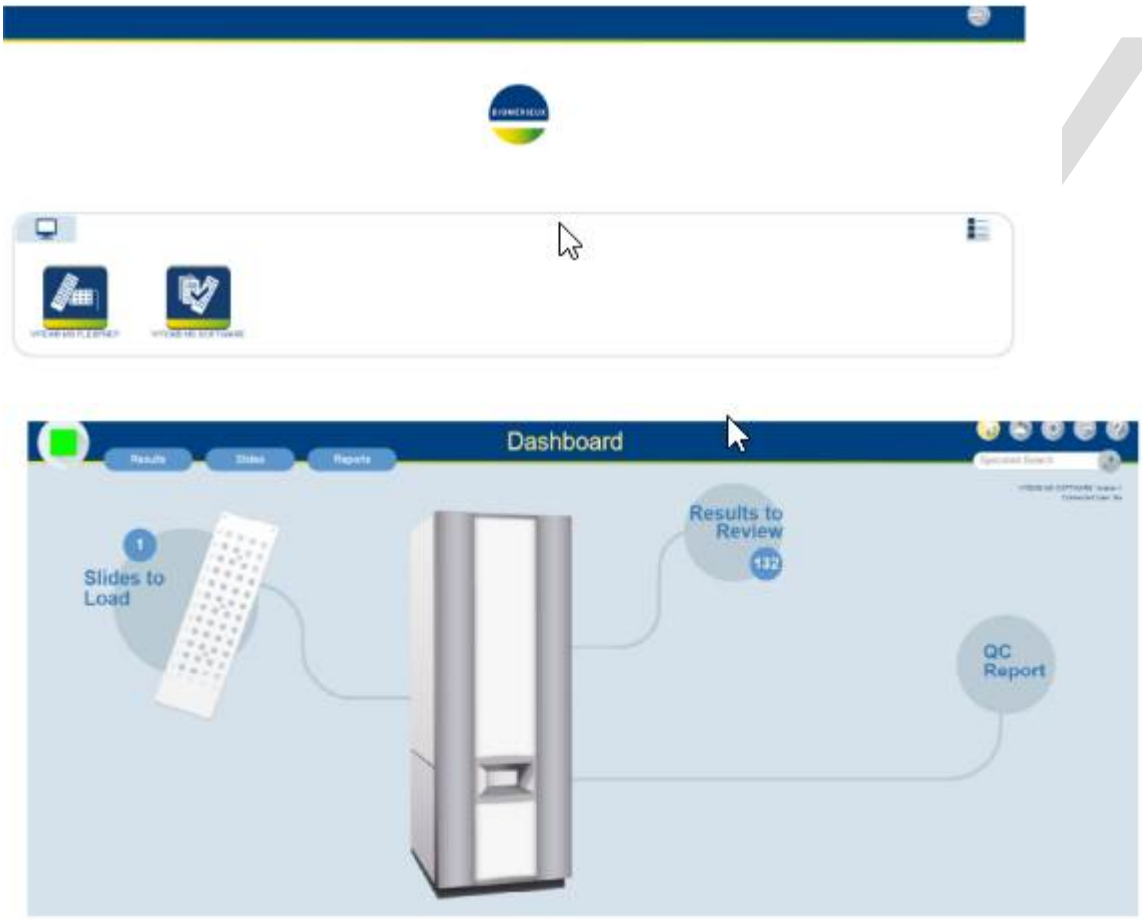
Remove the slides from the slot.

RESULTS/INTERPRETATIONS

Results are viewed in the VITEK MS Software within the VMS Portal.

Log in to VITEK® MS Portal using operator's User Name and Password.

Click on VITEK® MS Software



Click the "Results to Review" icon to access the VITEK MS Review screen or click on the Results button.

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The Results to Review screen is displayed showing the list of results to be reviewed.

Confidence Levels

Symbol	Description
	Good identification. The consolidated identification result can be sent as it is.
	Low discrimination. More than one significant organism or organism group is found, but not more than four. Validate the identification by selecting a result.
	No ID. More than four organisms or organism groups are found or when no match is found. Results cannot be validated, repeat the analysis.
No symbol	Acquisition in progress.

Manually Reviewing Results with High Confidence Values – Green Square

Click on the VALIDATE HIGH CONFIDENCE VALUES (X), available from the Results to Review screen. This allows you to validate HIGH confidence results all at once.

NOTE: To be validated using the Validate High Confidence Values function, results must meet the following conditions:

The confidence level of the consolidate results is high

The identified organism is not flagged as a pathogen

The accession ID is not flagged as a duplicate

The results with high confidence values are validated and moved to the Reviewed Results list.

Reviewing Low Discrimination Results – Orange Triangle

Click on the accession number with a Low Discrimination (Orange Triangle) result.

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Low Discrimination results occur when there are multiple identification possibilities and require a decision to choose the ID to report or reject.

Choose an ID, if appropriate, by selecting the radio button on the left, then click validate

Reject the results by clicking Reject if an ID cannot be chosen confidently.

Reviewing Red Confidence Results – Red Circle

Click on the Accession ID field of any result with no identification (Red Circle) to view the details. Reject all results that do not have an identification.

Make note of the detail message for the confidence results when
making decisions for subsequent workflow actions for the isolate.

NOTE: Warning Banner – Escherichia coli identified possibility as Shigella or Escherichia coli 0157. **MALDI-TOF methods cannot separate these organisms. Perform confirmatory testing for handling suspected Shigella or E. coli 0157.**

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MAINTENANCE

As Required:

To clean instrument covers:

Use a soft, damp, or antistatic cloth. Alternatively, you can use diluted dish detergent liquid.

Do not use cleaners containing alcohol (such as screen wipes) which corrodes plastic.

Do not use acid, alkaline solvents or abrasive creams.

To periodically clean the instrument touchscreen:

Use a soft, dry cloth.

Do not use tissue paper as this will damage the screen.

AUTO FINE-TUNING

Auto fine tuning (AFT) will be performed by the user where tuning frequency is dependent on the

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number of Samples Spots or Slides run on the instrument per day. Refer to the chart below for Auto Fine-Tuning testing.

Daily Routine		Recommended Fine Tuning Interval	
Sample Spots	Full Slides	Days	Months
96	2	185	6.2
192	4	93	3.1
288	6	62	2.1
384	8	46	1.5
576	12	31	1.0
768	16	23	0.8

AUTO FINE-TUNING PROCEDURE

Preparing a Liquid Suspension of Escherichia coli ATCC® 8739™

- Use a subculture of Escherichia coli ATCC® 8739™ incubated for 18 - 24h on blood agar plate at +35°C ±2°C, under aerobic condition.
- Transfer 70µl of VITEK® MS-CHCA matrix into an Eppendorf tube.
- Collect bacteria using a 1µl loop taking care to completely fill the loop with sample. If necessary, clean the excess bacteria on the culture medium so that only the inside of the loop is filled with bacteria. Resuspend the loop in the tube containing 70µl of VITEK MS-CHCA.
- Homogenize for 30 seconds at the maximum speed.
- Check that the suspension is homogeneous. If necessary, vortex again until the suspension is totally homogenized.
- Deposit on the VITEK® MS-DS target slide.

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First Acquisition Group (16 spots)

- Pipette and deposit 1µl/spot on the 16 spots and the associated calibrant spot.
- When depositing the 1µl, immediately cover the entire spot with the suspension.
- Leave to dry. It is not necessary to add VITEK MS-CHCA matrix.

Second Acquisition Group and Third Acquisition Group:

- Homogenize the suspension for 5 seconds and deposit as described for the First Acquisition Group.
- **Note:** Use the slide within the day for fine tuning with VITEK® MS PRIME.
- DEFINING AUTO FINE-TUNING SLIDE IN THE VITEK® FLEXPREP™ SOFTWARE:
-

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- Click on the VITEK FLEXPREP icon once logged onto the bioMérieux portal (web browser) with a user account with VITEK® MS Tech privileges created in User Management

- The Sample Preparation screen displays
- Click on the Layout icon to display VITEK® MS only
- Scan the Target Slide or enter manually
- Select Auto Fine Tuning
- Click OK

- Enter LAB ID: E. coli or ATCC8739 for each well and validate.
- Close slide
- **On VITEK® MS PRIME instrument:**
- Launch and log into the Acquisition Software (VITEK MS Prime Manager).
- Click on Tuning Tab.

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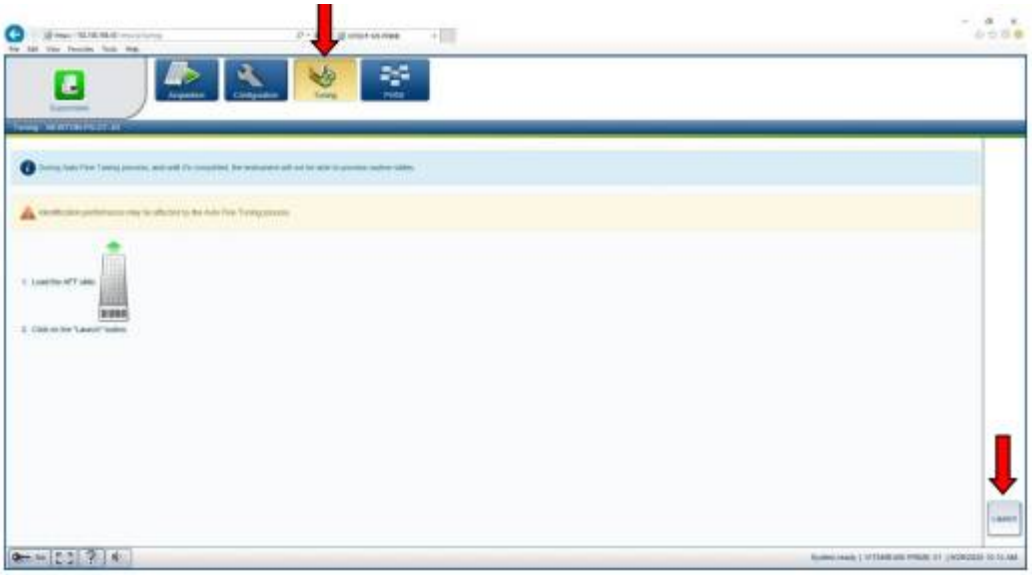
- 
- Load the AFT slide prepared on the VITEK® FLEXPREP software.
- Click on the Launch button. NOTE: By performing an auto fine-tuning, it is recommended not to perform other actions on the instrument.
- The auto fine-tuning starts. At the end, the status can be:
- Successful
- Failed: the instrument parameters remain the same as before performing the auto fine-tuning.

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REFERENCES

VITEK® MS PRIME The Basics Guide

User Manual-161150-1308 - A-en – VITEK MS Software User Manual for VITEK MS PRIME - Clinical Use

User Manual - 161150-1616-A-VITEK MS Software for VITEK MS PRIME

User Manual - 161150-1615-B-VITEK MS PRIME

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REVIEW DATES
4/2025, 2/2026
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All Revision Dates

3/2/2026

Approval Signatures

Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator, VCMC & SPH	3/2/2026
Policy Owner	Linda Conboy: Supervisor-Microbiology, Laboratory Services	3/1/2026
Policy Owner	M. Anwar Molani: Medical Director, Laboratory Services	3/1/2026
Policy Owner	Erlinda Roxas: Director, Laboratory Services	2/28/2026

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Status **Active** PolicyStat ID **19982918**

Origination	11/30/2020
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Next Review	3/1/2028
Owner	Linda Conboy: Supervisor-Microbiology, Laboratory Services
Policy Area	Laboratory Services - Microbiology

L.MIC 3.5 Cepheid SARS/FLU/RSV Assay

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Intended Use

The Xpert Xpress SARS-CoV-2/Flu/RSV test is a rapid, multiplexed real-time RT-PCR test intended for the simultaneous qualitative detection and differentiation of SARS-CoV-2, influenza A, influenza B, and respiratory syncytial virus (RSV) viral RNA in either nasopharyngeal swab, nasal swab or nasal wash/ aspirate specimens collected from individuals suspected of respiratory viral infection consistent with COVID-19 by their healthcare provider. Clinical signs and symptoms of respiratory viral infection due to SARS-CoV-2, influenza, and RSV can be similar.

Testing of nasopharyngeal swab, nasal swab, or nasal wash/aspirate specimens using the Xpert Xpress SARS-CoV-2/Flu/RSV test run on the GeneXpert Dx and GeneXpert Infinity systems is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a, that meet requirements to perform high and moderate complexity tests.

Results are for the simultaneous detection and differentiation of SARS-CoV-2, influenza A virus, influenza B virus and RSV nucleic acids in clinical specimens and is not intended to detect influenza C virus. SARS-CoV-2, influenza A, influenza B and RSV RNA identified by this test are generally detectable in upper respiratory specimens during the acute phase of infection. Positive results are indicative of the presence of the identified virus, but do not rule out bacterial infection or co-infection with other pathogens not detected by the test.

Clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status. The agent detected may not be the definite cause of disease. Laboratories within the United States and its territories are required to report all positive SARS-CoV-2 results to the appropriate public health authorities.

Negative results do not preclude SARS-CoV-2, influenza A virus, influenza B virus and/or RSV infection

and should not be used as the sole basis for treatment or other patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information.

Testing with the Xpert Xpress SARS-CoV-2/Flu/RSV test is intended for use by trained operators who are proficient in performing tests using either GeneXpert Dx, GeneXpert Infinity and/or GeneXpert Xpress systems. The Xpert Xpress SARS-CoV-2/Flu/RSV test is only for use under the Food and Drug Administration's Emergency Use Authorization.

Summary and Explanation

An outbreak of respiratory illness of unknown etiology in Wuhan City, Hubei Province, China was initially reported to the World Health Organization (WHO) on December 31, 2019.1 Chinese authorities identified a novel coronavirus (2019-nCoV), which has since spread globally, resulting in a pandemic of coronavirus disease 2019 (COVID-19). COVID-19 is associated with a variety of clinical outcomes, including asymptomatic infection, mild upper respiratory infection, severe lower respiratory disease including pneumonia and respiratory failure, and in some cases, death. The International Committee for Taxonomy of Viruses (ICTV) renamed the virus SARS-CoV-2.2

Influenza, or the flu, is a contagious viral infection of the respiratory tract. Transmission of influenza is primarily airborne (i.e., coughing or sneezing) and the peak of transmission usually occurs in the winter months. Symptoms commonly include fever, chills, headache, malaise, cough and sinus congestion. Gastrointestinal symptoms (i.e., nausea, vomiting or diarrhea) may also occur, primarily in children, but are less common. Symptoms generally appear within two days of exposure to an infected person. Pneumonia may develop as a complication due to influenza infection, causing increased morbidity and mortality in pediatric, elderly, and immunocompromised populations.

Influenza viruses are classified into types A, B, and C, the former two of which cause the most human infections. Influenza A (Flu A) is the most common type of influenza virus in humans and is generally responsible for seasonal flu epidemics and potentially pandemics. Flu A viruses can also infect animals such as birds, pigs, and horses. Infections with influenza B (Flu B) virus are generally restricted to humans and less frequently cause epidemics. Flu A viruses are further divided into subtypes on the basis of two surface proteins: hemagglutinin (H) and neuraminidase (N). Seasonal flu is normally caused by subtypes H1, H2, H3, N1 and N2.

Respiratory Syncytial Virus (RSV), a member of the Pneumoviridae family (formerly Paramyxoviridae), consisting of two strains (subgroups A and B) is also the cause of a contagious disease that affects primarily infants, and the elderly who are immunocompromised (e.g. patients with chronic lung disease or undergoing treatment for conditions that reduce the strength of their immune system).5 The virus can remain infectious for hours on countertops and toys and can cause both upper respiratory infections, such as colds, and lower respiratory infections manifesting as bronchiolitis and pneumonia.6 By the age of two years, most children have already been infected by RSV and because only weak immunity develops, both children and adults can be re-infected.5 Symptoms appear four to six days after infection and are usually self-limiting, lasting approximately one to two weeks in infants. In adults, infection lasts about 5 days and presents as symptoms consistent with a cold, such as rhinorrhea, fatigue, headache, and fever. The RSV season mirrors influenza somewhat as infections begin to rise during the fall through

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early spring.

Active surveillance programs in conjunction with infection prevention precautions are important components for preventing transmission of SARS-CoV-2, influenza and RSV. The use of assays providing rapid results to identify patients infected with these viruses can be an important factor for effective control, proper choice of treatment, and prevention of widespread outbreaks.

The Xpert Xpress SARS-CoV-2/Flu/RSV test is a molecular in vitro diagnostic test that aids in the detection and differentiation of RNA from Flu A, Flu B, RSV and SARS-CoV-2 virus and is based on widely used nucleic acid amplification technology. The Xpert Xpress SARS-CoV-2/Flu/RSV test contains primers and probes and internal controls used in RT-PCR for the in vitro qualitative detection and differentiation of RNA from Flu A, Flu B, RSV and SARS-CoV-2 virus in upper respiratory specimens.

Principle of the Procedure

The Xpert Xpress SARS-CoV-2/Flu/RSV test is an automated in vitro diagnostic test for qualitative detection and differentiation of RNA from Flu A, Flu B, RSV and SARS-CoV-2 virus. The Xpert Xpress SARS-CoV-2/Flu/RSV test is performed on GeneXpert Instrument Systems.

The GeneXpert Instrument Systems automate and integrate sample preparation, nucleic acid extraction and amplification, and detection of the target sequences in simple or complex samples using real-time PCR and RT-PCR assays. The systems consist of an instrument, computer, and preloaded software for running tests and viewing the results. The systems require the use of single-use disposable cartridges that hold the RT-PCR reagents and host the RT-PCR process. Because the cartridges are self-contained, cross-contamination between samples is minimized. For a full description of the systems, see the GeneXpert Dx System Operator Manual.

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The Xpert Xpress SARS-CoV-2/Flu/RSV test includes reagents for the detection of RNA from Flu A, Flu B, RSV and SARS-CoV-2 virus in either nasopharyngeal swab, nasal swab, or nasal wash/aspirate specimens. A Sample Processing Control (SPC) and a Probe Check Control (PCC) are also included in the cartridge utilized by the GeneXpert instrument. The SPC is present to control for adequate processing of the sample and to monitor for the presence of potential inhibitor(s) in the RT-PCR reaction. The SPC also ensures that the RT-PCR reaction conditions (temperature and time) are appropriate for the amplification reaction and that the RT-PCR reagents are functional. The PCC verifies reagent rehydration, PCR tube filling, and confirms that all reaction components are present in the cartridge including monitoring for probe integrity and dye stability.

The nasopharyngeal swab, nasal swab, or nasal wash/ aspirate specimen is collected and placed into a transport tube containing 3 mL of viral transport medium. The specimen is briefly mixed by rapidly inverting the collection tube 5 times. Using the supplied transfer pipette, the sample is transferred to the sample chamber of the Xpert Xpress SARS-CoV-2/Flu/RSV cartridge.

The GeneXpert cartridge is loaded onto the GeneXpert Instrument System platform, which performs hands-off, automated sample processing, and real-time RT-PCR for detection of viral RNA.

Reagents and Instruments

Materials Provided

The Xpert Xpress SARS-CoV-2/Flu/RSV kit contains sufficient reagents to process 10 specimens or quality control samples. The kit contains the following:

Xpert Xpress SARS-CoV-2/Flu/RSV Cartridges with Integrated Reaction Tubes 10

Bead 1, Bead 2, and Bead 3 (freeze-dried) 1 of each per cartridge

Lysis Reagent 1.0 mL per cartridge

Binding Reagent 1.0 mL per cartridge

Elution Reagent 3.0 mL per cartridge

Wash Reagent 0.4 mL per cartridge

Disposable Transfer Pipettes 10-12 per kit

Instructions to locate (and import) the ADF and EUA documentation such as

the Product Insert on www.cepheid.com

Note: Safety Data Sheets (SDS) are available at www.cepheidinternational.com under the SUPPORT tab.

Note: The bovine serum albumin (BSA) in the beads within this product was produced and manufactured exclusively from bovine plasma sourced in the United States. No ruminant protein or other animal protein was fed to the animals; the animals passed ante- and postmortem testing. During processing, there was no mixing of the material with other animal materials.

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Storage and Handling

Store the Xpert Xpress SARS-CoV-2/Flu/RSV cartridges at 2-28°C.

Do not open a cartridge lid until you are ready to perform testing.

Do not use a cartridge that is wet or has leaked.

Materials Required but Not Provided

GeneXpert Dx: GeneXpert instrument, computer, barcode scanner, operator manual.

For GeneXpert Dx System: GeneXpert Dx software version 4.7b or higher

Materials Available but Not Provided

External controls in the form of inactivated virus(es) are available from ZeptoMetrix (Buffalo, NY).

External Positive Control: Catalog #NATFRC-6C (NATtrol Flu/RSV/SARS-CoV-2)

External Negative Control: Catalog #NATCV9-6C (Coxsackievirus CVA9)

Warnings and Precautions

General

For in vitro diagnostic use.

For emergency use only.

Positive results are indicative of presence of Flu A, Flu B, RSV, or SARS-CoV-2 RNA.

Laboratories within the United States and its territories are required to report all SARS-CoV-2 results to the appropriate public health authorities.

Performance characteristics of this test have been established with the specimen types listed in the Intended Use Section only. The performance of this assay with other specimen types or samples has not been evaluated.

Treat all biological specimens, including used cartridges, as if capable of transmitting infectious agents. Because it is often impossible to know which might be infectious, all biological specimens should be handled using standard precautions. Guidelines for specimen handling are available from the U.S. Centers for Disease Control and Prevention and the Clinical and Laboratory Standards Institute.

Follow safety procedures set by your institution for working with chemicals and handling biological specimens.

Specimens · Maintain proper storage conditions during specimen transport to ensure the integrity of the specimen. Specimen stability under shipping conditions other than those recommended has not been evaluated.

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Assay/Reagent

Do not open the Xpert Xpress SARS-CoV-2/Flu/RSV cartridge lid except when adding specimen.

Do not use a cartridge that has been dropped after removing it from the packaging.

Do not shake the cartridge. Shaking or dropping the cartridge after opening the cartridge lid may yield non-determinate results.

Do not place the sample ID label on the cartridge lid or on the barcode label on the cartridge. Do not use a cartridge with a damaged barcode label.

Do not use a cartridge that has a damaged reaction tube.

Do not use reagents beyond their expiration date.

Each single-use Xpert Xpress SARS-CoV-2/Flu/RSV cartridge is used to process one test. Do not reuse processed cartridges.

Each single-use disposable pipette is used to transfer one specimen. Do not reuse disposable pipettes.

Do not use a cartridge if it appears wet or if the lid seal appears to have been broken.

Wear clean lab coats and gloves. **Change gloves between the handling of each specimen**.

In the event of a spill of specimens or controls, wear gloves and absorb the spill with paper towels. Then, thoroughly clean the contaminated area with a 10% freshly prepared household chlorine bleach. Allow a minimum of two minutes of contact time. Ensure the work area is dry before using 70% denatured ethanol to remove bleach residue. Allow surface to dry completely before proceeding.

Biological specimens, transfer devices, and used cartridges should be considered capable of transmitting infectious agents requiring standard precautions. disposal of used cartridges and unused reagents in a red biohazardous waste container.

Specimen Collection, Transport, and Storage

Proper specimen collection, storage, and transport are critical to the performance of this test. Inadequate specimen collection, improper specimen handling and/or transport may yield a false result. See below for nasopharyngeal swab collection procedure and nasal swab collection procedure. Nasopharyngeal swab and nasal swab specimens can be stored at room temperature (15-30 °C) for up to 24 hours in viral transport medium until testing is performed on the GeneXpert Instrument Systems. Alternatively, nasopharyngeal swab and nasal swab specimens can be stored refrigerated (2–8 °C) up to seven days in viral transport medium until testing is performed on the GeneXpert Instrument Systems.

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Nasopharyngeal Swab Collection Procedure

Insert the swab into either nostril, passing it into the posterior nasopharynx (see Figure 1). Rotate swab by firmly brushing against the nasopharynx several times. Remove and place the swab into the tube containing 3 mL of viral transport medium. Break swab at the indicated break line and cap the specimen collection tube tightly.

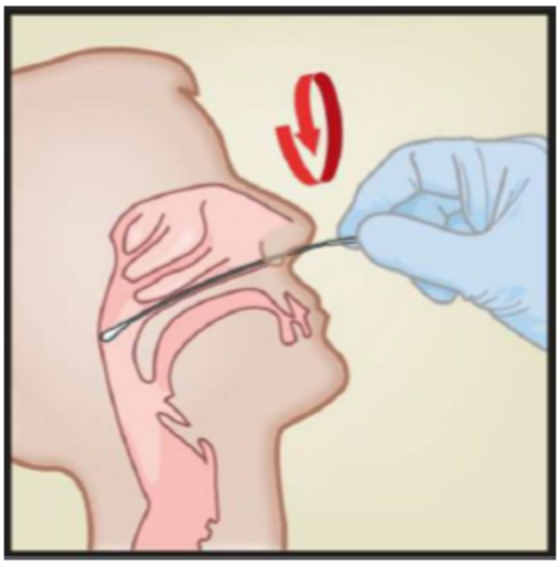

Figure 1. Nasopharyngeal Swab Collection

Nasal Swab Collection Procedure

Insert a nasal swab 1 to 1.5 cm into a nostril. Rotate the swab against the inside of the nostril for three seconds while applying pressure with a finger to the outside of the nostril (see Figure 2).

Figure 2. Nasal Swab Collection for First Nostril

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Repeat on the other nostril with the same swab, using external pressure on the outside of the other nostril (see Figure 3). To avoid specimen contamination, do not touch the swab tip to anything other than the inside of the nostril.

Figure 3. Nasal Swab Collection for Second Nostril

Remove and place the swab into the tube containing 3 mL of viral transport medium. Break swab at the indicated break line and cap the specimen collection tube tightly.

Procedure

Note:

Specimens should be processed in the Molecular Hood away from other specimens.

The specimen must be handled to minimize aerosolization.

Specimens should be handled individually to prevent cross contamination during processing

Gloves must be worn and frequently changed during the processing especially when transitioning from molecular hood to testing area.

Biological hood will be cleaned with 70% ethanol or equivalent and allow to set for 5 minutes prior to wiping each time a specimen is processed to prevent cross contamination.

Preparing the Cartridge

Important: Start the test within 30 minutes of adding the sample to the cartridge.

Remove a cartridge from the package.

Check the specimen transport tube is closed.

Mix specimen by rapidly inverting the specimen transport tube 5 times. Open cap on the specimen transport tube.

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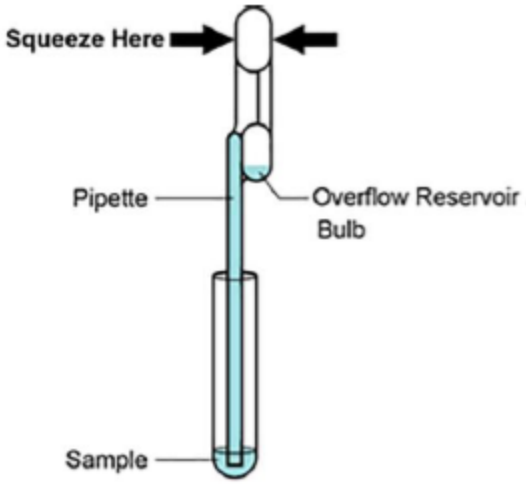
Open the cartridge lid.

Remove the transfer pipette from the wrapper.

Squeeze the top bulb of the transfer pipette **completely until the top bulb is fully flat**. While continuing to hold the bulb fully flat, place the pipette tip in the specimen transport tube.



Keeping the pipette below the surface of the liquid, release the top bulb of the pipette slowly to fill the pipette with sample before removing from the tube. It is okay if liquid goes into the overflow reservoir (see Transfer Pipette). Check that the pipette does not contain bubbles.

To transfer the sample to the cartridge, squeeze the top bulb of the pipette completely again until it is

fully flat to empty the contents of the pipette (300 µL) into the large opening (Sample Chamber) in the cartridge shown in Xpert Xpress SARS-CoV-2/F. Some liquid may remain in the overflow reservoir. Dispose of the used pipette.

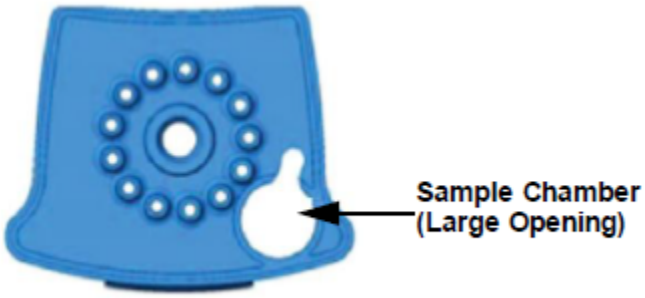


Figure 5. Xpert Xpress SARS-CoV-2/Flu/RSV Cartridge (Top View)

Note: Take care to dispense the entire volume of liquid into the Sample Chamber. False negative results may occur if insufficient sample is added to the cartridge.

External Controls

External controls will be run each new lot/shipment as qualified by laboratory IQCP.

To run a control using the Xpert Xpress SARS-CoV-2/Flu/RSV test, perform the following steps:

Mix control by rapidly inverting the external control tube 5 times. Open cap on external control tube.

Open the cartridge lid.

Using a clean transfer pipette, transfer one draw of the external control sample (300 µL) into the large opening (Sample Chamber) in the cartridge shown in Xpert Xpress SARS-CoV-2/F.

Close cartridge lid.

Starting the Test

Scan or type in the Patient ID (optional). If typing the Patient ID, make sure the Patient ID is typed correctly. The Patient ID is shown on the left side of the View Results window and is associated with the test result.

Scan or type in the Sample ID. If typing the Sample ID, make sure the Sample ID is typed correctly. The Sample ID is shown on the left side of the View Results window and is associated with the test result.

Scan the barcode on the Xpert Xpress SARS-CoV-2/Flu/RSV cartridge. Using the barcode information, the software automatically fills the boxes for the following fields: Reagent Lot ID, Cartridge SN, Expiration Date and Selected Assay.

Note: If the barcode on the -2/Flu/RSV cartridge does not scan, then repeat the test with a new cartridge.

Click Start Test (GeneXpert Dx) or Submit (Infinity) if Auto-Submit is not enabled. In the dialog box that

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appears, type your password, if required.

For the GeneXpert Dx Instrument

Locate the module with the blinking green light, open the instrument module door and load the cartridge.

Close the door. The test starts and the green light stops blinking. When the test is finished, the light turns off and the door will unlock. Remove the cartridge.

Dispose of used cartridges in the appropriate sample waste containers according to your institution's standard practices.

Viewing and Printing Results

For detailed instructions on how to view and print the results, see the *GeneXpert Dx System Operator Manual*

Quality Control

Internal Controls

Each cartridge includes a Sample Processing Control (SPC) and Probe Check Control (PCC).

Sample Processing Control (SPC) - Ensures that the sample was processed correctly. The SPC verifies that sample processing is adequate. Additionally, this control detects sample-associated inhibition of the real-time PCR assay, ensures that the PCR reaction conditions (temperature and time) are appropriate for the amplification reaction, and that the PCR reagents are functional. The SPC should be positive in a negative sample and can be negative or positive in a positive sample. The SPC passes if it meets the validated acceptance criteria.

Probe Check Control (PCC) - Before the start of the PCR reaction, the GeneXpert System measures the fluorescence signal from the probes to monitor bead rehydration, reaction tube filling, probe integrity, and dye stability. The PCC passes if it meets the validated acceptance criteria.

Interpretation of Results

The results are interpreted automatically by the GeneXpert System and are clearly shown in the **View Results** window. The Xpert Xpress SARS-CoV-2/Flu/RSV test provides test results based on the detection of respective gene targets according to the algorithms.

See Table 1. Xpert Xpress_SARS-CoV-2_Flu_RSV1 to interpret test result statements for the Xpert Xpress SARS-CoV-2/Flu/RSV test.

Result	Interpretation
SARS-CoV-2 POSITIVE	The SARS-CoV-2 target nucleic acids are detected. • The SARS-CoV-2 signal has a Ct within the valid range and endpoint above the minimum setting. • SPC: NA (not applicable); SPC is ignored because SARS-CoV-2 target amplification occurred. • Probe Check: PASS; all probe check results pass.

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Flu A POSITIVE	• The Flu A signal for either the Flu A1 nucleic acid target or the Flu A2 nucleic acid target or signals for both nucleic acid targets has a Ct within the valid range and endpoint above the threshold setting. • SPC - NA; SPC is ignored because the Flu A target amplifica-tion occurred. • Probe Check - PASS; all probe check results pass.
Flu B POSITIVE	• The Flu B signal has a Ct within the valid range and endpoint above the minimum setting. • SPC: NA; SPC is ignored because Flu B target amplification occurred. • Probe Check: PASS; all probe check results pass
RSV POSITIVE	• The RSV signal has a Ct within the valid range and endpoint above the minimum setting. • SPC: NA; SPC is ignored because RSV target amplification occurred. • Probe Check: PASS; all probe check results pass.
SARS-CoV-2 NEGATIVE; Flu A NEGA-TIVE; Flu B NEGATIVE; RSV NEGATIVE	SARS-CoV-2 target RNA is not detected; Flu A target RNA is not detected; Flu B target RNA is not detected; RSV target RNA is not detected. • SARS-CoV-2, Flu A, Flu B and RSV target RNAs are not detected. • SPC - PASS; SPC has a Ct within the valid range and endpoint above the minimum setting. • Probe Check - PASS; all probe check results pass.
INVALID	SPC does not meet acceptance criteria and all targets not detected. Repeat test according to the Retest Procedure in **Error! Reference source not found.**. • • SPC: FAIL; SPC and SARS-CoV-2, Flu A, Flu B and RSV signals do not have a Ct within valid range and endpoint is below minimum setting. • • Probe Check - PASS; all probe check results pass
ERROR	Presence or absence of SARS-CoV-2, Flu A, Flu B and RSV nucleic acids cannot be determined. Repeat test according to the Retest Procedure in **Error! Reference source not found.**. • • SARS-CoV-2: NO RESULT • • Flu A: NO RESULT • • Flu B: NO RESULT • • RSV: NO RESULT • • SPC: NO RESULT

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	• • Probe Check: FAIL1; all or one of the probe check results fail 1 If the probe check passes, the error is caused by the maximum pressure limit exceeding the acceptable range, no sample added, or by a system component failure.
NO RESULT	Presence or absence of SARS-CoV-2, Flu A, Flu B and RSV nucleic acids cannot be determined. Repeat test according to the Retest Procedure in **Error! Reference source not found.**. A **NO RESULT** indicates that insufficient data were collected. For example, the operator stopped a test that was in progress. • • SARS-CoV-2: NO RESULT • • Flu A: NO RESULT • • Flu B: NO RESULT • • RSV: NO RESULT • • SPC: NO RESULT • • Probe Check: NA
If the SPC is negative and the results for any of the targets are positive, the results for all targets are considered valid.	

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Retests

Reasons to Repeat the Assay

If any of the test results mentioned below occur, repeat the test once according to instructions in **Error! Reference source not found.**.

An **INVALID** result indicates that the control SPC failed. The sample was not properly processed, PCR is inhibited, or the sample was not properly collected.

An **ERROR** result could be due to, but not limited to, Probe Check Control failure, system component failure, no sample added, or the maximum pressure limits were exceeded.

A **NO RESULT** indicates that insufficient data were collected. For example, cartridge failed integrity test, the operator stopped a test that was in progress, or a power failure occurred.

If an External Control fails to perform as expected, repeat external control test and/or contact Cepheid for assistance.

Retest Procedure

To retest a non-determinate result (INVALID, NO RESULT, or ERROR), use a new cartridge.

Use the leftover sample from the original specimen transport medium tube or new external control tube.

Put on a clean pair of gloves. Obtain a new Xpert Xpress SARS-CoV-2/Flu/RSV cartridge and a new transfer pipette.

Check the specimen transport tube or external control tube is closed.

Mix the sample by rapidly invert the specimen transport medium tube or external control tube 5 times. Open the cap on the specimen transport tube or external control tube.

Open the cartridge lid.

Using a clean transfer pipette (supplied), transfer sample (one draw) to the sample chamber with the large opening in the cartridge.

Close the cartridge lid.

Limitations

Performance of the Xpert Xpress SARS-CoV-2/Flu/RSV test has only been established in nasopharyngeal swab specimens. Use of the Xpert Xpress SARS-CoV-2/Flu/RSV test with other specimen types has not been assessed and performance characteristics are unknown.

Nasal swabs (self-collected under supervision of, or collected by, a healthcare provider) are considered acceptable specimen types for use with the Xpert Xpress SARS-CoV-2/Flu/RSV test but performance with these specimen types has not been established.

As with any molecular test, mutations within the target regions of the Xpert Xpress SARS-CoV-2/Flu/RSV test could affect primer and/or probe binding resulting in failure to detect the presence of virus or the virus being detected less predictably. This test cannot rule out diseases caused by other bacterial or viral pathogens.

The performance of this test was validated using the procedures provided in this package insert only. Modifications to these procedures may alter the performance of the test.

Erroneous test results might occur from improper specimen collection; failure to follow the recommended sample collection, handling, and storage procedures; technical error; or sample mix-up. Careful compliance with the instructions in this insert is necessary to avoid erroneous results.

False negative results may occur if virus is present at levels below the analytical limit of detection.

Negative results do not preclude SARS-CoV-2, influenza or RSV infection and should not be used as the sole basis for treatment or other patient management decisions.

Results from the Xpert Xpress SARS-CoV-2/Flu/RSV test should be correlated with the clinical history, epidemiological data, and other data available to the clinician evaluating the patient.

Viral nucleic acid may persist *in vivo*, independent of virus viability. Detection of analyte target(s) does not imply that the corresponding virus(es) are infectious or are the causative agents for clinical symptoms.

This test has been evaluated for use with human specimen material only.

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This test is a qualitative test and does not provide the quantitative value of detected organism present.

This test has not been evaluated for monitoring treatment of infection.

This test has not been evaluated for screening of blood or blood products for the presence of SARS CoV-2, influenza or RSV.

The effect of interfering substances has only been evaluated for those listed within the labeling. Interference by substances other than those described can lead to erroneous results.

Results from analytical studies with contrived co-infected samples showed potential for competitive interference when SARS-CoV-2, Flu or RSV was present at LoD levels.

Cross-reactivity with respiratory tract organisms other than those described herein can lead to erroneous results.

Recent patient exposure to FluMist® or other live attenuated influenza vaccines may cause inaccurate positive results.

As the Xpert Xpress SARS-CoV-2/Flu/RSV test does not differentiate between the N2 and E gene targets, the presence of other coronaviruses in the B lineage, *Betacoronavirus* genus, including SARS-CoV-1 may cause a false positive result. None of these other coronaviruses is known to currently circulate in the human population.

This test is not intended to differentiate RSV subgroups, influenza A subtypes or influenza B lineages. If differentiation of specific RSV or influenza subtypes and strains is needed, additional testing, in consultation with state or local public health departments, is required.

This test has been authorized only for the simultaneous qualitative detection and differentiation of nucleic acids from SARS-CoV-2, influenza A, influenza B, and respiratory syncytial virus (RSV), and not for any other viruses or pathogens.

COPY

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All Revision Dates

3/2/2026

Approval Signatures

Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator, VCMC & SPH	3/2/2026
Policy Owner	Linda Conboy: Supervisor-Microbiology, Laboratory Services	3/1/2026
Policy Owner	M. Anwar Molani: Medical Director, Laboratory Services	2/24/2026
Policy Owner	Erlinda Roxas: Director, Laboratory Services	2/24/2026

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Owner	Linda Conboy: Supervisor-Microbiology, Laboratory Services
Policy Area	Laboratory Services - Microbiology

L.MIC 4.1 Making Smears on Slides

COPY

EFFECTIVE DATE: 5/29/2001	REVIEW DATES: 4/2002, 2/2003, 2/2004, 8/2005, 10/2007, 12/2008, 8/2009, 12/15/2016, 12/21/2017, 01/31/2019, 12/15/2020, 11/15/2021, 11/17/2023, 4/2025, 2/2026
	REVISION DATES: 1/2006

MAKING SMEARS ON SLIDES

LABELING THE SLIDE

ACC. #
LAST NAME
SOURCE
MO/DAY

MAKING SMEARS FOR GRAM STAIN

FLUIDS

If fluid is clear and more than one ml of sample submitted, Use Cytospin to make the smear.
If hazy &/or less than one ml of sample submitted, use sterile pipette to place one free-falling drop of well-mixed specimen on slide.
Spread drop to the diameter about the size of a dime if specimen is thick.

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TRANSPORT SWAB SYSTEMS WITH GEL PRESERVATION MEDIA

Inoculate 1ml of sterile saline with the swabbed specimen and vortex 10-20 seconds.

Use sterile pipette to inoculate media and place one drop of specimen on slide

Spread the inoculums on the slide in the area designated.

TRANSPORT SWAB SYSTEM WITH LIQUID PRESERVATION MEDIA (eSWAB)

Vortex the eSWAB tube containing the swab sample for 5 seconds to release the sample from the swab tip and evenly disperse and suspension of the specimen in the Liquid Amies transport medium.

Unscrew the eSWAB cap and using a sterile pipet, transfer 1-2 drops of Liquid Amies sample suspension to the glass slide.

In case of bloody or thicker specimens particular care should be taken to thinly spread the sample on the slide.

PURULENT MATERIAL IN STERILE CONTAINER, E.G., SPUTUM, PUS

Using a sterile swab, pick pus-laden areas of the specimen. If sputum, avoid saliva. Twirl the purulent material onto the swab. Swab the specimen onto the designated area of the slide.

If the specimen is too thick, purulent, & tenacious, swab some specimen onto the slide. Then use another clean slide to place on top of the material on the first to make a “pull slide.”

COPY

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3/3/2026

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Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator, VCMC & SPH	3/3/2026

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Policy Owner	Erlinda Roxas: Director, Laboratory Services	3/3/2026
Policy Owner	M. Anwar Molani: Medical Director, Laboratory Services	3/2/2026
Policy Owner	Linda Conboy: Supervisor-Microbiology, Laboratory Services	3/2/2026

COPY

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Owner	Linda Conboy: Supervisor-Microbiology, Laboratory Services
Policy Area	Laboratory Services - Microbiology

L.MIC 4.3 Quantitative Cultures of Wound Tissues

COPY

EFFECTIVE DATE: 7/3/2010	REVIEW DATES: 9/2011, 12/2013,12,2016, 12/2017,1/2019, 12/2020, 11/2021, 11/2023,4/2023, 2/2026
	REVISION DATES:

PRINCIPLE:

Patients that were grafted when the wound biopsies were determined to be less than or equal to 10 to the fifth CFU's per gram of tissue had a 94% survival; those that had higher counts had less than 20% graft survival.

Beta hemolytic Streptococci has continually proven to be clinically significant at numbers that are much lower.
The gold standard is to not execute a skin graft or close a wound in the presence of beta hemolytic Streptococci, regardless of the numeric assessment.

SPECIMEN COLLECTION:

Tissues

Submit 2 by 1 cm or larger tissue samples collected after cleansing and/or surgical debridement to yield the most useful information.

This will yield approximately 500mg (0.5gm) of tissue, depending on the density.

Submit as soon as possible without transport medium, but keep moist in a sealed, sterile container.

Swab collection

Follow standard wound collection procedure
Use only an alginate swab for qualitative culture.

MATERIALS:

Media
BAP
CHOC
MAC
Saline for dilution
Reagents
Stain reagents for Gram stain
0.85% sterile saline
Other supplies
Sterile plastic disposable loops to deliver 1ul and 10ul
Mechanical pipette and sterile tips to deliver 100ul
Sterile bent plastic disposable rods to spread inoculums
Analytical balance
Tissue grinder (disposable)
Vortex mixer
CO2 incubator at 35 to 37 degrees C
Anaerobic atmosphere (optional)

COPY

PROCEDURE:

Specimen processing

Tissues

Weigh the tube or petri dish containing the tissue.

Remove the tissue and place it in a different sterile petri dish

Weigh the original tube or petri dish and subtract this weight from the first weight.

Homogenize the tissue using a small amount of the 5ml saline and the disposable tissue grinder. **(SOLUTION #1)**

Plate 100ul **(BLUE PIPETTE)** of the original homogenate on each of the plates labeled 10 to the first: BAP, CHOC, MAC and thio broth.

Make one serial 1:10 dilution of the homogenate by placing 0.5ml **(YELLOW PIPETTE)** of the homogenate into 4.5ml of sterile 0.85% saline. **(SOLUTION #2)**

Plate 100ul **(BLUE PIPETTE)** of the 1:10 dilution onto a BAP, CHOC and MAC. This equals the 10 to the second dilution. **(SOLUTION #2)**

Place 10ul **(BLUE OR YELLOW LOOP)**of the 1:10 dilution on a BAP, CHOC and MAC. This equals the 10 to the third dilution. **(SOLUTION #2)**

Place 1ul **(GREEN LOOP)** of the 1:10 dilution on a BAP, CHOC and MAC. This equals the 10 to the fourth dilution. **(SOLUTION #2)**

Evenly distribute the inoculums with the disposable bent rod. You may use the same bent rod if you begin the spreading with the 10 to the fourth dilution.

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Swabs

Place a swab in 5ml of Ringer's solution. Vortex and remove remaining swab material (Swab should dissolve) **(SOLUTION #1)**

As in procedure above, serially make 10 fold dilutions in 0.85% saline and process as for tissue. **(SOLUTION #2)**

Gram stains

Prepare Gram stain of tissue specimens by spreading 10ul aliquot of the homogenate on a 1 X 1 cm area of a glass slide
Allow to dry, fix with methanol and Gram stain.

Examine 10 fields under 100 X oil immersion objective

Organisms are visible in Gram stain when at least 10 to the fifth organisms per gram of tissue are present in the specimen.
Examination of cultures: tissue and swabs

Determine the number of organisms per gram of tissue by counting the colonies on the plate that grew between 30 and 300 colonies

NOTE: Only use the MAC if overgrowth on the BAP or CHOC precludes accurate counting of gram negative bacilli.

Calculate the total number of organisms by using the colony count times the dilution factor (use 5 as the factor for the homogenate dilution and the dilutions labeled on the plates for the subsequent dilution) divided by the original weight of the tissue.

Report total count "per gram of tissue" or "per swab"

Work up pathogenic organisms for identification and AST according to wound culture procedure when count >10 to the fifth organisms per gram. Special considerations must be made case by case for counts of <10 to the fifth organisms per gram depending on the identity of the isolates.

QUALITY CONTROL:

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Verify that media meet expiration date and QC parameters per current CLSI M22 document.

Validate the method of quantitation using know cultures at various colony counts.

INTERPRETATION:

The probability that tissue from a traumatic wound or burn is infected or will fail to heal can be predicted from cultures showing >10 to the fifth organisms per gram of tissue

Colony counts of approximately 10 to the fifth CFU/gm of tissue were found to be equivalent to colony counts of 10 to the third CFU/ml of specimen obtained on a moist **alginated** swab.

LIMITATIONS:

These tests should only be done under certain circumstances and after consultation with the physician or clinical service.
Loops are not as accurate as pipettes to deliver the inoculums.

Spreading with a loop is not as accurate as spreading with a bent rod.

The lack of isolation of a pathogen does not mean that the laboratory was unable to detect the agent. Other inflammatory diseases can have the same presentation as infectious diseases, including the presence of PMN's on the Gram stain.

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COPY

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Approval Signatures

Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator, VCMC & SPH	3/3/2026
Policy Owner	Erlinda Roxas: Director, Laboratory Services	3/3/2026
Policy Owner	M. Anwar Molani: Medical Director, Laboratory Services	3/2/2026
Policy Owner	Linda Conboy: Supervisor-Microbiology, Laboratory Services	3/2/2026

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Owner	Linda Conboy: Supervisor-Microbiology, Laboratory Services
Policy Area	Laboratory Services - Microbiology

L.MIC 4.4 Quantitative Culture of Bronchoalveolar Lavage (BAL) and Protected Brush Specimens (PBS)

COPY

EFFECTIVE DATE: 10/28/2005	REVIEW DATES: 10/2007, 9/2008, 7/2009, 9/2010, 9/2011, 12/2013, 12/2016, 12/2017, 1/2019, 12/2020, 11/2021, 11/2023, 4/2023, 2/2026
	REVISION DATES: 6/2006, 5/2014

PRINCIPLE

Patients with severe community acquired pneumonia (CAP), pneumonia in the immunocompromised patient, cystic fibrosis patients and acute episodes in chronic obstructive pulmonary disease may develop respiratory failure and require ventilator support.

Diagnosis of the microbial pathogens causing VAP (ventilator associated pneumonia) requires pulmonologists to perform a bronchoalveolar lavage (BAL) for collection of samples from the alveoli of the lung, including protected brush specimens (PBS) for anaerobic culture. PBS is the preferred sample for anaerobic culture, since both bronchial wash and BAL samples and transbronchial biopsy samples are contaminated b y respiratory anaerobic microbiota.

Quantitative cultures increase the specificity of the diagnosis, but the sensitivity (82-91%) for BAL specimens is dependent on the threshold chosen for a positive result. Many authors report a colony count of ≥10^4 CFU/ml for BAL specimens (>=10^3 CFU/ml for PBS) to be consistent with

bacterial pneumonia, whereas counts below 10^4 (10,000) CFU/ml for BAL (10^3 CFU/ml for PBS) specimens likely indicate contamination with oronasal microbiota. This theory has been validated in numerous clinical studies, and quantitative culture of BAL fluid specimens has become the reference method for the diagnosis of pneumonia by BAL.

There are two methods of performing quantitative cultures: the serial dilution method and the calibrated-loop method. We will be performing the calibrated-loop method.

After incubation the colonies are counted and multiplied by the appropriate dilution factor to determine the number of bacteria present in 1 ml of fluid.

SPECIMEN COLLECTION, TRANSPORT, AND HANDLING

Specimen collection is performed by a trained physician.

Collection of BAL: Collect BAL fluid by carefully wedging the tip of the bronchoscope into an airway lumen and instilling as large a volume of 0.85% sterile, non-bacteriostatic saline as possible per aliquot (25 to 30 ml for adults and 5 to 10ml for children).
Several aliquots MAY be used in the same lung location to wash the alveoli in order to collect enough fluid to perform all of the required tests. The sample returned contains secretions of distal bronchioles and alveoli. The initial fluid is discarded as contaminated, and the rest is submitted for culture and staining.

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Collection of PBS: Instill a brush to collect cellular material from the airway wall. This is the best specimen for viral and cytology studies.

Only a PBS is acceptable for anaerobic bacterial culture.
Obtain by inserting a telescoping double catheter plugged with polyethylene glycol at the distal end (to prevent contamination of the bronchial brush) through the biopsy channel of the bronchoscope.

Place the PBS in a sterile vial containing 1ml of nonbacteriostatic saline.

Specimen transport.

Submit to laboratory in sterile, leak-proof containers.

Label with specimen source and tests requested for each specimen type.

Specimens should be placed in biohazard bags prior to transport to minimize contamination of the external environment if leakage occurs during transport.

Deliver immediately to laboratory.

Store specimens at 2 to 8 degrees C until specimens can be processed by the laboratory. NOTE: A delay in processing of more than 1 to 2 hours may result in a decreased ability to recover fastidious pathogens, such as *S. pneumonia and H. influenza,* and/or overgrowth of upper respiratory microbiota.

Rejection criteria

BAL specimens and PBS specimens should never be rejected since the patient has undergone an invasive procedure in order to have them collected.

For specimens delayed in transit for more than 2 hours without refrigeration, indicate on the report that the delay in transit may compromise the culture results.

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Bronchial wash samples should not be cultured quantitatively; only a semi-quantitative bacterial culture result is required.
BAL fluid is preferred to bronchial washings for bacterial culture. Bronchial washings are acceptable for mycobacterial, *Legionella*, and fungal cultures.

NOTE: The difference between BAL fluid and bronchial washings is not apparent from the appearance of the specimen. The BAL sample is from the distal respiratory bronchioles and alveoli. Bronchial washings sample the major airways, which is the same area sampled by an endotracheal aspirate. They can be used for fungal, *Legionella,* or acid-fast bacillus (AFB) culture but are contaminated with upper airway secretions and are not appropriate for quantitative bacterial culture, if BAL fluid is also available.
Bronchial brush specimens not collected with catheter protection are best submitted for viral culture and not bacterial culture, since they contain cellular material.

PBS is the preferred sample for anaerobic culture, since both bronchial wash and BAL samples and transbronchial biopsy samples are contaminated by respiratory anaerobic microbiota.

MATERIALS

Primary media

BAP, CHOC and MAC

Other supplies

100 mcl pipetter with sterile tips (BLUE MLA Pipette)

0.001-ml (1-mcl) loop (GREEN URINE LOOP)

0.01-ml (10mcl) loop or (BLUE LOOP)

Sterile bent plastic disposable rods to spread inoculum

Incubator at 35°C with CO_2

QUALITY CONTROL

Calibrate pipetters as needed.

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PROCEDURES

Inoculation

Vortex specimen vial vigorously for 30 to 60 seconds. PBS should arrive in 1ml of nonbacteriostatic saline. If greater than 1 ml of **nonbacteriostatic saline is submitted, the entire specimen should be centrifuged in a sterile container at 1,500 rpm for 5 minutes and the excess of 1 ml of fluid removed.**

Label a BAP, MAC and CHOC for each dilution.

For BAL and PBS specimens, inoculate BA, MAC,CHOC with 100 mcl (using BLUE PIPETTE) of specimen to each plate labeled "X10".
Each colony from this plate = 10 CFU/ml.

Using a 10 mcl loop, place 10 mcl on each plate labeled "x 100." Each colony from this plate = 100 CFU/ml.

Using 1:1000 loop, place 1 mcl on each plate labeled "x 1,000." Each colony from this = 1,000 CFU/ml.

For all dilutions, spread the inoculum over the surface of each plate evenly by using a sterile disposable plastic rod.

Begin with the most dilute inoculum (1:1000) and proceed to the least dilute using the same sterile rod for each place.

Incubate the plates, except the MAC (which goes in the regular ambient incubator) in a 35°C CO_2 incubator.

Prepare a Gram stain from the BAL and PBS sample, using the cytocentrifuge.

The remainder of the specimen may be centrifuged for culture of viruses, mycobacteria, Legionella, and fungi and for smears for viruses, Pneumocystis, AFB, and fungi, upon request.

Hold anaerobic cultures for 6 days before considering culture as negative.

INTERPRETATION

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Count the colonies from the dilution with the greatest number of colonies without confluence. Multiply by the dilution factor listed for each dilution (e.g., 40 colonies on the "x 1,000" plate is 40 x 1,000 or 40,000 or 4 x 10^4 CFU/ml.

Count each morphotype individually.

If growth is too numerous to count on the highest dilution, report the count as greater than that dilution.

Counts for BAL fluid of less than 10^4 (10,000CFU/ml) are considered to indicate contamination.

Counts for BAL fluid of greater than or equal to 10^4 (10,000CFU/ml) are considered to be consistent with bacterial pneumonia. **(BALCOM)**

Counts for PBS fluid of greater than or equal to 10^3 (1,000CFU/ml) are considered to be consistent with bacterial pneumonia. **(PBSCOM)**

Counts for PBS of less than 10^3 (1,000CFU/ml) are considered to indicate contamination.

REPORTING RESULTS

Gram stain: Report smear as indicated. Any organism seen in a cytocentrifuged smear of BAL fluid is considered indicative of bacterial pneumonia.

Quantitative culture: Report number of each pathogen found as CFU per milliliter of specimen**.** **If culture count is lower than the threshold, identification and susceptibility testing are not generally indicated unless there is a pure growth of a primary pathogen.**

LIMITATIONS

Counts near thresholds may be difficult to interpret accurately.

Not all pathogens will grow on the media used and may result in a false negative culture.

Anaerobes are implicated in disease, especially in the elderly or those obtunded with aspiration pneumonia. Cultures are generally not cost-effective or helpful because they vary in sensitivity from 20 to 60%, possibly due to aeration during collection and dilution of the specimen.

Loop cultures are not as accurate as pipette cultures, but both are quite sensitive provided that a rod is used to spread the colonies on the plate. Spreading with a loop is not as sensitive a method and will underestimate the quantity of organisms present.

Even a single dose of antimicrobial therapy prior to specimen collection can negate the ability to isolate the causative agent of disease from the specimen.

REFERENCE

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COPY

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Approval Signatures

Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator, VCMC & SPH	3/3/2026
Policy Owner	Erlinda Roxas: Director, Laboratory Services	3/3/2026
Policy Owner	M. Anwar Molani: Medical Director, Laboratory Services	3/2/2026
Policy Owner	Linda Conboy: Supervisor-Microbiology, Laboratory Services	3/2/2026

COPY

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Next Review	3/2/2028
Owner	Linda Conboy: Supervisor-Microbiology, Laboratory Services
Policy Area	Laboratory Services - Microbiology

L.MIC 4.5 Cystic Fibrosis Specimen Processing

COPY

DEPARTMENT: Laboratory AFFECTS: MICROBIOLOGY	EFFECTIVE DATE: 4/15/2004	REVIEW DATES: 8/2005, 5/2006, 9/2008, 7/2009, 9/2010, 9/2011, 12/2016, 12/2017, 1/2019, 12/2020, 11/2021, 11/2023, 4/2025,2/2026
		REVISION DATES: 10/2012, 12/2013

SPECIMENS

Bronchoalveolar Lavage Fluid is the optimal specimen for assessing the microbiology of the lower respiratory tract. The procedure is invasive, expensive, and requires skilled personnel and has some risk for the patient so it is often not performed. Process specimen with Mucolyse or COPAN SL solution before plating.

Sputum is often submitted from those patients capable of expectorating. Process specimen with Mucolyse or COPAN SL solution agent before plating.

Oropharyngeal (throat) Swabs are the optimal alternative specimen. Do not process with Mucolyse or COPAN SL agent before plating.

SPECIMEN HANDLING AND PROCESSING

Transport to Lab as soon as possible within same working day, preferably in less than 3 hours. Otherwise refrigerate prior to transport.

If unable to process upon receipt, refrigerate specimen at 4°C.

SMEAR FOR GRAM STAIN (DONE ONLY ON HOSPITALIZED PATIENTS ONLY)

Prepare before processing specimen with mucolytic agent.

Bronchoalveolar Lavage: For evaluation of the presence of leucocytes and microorganisms.

Sputum: To ensure adequacy and quality of specimen. Make smear before processing with mucolytic agent.

Oropharyngeal Swabs: No Gram stain is performed on this specimen

COPY

MEDIA AND INCUBATION

BLOOD AGAR, incubate at 35 degrees C, in CO_2 for 4 days.

MACCONKEY, incubate at 35 degrees C, aerobic for 4 days.

MANNITOL SALT, incubate at 35 degrees C, aerobic for 4 days.

HORSE BLOOD AGAR, incubate 35 degrees C, anaerobically, for 4 days.

BURKHOLDERIA CEPACIA AGAR, incubate at 35 degrees C, aerobically for 4 days.

PRINCIPLE OF COPAN MUCOLYTIC AGENT:

Copan's SL solution is a ready to use mucolytic agent for sputum samples with the principle active ingredient being DTT (Dithiotreitol).

SL solution quickly liquefies sputum specimens without affecting the morphology, growth or microscopic staining of pathogens in the sputum.
The Sputum Dipper, exclusive to Copan, allows for easy transfer of sputum samples from specimen container to SL solution tube.

SPECIMEN PROCESSING USING COPAN SL SOLUTION KIT

Peel open one sputum dipper

Open the plastic pack containing the tube of SL solution, remove one tube and unscrew the cap.

By means of the Sputum Dipper, transfer the sputum sample into the opened tube. Break the sputum dipper into the tube by exerting slight pressure against the tube surface near the breaking point

Re-cap the tube of SL solution

Vortex the tube for 30 seconds at 2000/2500 rpm or until it is liquefied. Leave the mixture at room temperature for up to 15 minutes prior to inoculation in cases of increased mucous. Prolonged contact time up to 6 hours does not inhibit bacteria and fungi survival into the sample.

Aseptically remove aliquots of the liquefied sputum and inoculate onto appropriate bacteriology culture medium

Throat swabs: Inoculate directly to the media described under MEDIA AND INCUBATION. Do not process with Mucolyse

NOTE: Best results are obtained with a biological sample: SL solution ratio of 1:1

INOCULATION

Use a swab to inoculate the media described in MEDIA AND INCUBATION and streak plates for isolation using the three sector streak method.

WASTE DISPOSAL

Unused reagents may be considered as non hazardous waste and disposed of accordingly.

Dispose of used reagents as well as any other contaminated disposable materials following procedures for infectious or potentially infectious products.

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LIMITATIONS

In the laboratory, wear latex gloves and other protection commensurate with universal precautions when handling clinical specimens.

Condition, timing, and volume of specimen collected for culture are significant variables in obtaining reliable culture results.

Proper specimen collection from the patient is extremely critical for successful isolation and identification of infectious organisms.

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COPY

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Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator, VCMC & SPH	3/3/2026
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Policy Owner	M. Anwar Molani: Medical Director, Laboratory Services	3/2/2026
Policy Owner	Linda Conboy: Supervisor-Microbiology, Laboratory Services	3/2/2026

COPY

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Owner	Linda Conboy: Supervisor-Microbiology, Laboratory Services
Policy Area	Laboratory Services - Microbiology

L.MIC 5.1 Gram Stain

COPY

PROCEDURE: GRAM STAIN		POLICY NO: Micro 5.1
DEPARTMENT: General Laboratory AFFECTS: LABORATORY	EFFECTIVE DATE: 6/12/2006	REVIEW DATES: 10/2007,12/2008,1/2009, 11/2010, 5/2011, 12/2012, 12/2015, 12/15/2016, 12/21/2017, 1/31/2019, 12/15/2020, 11/15/2021, 4/2025, 2/2026
		REVISION DATES: 12/2013, 7/2015, 4/2020, 8/2023

PRINCIPLE

The Gram stain is used to classify bacteria based on their forms, sizes, cellular morphologies, and Gram reactions. In a clinical microbiology laboratory, it is additionally a critical test for the rapid presumptive diagnosis of infectious agents and serves to assess the quality of clinical specimens.

The PREVI Color Gram is designed to Gram stain specimen smears on microscope slides. A Gram stain aids in the presumptive diagnosis of the illness, and it gives preliminary classification of the causative agent.

Bacteria stain either Gram-positive or Gram-negative based on differences in their cell wall compositions and architectures. Gram-positive species have a thick peptidoglycan layer and larger

amounts of teichoic acids. They are unaffected by alcohol decolorization and retain the initial stain, appearing deep violet if their cell walls are undamaged by age, antibiotics, or other factors. Gram-negative cell walls have a single peptidoglycan layer attached to an asymmetric lipopolysaccharide-phospholipid bilayer outer member interspersed with protein. The outer membrane is damaged by alcohol decolorizer, allowing the crystal violet-iodine complex to leak out and be replaced by the counterstain.

Interpretation of Gram-stained smears involves consideration of staining characteristics and cell size, shape, and arrangement. These characteristics may be influenced by many factors including culture age, medium, incubation atmosphere, staining methods, and presence of particular host cell types and phagocytosis.

SPECIMEN COLLECTION, TRANSPORT, AND HANDLING

Specimens

Clinical specimens, generally excluding throat swabs, nasal swabs, and prosthetic devices. Direct smears are particularly useful for wounds, eye lesions, body tissues, and certain discharges.

Smears may be prepared from broth and blood cultures, or colonies growing on solid medium.

Young colonies (<24 h) from non-inhibitory media and fresh clinical specimens yield the most favorable results. When morphology is important (e.g., streptococci and gram –positive rods), broth cultures are preferred.

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Specimen Collection

Generally, the smear is made in the laboratory; however, when there is a concern that transport will be delayed or that the preservative for culture will alter the specimen, smears may be prepared by the collector and the slides transported to the laboratory for staining.

Rejection Criteria

Gram stains are of little value as direct smears of stool, throat samples, and sputum from cystic fibrosis patients, and are used only occasionally for urine.

Gram stains are also not routinely performed on blood cultures due to the low organism density and low yield in most samples.
Stains are not part of standard protocols for evaluation of catheter tip specimens.

MATERIAL REQUIRED

PREVI Color Gram V2 Stainer and carousel

90% or greater Methanol

Acetone Safranin-A solution, P/N 29582

Iodine -B solution P/N 29586

Crystal Violet-C solution P/N 29587

70% Ethanol

Nozzle Cleaning solution

NOTE: Indicate the "in use" date on the stain solution bottles and in the work record.

Pre-cleaned glass slides (25 x 75 mm), frosted ends.

Sterile Pasteur pipettes, wood applicator sticks; inoculating loops, or sterile swabs

Supplies for disposal of biological waste, including sharps receptacle.

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QUALITY CONTROL

Frequency: Slide QC is to be performed at least weekly. QC should also be performed when new lot of stain is used.
Quality control is performed for intended reactivity and recorded for each new batch or lot, and shipment of stains and at least weekly against known gram positive and gram-negative control organisms.

For laboratory staff that performs Gram stains infrequently, it may be appropriate to have them test a positive and negative control with each patient specimen tested.

Use commercially obtained Gram Stain Control or in-house slides prepared as in item 5 below.

Organisms:

E. coli (ATCC 25922) and *Staph aureus* (ATCC 25923).

Prepare a faintly turbid broth culture of the above organisms.

Make slides using 2 drops per slide spread in the size of a dime

Fix in methanol and store at room temperature.

Expected results:

E. coli, ATCC 25922 = Gram-negative rods = pink/red

Staph aureus, ATCC 25923 = Gram-positive cocci = deep violet

Document QC on gram stain reagent QC log.

*Verify that the quality of smear preparation and staining is satisfactory for all microbiology stains. This can be evaluated by reviewing QC slides and random clinical slides.

Take corrective action when stained smear preparations show evidence of poor quality, stains are difficult to interpret, or interpretations are inaccurate.
Poor staining characteristics (e.g., faintly staining gram –positive organisms, retention of crystal violet by gram-negative organisms, staining only of the edges of a smear, precipitate on slide, etc.) may be due to specimen preparation, reagents, or staining procedure.

The following are some common causes of poor Gram stain results.

Use of glass slides that have not been pre-cleaned.

Smear preparations that are too thick.

Overheating of smears when heat fixation is used.

Excessive rinsing during the staining procedure, especially if smear is not properly fixed.

Precipitate in reagents.

Ensuring accuracy of interpretation

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Review of selected Gram stains by supervisory personnel to determine training needs and aid in correlating relevant clinical information.

Review by microbiology department personnel of gram stains and reporting performed by lab personnel other than those assigned to the microbiology department.

Compare final culture results with Gram stain reports to check for recovery of morphologies noted in the Gram stain but not recovered in the culture.
Review both the smear and the culture when organisms in 3+ to 4+ quantities are recovered in culture but not observed on the Gram stain.

NOTE: An appreciable number of organisms discerned on a smear can be cultivated. Discrepancies should be investigated for errors in smear evaluation or for indications for further culturing methods (e.g., anaerobic, fungal, or acid-fast bacilli (AFB) culture).
Maintain a set of reference slides for competency training.

The microbiology department at least annually assesses morphologic observations among personnel performing Gram and other organism stains, to ensure consistency and accuracy.

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PROCEDURE

Smear Preparation

Use clean, grease-free glass slides that are not cracked, chipped, or etched.

Label the frosted ends with the accession number, last name of patient, source, and the date of smear.

Wear gloves and other PPE commensurate with standard precautions when handling clinical specimens. When preparing from clinical specimens in a biological safety cabinet (BSC), observe other BSL 2 recommendations.

For direct smears, prepare a monolayer of organisms sufficiently dense for easy visualization but sparse enough to reveal characteristic arrangements. As a guideline, newspaper print should be visible through the smear.

Always inoculate culture media before preparing smear when using the same pipette or swab.

Samples at the extreme edges of the slide may be under- or over decolorized, depending on the state of the nozzle spray pattern.

For the best results, the center area of the slide should be used for specimen loading.

Body fluids, bronchoalveolar lavage (BAL), and CSF.

Place 3 drops of sample into cytospin specimen chamber. Follow procedure for Cytofuge.

As an alternative when the specimen is viscous or cloudy or the quantity is not sufficient for concentration, use a sterile transfer pipette to transfer 1 or 2 drops of the specimen directly to the slide, after marking the location with a wax pencil. Allow the drop(s) to form one large drop.
Do not spread the fluid. Optionally, add a second drop of fluid to the same area to increase the concentration of fluid for examination.

Urine specimens

Place one well-mixed, *uncentrifuged*, free-falling drop from a sterile transfer pipette onto a glass slide.

Air dry without spreading.

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Specimens received on swabs with gel preservation media.

Place swab in 1 ml of saline or THIO broth, break off swabs, cap tube, and vortex. Leave swabs in tube. Use sterile transfer pipette to place one drop onto slide. Use remaining suspension to inoculate culture media.

NOTE: Never mix open tube vigorously. Avoid creation of aerosols.

Specimens received on swabs with liquid preservation media (eSwab)

Vortex the eSwab tube containing the swab sample for 5 seconds to release the sample from the swab tip.

Using a sterile pipet, transfer 1-2 drops of Liquid Amies sample suspension to the slide.

Specimens not received on swabs: aspirates, exudates, sputa, etc.,

Transfer specimen to the cleaned slide.

If the specimen is received in a syringe, first inoculate all culture media, and then transfer a small amount to the glass slide. Transfer contents of syringe into sterile tube. Label with patient and specimen information.

Select purulent or blood-tinged portions of pus or sputum with a sterile swab.

Spread the sample over a large area of the slide to form a thin film.

For extremely thick or purulent specimens

Dilute in a drop of sterile saline on the slide for easier smear preparation.

Alternately, make a pull slide.

Dried material or very small amounts of clinical specimen

Emulsify specimen in 0.5 ml of sterile broth or saline. Vortex, if necessary.

Sterile transfer pipette to transfer 1 drop to a slide.

Use the pipette tip to spread the drop into an even thin film.

Biopsy specimens and tissue sections

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Touch preparation

Place tissue in sterile Petri dish, and mince with sterile scalpel.

With sterile forceps to hold pieces, touch the sides of one or more of the minced fragments to a sterile glass slide, grouping the touches together for easier examination.

Thin-smear preparation

When specimen sample is soft tissue or thick exudates, prepare smear by taking a small portion of tissue, and place it on sterile slide with a swab or sterile forceps.

Place second sterile slide over sample and press slides together.

Separate slide by sliding the two away from each other.

If there is no other option, use a ground specimen preparation. Spread 1 drop to the size of a dime.

NOTE: Homogenizing or grinding tissue specimens before preparing the smear will often destroy characteristic cellular entities and bacterial arrangements

Broth cultures

Prepare one smear per slide to avoid washing off "dried" liquid from one area to another

during staining.

Use sterile transfer pipette (or a venting needle or syringe adapter for containers with septa, such as blood culture bottles, to avoid manipulating a needle and syringe) to transfer 1 to 2 drops to the slide.

Spread drop into an even thin film.

Colonies from solid media

May place a small amount from applicator stick directly onto slide.

Place a drop of sterile saline or water on slide. Distilled water may distort cellular morphology of fragile organisms.

Transfer a small portion of colony with a sterile applicator stick, wire, needle, or loop.

Gently mix to emulsify. The resulting smear should be slightly cloudy and homogeneous. If swirl lines are evident as the smear dries, the inoculum was too heavy, the drop of saline was too small, and/or the smear was spread over too small an area.

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Smear Fixation

Allow the smear to air dry in BSC.

Place slide on heat block to dry. To avoid distortions, do not overheat.

Allow slide to cool before staining.

Alternatively, fix with methanol to prevent the lysis of RBC's, produce a cleaner background, and prevent washing off of liquid specimens.

Place a few drops of methanol on an air-dried slide for 1 min, drain off remaining methanol without rinsing, and allow the slide to air dry again.

Do not heat before staining.

PREVI Color AUTOMATIC STAIN PROCEDURE

Loading Slides

Remove the carousel from the bowl and place it on a solid level surface.

Remove the carousel lid by pressing the button and lifting the lid.

Insert the slides into the carousel **with the first slide in position 1**.

Be sure that the slides are loaded in balanced pairs. If an odd number of slides needs to be stained, use a blank slide to balance the carousel.

If there are empty slots in the carousel, use blocking slides to prevent overspray. Refer to Using Blocking Slides section in the User Manual.

If using a 12-slide carousel, make sure the slides are loaded with all the slide labels toward the outer rim of the carousel.

If using a 30-slide carousel, make sure the slides are loaded with all the slide labels toward the center of the carousel.

Always load slides with the specimen facing clockwise.

Always begin loading the slides in position 1, then in position 2, position 3, position 4 and so on.

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Replace the carousel lid by pressing the button and lowering the lid over the indexing posts.

Release the button and press the lid handle until it clicks into place.

WARNING: Do not place cracked, chipped, or broken slides into the carousel.

Starting a Staining Cycle

Insert a carousel and close the instrument lid.

Select number of slides loaded into the carousel to be stained. Do not count the blocking slides as part of the total.

Select Start. The instrument will indicate the progress of the program, and a signal tone will indicate the end of the cycle.

Wait until the carousel rotation ceases prior to opening the lid. Select the Checkmark button and open the lid, or just open the lid.

Unloading the Carousel

Remove the carousel from the bowl and place it on a solid, level surface.

Remove the carousel lid by pressing the button and lifting the lid.

Carefully remove each slide already dried and read the Gram stain slide with a microscope.

Instrument Maintenance

Daily, Weekly, Monthly, Quarterly, and Annual maintenance should be performed as directed on the PREVI-Color Gram maintenance checklist. Additional information can be found in PREVI-Color Gram User's Manual, *Section 5-1 Maintenance and Cleaning*
Shutdown/Long-term storage One week is the maximum time between two successive staining runs. If the PREVI-Color Gram is not used for more than one week, the long-term storage procedure must be applied. Refer to PREVI-Color Gram User's Manual*, Section 5-1, page 5-16 Long-term storage*.
Troubleshooting Refer to Section 6, Troubleshooting in the PREVI-Color Gram User's Manual for a table that gives a brief description of the error messages and the troubleshooting action.

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MANUAL STAINING PROCEDURE

Perform and document QC each day of use to confirm acceptability of performance.

Do not apply stains, water, or decolorize directly to specimen area. Drops may be applied to the frosted end of the slide, allowing reagent to flow over the remaining surface.

Flood the fixed smear with the crystal violet solution. Allow the stain to remain for one minute.

Decant the crystal violet, and rinse slide gently with running tap water by applying the flow of water to the underside of the angled slide to ensure a gentle flow across the smear side.

Decant off excess water, and then flood the slide with Gram's Iodine solution. Allow to remain for one minute.

Rinse slide gently with flowing tap water as before in step C.

Decolorize by letting the acetone-alcohol flow over the smear while the slide is held at an angle for about 5 seconds. Stop when the runoff becomes clear. Adjust decolorization time to thickness of smear.

Remove excess decolorizer with gentle flow of tap water as before in step C.

Flood the slide with safranin beginning at the frosted end of the slide and allow the counterstain to remain for one minute.

Remove excess counterstain with a gentle flow of tap water as before in step C.

Drain the slide, and air dry in an upright position in slide rack.

SMEAR EXAMINATION

Evaluate the general nature of the smear under low power (10 X objective with 10 X eyepiece).

Observe for stain crystals.

If an excess of precipitated stain is observed, decolorize and re-stain slide.

Alternatively, prepare another Gram-stained smear.

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If precipitate continues, use freshly filtered crystal violet or counterstain in a clean container.

Determine if smear has been for properly decolorized.

Depending on the source of the specimen, the background should be generally clear or gram negative.

If WBCs are present, they should appear completely gram negative.

If slide is over-decolorized, completely decolorize and re-stain slide.

Determine if thickness of smear is appropriate. For proper interpretation, areas must be no more than one cell thick, with no overlapping of cells. Prepare new slide if unreadable.

For smears prepared from clinical specimens, examine several fields (10 for urine, 20 to 40 for other specimens) under low power for evidence of inflammation.

Observe distribution of organisms and cells.

Determine areas representative of inflammation or purulence and areas of apparent contamination with squamous epithelial cells (SECs). If no purulence is seen, choose areas of apparent necrosis, inflammatory cell debris, and mucus.
If cells are present, determine the average count of WBCs and epithelial cells in 20 to 40 representative fields that contain cells.

In a representative area with a preponderance of inflammation or purulence using the oil immersion lens (100 X objective with 10 X eyepiece), examine 20 to 40 fields to quantitate bacteria, observe cell morphology, and assess gram reaction.
If rare or no organisms are seen from a normally sterile site specimen, but the specimen appears purulent, or the specimen looks suspicious, perform a more extensive review of the slide.

Certain critical specimens where low numbers of organisms may be seen (e.g., CSF) should be read more extensively, and the entire slide may need to be read to substantiate a negative result.

Preservation of direct smear slides

Drain or gently blot excess oil from slide and save slides for further evaluation for a minimum of 6 months.

Should a slide need to be re-stained to repeat Gram stain or prepare a special stain to confirm findings suggested by a Gram stain, remove the immersion oil with xylene or a xylene substitute (Clear-Rite) and decolorize smear. Then re-stain slide.

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INTERPRETATION

Low-power Observations

WBCs and RBCs suggest infectious process.

NOTE: Neutropenic patients may have few WBCs, but they may have necrotic debris and protein in the background.
Squamous Epithelial cells, food debris, etc., suggest an improperly collected specimen.

Oil Immersion Observations

Observe microorganisms for characteristic morphology and presentation.

Gram reaction

Gram positive: deep violet

Gram negative: pink or red

Gram variable: both gram-positive and gram-negative cells with the same morphology.

NOTE: This may result from a smear of uneven thickness, incomplete de-colorization, over-decolorization, presence of older cells, damage of cell walls, or gram-variable nature of the organism.

Gram neutral: taking up neither the crystal violet nor the counterstain.

NOTE: These cells appear colorless against a generally gram-negative background and may be intracellular. This reaction has been seen in smears of clinical specimens when fungal elements or *Mycobacterium* spp. are present.

Staining Characteristics, predominant shapes of microorganisms, relative sizes, and characteristic arrangements.

Predominant shapes of microorganisms

Overall shape: round, coccoid, coccobacillary, rod, filament, yeast-like

Appearance of ends: rounded, pointed, tapered, flattened, clubbed (swollen), concave

NOTE: Swelling of sides can suggest the presence of spores but can also be due to vacuoles, inclusions, marked pleomorphism, or irregular staining.

Appearance of sides: parallel, ovoid (bulging), concave, irregular

Nature of axis: straight, curved, spiral

Pleomorphism: variation in shape

NOTE: The descriptive term "diphtheroid" or coryneform" is used to describe gram-positive bacteria that are pleomorphic, club shaped, or irregularly staining or that have palisading and/or angular arrangements (V and L shapes)

Branching or cellular extensions

Relative size

NOTE: The average size of an RBC is 7 mcm, and cytoplasmic granules in neutrophils average 0.2 to 0.3 mcm. The size references given here are only guidelines.

Overall: minute or tiny < (0.3 mcm), small (about 0.3 to 0.5 mcm), medium, or large

Length: short (about 0.5 to 1 mcm, medium, long, or filamentous (10 to 30 mcm)

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Width: thin medium, or fat

Pleomorphic: variation in size

Characteristic arrangements: singles, pairs, chains, tetrads, clusters, palisades, Chinese letters, packets, angular forms (V and L shapes), etc
.
The presence of a microorganism from a normally sterile site is likely to indicate infection with that organism.

The presence of large numbers of a single type of microorganism in a noninvasively collected specimen, especially if associated with WBC's, is likely to indicate infection.

Be wary of interpretations made from observing very few organisms (especially in the absence of inflammation or if the organisms are unevenly distributed), because collection tubes, slides, and media may harbor nonviable bacteria**.**
For critical specimens, where the results will define an infectious process (e.g., CSF smears), prepare a second smear to confirm rare findings of microorganisms.

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REPORTING RESULTS

If no organisms or cells are detected in a smear of a clinical specimen, report "No organisms seen" or "No cells seen," respectively.

NOTE: While there is no scientific basis for a policy on enumeration of cells and bacteria in stained smears, the following is most applicable to all specimens will provide consistency in the lab. The enumeration of cells is based on the publications documenting the relationship between cells and contaminated respiratory specimens, and the enumeration of bacteria is based on the publications for counts for female genital specimens. *Counts should only be performed in areas representative of inflammation or necrosis, if present*.

Determine number of cells and bacteria in 20 to 40 fields of the smear. Skip fields where there are no cells or bacteria, and do not average these fields in the counts if there are fields where cells and/or bacteria are present.

Count cells under low-power objective and report relative numbers accordingly.

1+ = <1 per LPF

2+ = 1 to 5/LPF

3+ = 10 to 25/LPF

4+ = >25/ LPF

NOTE: There is no clinically useful reason to report cells present in amounts less than 10 per 40 fields from a Gram stain, which is not primarily a stain to show host cellular morphology

Follow cellular enumeration with the description of the type of the cells.

SECs

WBCs

RBCs

Host cellular material

The gram stain is not a stain that demonstrates host cellular morphology, and the main cells routinely enumerated are WBCs, which determine if the sample is purulent as an indication of infection. For other types of cells, there is no clinically useful reason to report cells present in amount of <10/40fields from a Gram stain. LPF, low-power field.

Count bacteria and yeasts from areas associated with cells under oil immersion objective and report:

1+ = <1/OIF

2+ = 1 to 5/OIF

3+ = 6-30/OIF

4+ = >30/ OIF

Follow microorganism enumeration with the description of the morphology of the bacteria, providing as much information as possible.

Descriptions which can be used include the following.

Gram positive
- cocci in pairs (and chains)
- cocci in clusters
- large bacilli
- small bacilli
- branching bacilli

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coryneform bacilli

Gram negative
diplococci
bacilli
bacilli, filamentous (or pleomorphic)

Gram variable rod or coccobacilli

budding yeast cells

NOTE: Experienced microbiologists are encouraged to specify Gram stain morphology and resemblance to organism group consistent with the source if the presentation is classic' however, use caution when in doubt, as other species may mimic the typical presentations listed below:

Gram-positive cocci in clusters resembling Staphylococcus

Gram-positive cocci in chains resembling Streptococcus

Gram-negative coccobacilli, resembling with Haemophilus

Gram-positive bacilli, resembling dipheroids

Gram-negative diplococci, resembling with *Neisseria* or *Moraxella*

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Refer to Micro 5.1b for special reporting of respiratory and female genital specimens, respectively.

Notify the caregiver or physician of record, depending on policy, of any clinically significant findings (any bacteria from a normally sterile site). Document notification, including date and time of notification.

LIMITATIONS

The sensitivity of the Gram stain is 100,000 cells/ml or 1,000/ml if the specimen has been prepared with the cytofuge. This is particularly applicable to the smear of a drop of urine, where an average of one bacterial cell per field from an examination of 20 fields corresponds to a count of ≥ 100,000 CFU/ml.

Gram stain of cytofuged BAL with one or more organisms per OIF correlates with active bacterial pneumonia.

Use results of Gram stains in conjunction with other clinical and laboratory findings. Use additional procedures (e.g., special stains, inclusion of selective media, etc.) to confirm findings suggested by Gram-stained smears.
Careful adherence to procedure and interpretive criteria is required for accurate results. Accuracy is highly dependent on the training and skill of microscopists.

Gram stain-positive, culture-negative specimens may be the result of contamination of reagents and other supplies, presence of antimicrobial agents, or failure or organisms to grow under usual culture conditions (medium, atmosphere, etc.).

False negative Gram stain results may be related to inadequately collected specimens or delays in transit.

REFERENCE

BioMerieux S.A. **PREVI-Color Gram User's Manual**, REF29675 v. B 03/2009

Leber,Amy L. et al, **Clinical Microbiology Procedures Handbook**, 4th Edition, Volume 1, ASM Press, Washington, D.C., 2016, pages 3.2.1.1 to 3.2.1.18.

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All Revision Dates

3/3/2026

Attachments

- Micro 5.1b Gram stain Evaluation.docx
- Micro 5.1b Mnemonics Gram Stain Computer Entry.xls

Approval Signatures

Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator, VCMC & SPH	3/3/2026

Policy Owner	Erlinda Roxas: Director, Laboratory Services	3/3/2026
Policy Owner	M. Anwar Molani: Medical Director, Laboratory Services	3/2/2026
Policy Owner	Linda Conboy: Supervisor-Microbiology, Laboratory Services	3/2/2026

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Status **Active** PolicyStat ID **20035593**

Origination	3/3/2026	Owner	Linda Conboy: Supervisor-Microbiology, Laboratory Services
Last Approved	3/3/2026		
Effective	3/3/2026	Policy Area	Laboratory Services - Microbiology
Last Revised	3/3/2026		
Next Review	3/2/2028		

L.MIC 5.2 Sputum Quality Evaluation

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EFFECTIVE DATE: 7/27/2006	REVIEW DATES: 10/2007, 12/2008, 7/2009, 12/2015, 12/2016, 12/2017, 1/2019, 12/2020, 11/2021, 11/2023, 4/2025, 2/2026
	REVISION DATES: 7/2010, 5/2011, 7/2015

PRINCIPLE:

Despite the frequency of lower respiratory tract infection, diagnostic studies to detect and identify the etiologic agent are insensitive. Everyone does agree that the culture of poorly collected respiratory samples is a wasteful use of laboratory resources and can lead to erroneous reporting and treatment of patients.

Expectorated sputum or sputum obtained by endotracheal aspirates from mechanically ventilated adult patients can be screened by Gram stain to evaluate the quality of the specimen. Fundamental to the evaluation of quality is the premise that an abundance of squamous epithelial cells (SEC) is suggestive of superficial oropharyngeal contamination, requiring specimen recollection.

A sputum specimen for diagnosis of pneumonia is difficult to obtain from children. More commonly, a tracheal or endotracheal tube aspirate is obtained. Although grading systems for assessment of the quality of pediatric tracheal aspirates have been proposed, careful evaluation is required prior to their implementation. Some have concluded that squamous epithelial cells were

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not a useful screening criteria in children, since only 5% of the patients had >10 SECs (Squamous Epithelial Cells) per low power field.

REAGENTS:

See Gram stain procedure

PROCEDURE:

Examine 20 to 40 fields from sputum smears under low power. Average the number of cells in representative fields that contain cells. Reject the following for culture, as poorly collected or not consistent with a bacterial infectious process.
Sputum: >= 10 SECs/LPF
Tracheal aspirates from adults: >= 10 SECs/LPF

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REPORTING RESULTS:

When rejecting the specimen for culture, report the following statement
"MSC" under the non billable test "MSC"

"Smear contains >= 10 squamous epithelial cells per low power field, suggestive of poor quality; culture not performed. Please recollect if clinically indicated."

Notify the caregiver that the specimen will not be cultured. Document the date, time and caregiver to whom the report was called.
Charge for the smear but not for the culture.

When the Quality score is acceptable, the following guidelines for organism enumeration apply:

Staph like organisms: report when >50 organisms/oif

Strep pneumonia like organisms: report when >25 organisms/oif

Moraxella like organisms: report when >25/oif

Enteric like gram negative rods: report when >10/oif

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Pseudomonas like gram negative rods: report when >10/oif

Haemophilus like gram negative coccobacilli: report when >10/oif

All other bacteria and yeast are to be called out as "Mixed Bacteria"

The presence of multiple microorganisms consistent with normal flora (>50/oif) in a good quality specimen (>25WBC's/lpf with intracellular bacteria) may indicate aspiration pneumonia and should be reported as such.

Use the comment **MASP** under the culture report result

Gram stained smears of lower respiratory tract secretions provide information that can be useful in the medical management of patients with aspiration pneumonia because bacterial aspiration pneumonia can be difficult to diagnose clinically, is rarely confirmed by culture, and requires antimicrobial therapy targeting both aerobic and anaerobic bacteria.

LIMITATIONS:

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Do not reject sputum and endotracheal aspirations for culture for Legionella or AFB, or specimens from cystic fibrosis patients.

Squamous Epithelial Cells are not a useful screening criterion in children or neonates.

Gram stains should not be done on upper respiratory specimens: nasal washes, nasopharyngeal aspirates, nasopharyngeal swabs or throat swabs.

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All Revision Dates

3/3/2026

Attachments

Micro 5.2a Quantitation of Sputum Gram Smears.doc

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Approval Signatures

Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator, VCMC & SPH	3/3/2026
Policy Owner	Erlinda Roxas: Director, Laboratory Services	3/3/2026
Policy Owner	M. Anwar Molani: Medical Director, Laboratory Services	3/2/2026
Policy Owner	Linda Conboy: Supervisor-Microbiology, Laboratory Services	3/2/2026

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Status **Active** PolicyStat ID **20035647**

VENTURA COUNTY HEALTH CARE AGENCY

Origination	3/3/2026
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Last Revised	3/3/2026
Next Review	3/2/2028
Owner	Linda Conboy: Supervisor-Microbiology, Laboratory Services
Policy Area	Laboratory Services - Microbiology

L.MIC 5.4 Direct Examination of Stool Specimens

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EFFECTIVE DATE: 7/17/2009	REVIEW DATES: 11/2010, 10/2011, 12/2013, 7/2013, 12/2015, 12/2016, 12/2017, 1/2019, 12/2020, 11/2021, 11/2023, 4/2025, 2/2026
	REVISION DATES:

DIRECT EXAMINATION OF STOOL SPECIMENS

PRINCIPLE:

The presence of WBCs is one factor suggestive of an invasive infectious process. A Gram stain or methylene blue stain may be used to detect leucocytes. Fecal leucocyte examinations have been recommended for the differentiation of inflammatory diarrheas (fecal leucocyte positive) from secretory diarrheas (leucocyte negative). Infectious, inflammatory diarrheas are caused by invasive bacteria, viruses, and protozoan pathogens.

SPECIMEN COLLECTION:

Collect stool specimen for wet mount into a sterile, leakproof widemouthed container.
If fresh stool cannot be transported and processed for wet mount within 2 hours after collection, place in 10% formalin and / or PVA or SAF preservative. Preserved stool may be indefinitely

transported and stored prior to wet mount exam.

REJECTION CRITERIA:

Reject fresh stool delayed in transport and received greater than 2 hours after collection.

REAGENTS:

Reagent: Methylene Blue, Loeffler's, Hardy Diagnostics, 15-ml dropper bottle or Crystal Violet, Gram's Iodine, Acetone-Alcohol, Decolorizer, and Safranin
Glass microscope slide
Coverglass, 22 x 22 mm
Stool specimen in Clean Vial or SAF
Transfer pipette or applicator stick
EDTA tube of blood

PROCEDURE

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Select mucous portions of the stool for examination.
WET MOUNT WITH LOEFFLER'S METHYLENE BLUE

Using a wooden applicator stick, mix 1 drop of Loeffler's methylene blue stain with an equal portion of stool on a microscope slide.
Place coverglass over sample; wait 2 to 3 minutes.
Observe for and count WBC's (polys) and RBCs in 10 to 20 fields using the 400X magnification (HPF) to get an accurate determination of the specimen content.
Dispose of slides in Biohazardous container, wipe microscope with 70% alcohol, and remove gloves.

GRAM STAIN

Prepare a thin smear of the fecal material.
Refer to Gram Stain procedure L.MIC 5.1 for stain procedure.

Examination:

Look for predominating number of WBC's (polys), Gram-positive cocci in clumps, yeast cells, or absence of Gram-negative organisms.

Reporting:

Report quantity as per *Gram Stain Procedure L.MIC 5.1 procedure.*

QUALITY CONTROL:

WET MOUNT WITH LOEFFLER'S METHYLENE BLUE

Positive Control: Each day of use, examine 1 drop of buffy coat from an EDTA collected blood sample for cellular components (WBCs and RBCs)

GRAM STAIN

Use weekly Quality Control Slide Result for Gram Stain

RESULTS:

COPY

WET MOUNT WITH LOEFFLER'S METHYLENE BLUE

Report the number of WBCs and RBCs per high power field. Average several fields and report as follows:

>= 5 / HPF

1 to 4 / HPF

<1 / HPF

GRAM STAIN

Report quantity of WBCs and RBCs per Gram Stain Procedure

Report bacteria as either:

Mixed bacteria for Stool or Predominance of _____

LIMITATIONS

The sensitivity of the technique varies with the experience of the microscopist and is generally about 60%. Because of the variability in results for the presence of WBCs in stool and sensitivities

of 50 to 60% in gastroenteritis and as low as 14% for C.difficile colitis, the test cannot be used as a screening test but as one of several tests to evaluate a patient's condition.

REFERENCE

Garcia, Lynne and Isenberg, Henry D. **Clinical Microbiology Handbook,** 2nd edition, 2007, ASM Press, Washington D.C., pp. 3.2.3.1 to 3.2.3.3

All Revision Dates

3/3/2026

Approval Signatures

Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator, VCMC & SPH	3/3/2026
Policy Owner	M. Anwar Molani: Medical Director, Laboratory Services	3/3/2026
Policy Owner	Erlinda Roxas: Director, Laboratory Services	3/3/2026
Policy Owner	Linda Conboy: Supervisor-Microbiology, Laboratory Services	3/2/2026

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VENTURA COUNTY HEALTH CARE AGENCY

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Last Revised	3/3/2026
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Owner	Linda Conboy: Supervisor-Microbiology, Laboratory Services
Policy Area	Laboratory Services - Microbiology

L.MIC 5.5 Direct Microscopic Examination of Mycology Specimens

COPY

	REVIEW DATES: 3/2000, 7/2001, 9/2002, 5/2003, 1/2005, 6/2006, 10/2007, 12/2008, 7/2009, 11/2010, 10/2011, 12/2013, 7/2015, 12/2015, 12/2016, 12/2017, 1/2019, 12/2020,11/2021, 11/2023, 4/2025, 2/2026
	REVISION DATES:

PRINCIPLE:

Any specimen submitted for fungus culture can be examined microscopically for fungal elements. The examination is made in addition to, not instead of, a culture. As well as providing the physician with early information regarding the possible need for treatment, it may be helpful in determining the significance of the organism that will later be identified on culture.
Most organic substances that might be confused with fungi when seen through the microscope are converted to an almost clear background in the presence of moderately strongly alkaline solutions. The fungi remain unaffected and are therefore rather easily demonstrated.

MATERIALS REQUIRED

Glass microscopic slides

22 X 22 mm coverslips

10% KOH (Difco or BD) droppers

12 X 75 mm test tube or small test tube

Pasteur pipettes

Applicator sticks

PROCEDURE

Place a portion of specimen in the test tube.

Add equal quantity of KOH to the tube; mix.

Allow the mixture to stand until it becomes less viscous, if sputum or pus, or if hair, skin, or nails, until softened (use applicator stick to probe).

Place a drop of KOH prepared specimen on a labelled glass slide.

Put a coverslip over the preparation.

The slide must be carefully examined microscopically to detect hyphal elements, spore or conidia, budding yeast, spherule, or sclerotic bodies. Cotton swabs should not be used in preparing these slides, as the cotton strands may resemble hyphae.

KOH preparations are not permanent; the reagent will eventually destroy the fungi. The addition of a small amount of glycerol to the preparation will preserve it for several days.

REPORTING RESULTS

If fungal elements seen, report: Fungal elements seen resembling _____.

If no fungal elements seen, report: No fungal elements seen.

STAINED PREPARATION

Gram stain is useful for the examination of specimens for the presence of aerobic actinomyces.

A modified Kinyoun acid-fast stain is used to detect the partially acid-fast filaments of ***Nocardia spp.***

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Wright's stain (commonly performed in Hematology) or Giemsa stain is used for detecting intracellular yeast forms of ***Histoplasma capsulatum*** in blood and bone marrow.

The periodic acid-Schiff (PAS) and Gomori's methenamine silver stains (GMS) are considered the best for demonstrating fungi in tissues. Both procedures are performed in Histology.

REFERENCE

Larone, Davise H., **Medically Important Fungi: A Guide to Identification, 3rd edition,** ASM Press, Washington D.C., 1995, pp.212-214

All Revision Dates

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Approval Signatures

COPY

Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator, VCMC & SPH	3/3/2026
Policy Owner	M. Anwar Molani: Medical Director, Laboratory Services	3/3/2026
Policy Owner	Erlinda Roxas: Director, Laboratory Services	3/3/2026
Policy Owner	Linda Conboy: Supervisor-Microbiology, Laboratory Services	3/2/2026

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L.MIC 5.7 Wet Mount

COPY

EFFECTIVE DATE: 8/9/2000	REVIEW DATES: 9/2002, 4/2004, 1/2005, 5/2006, 10/2007, 12/2008, 7/2009, 11/2010, 10/2011, 12/2013, 7/2015, 12/2015, 12/2016, 12/2017, 1/2019, 12/2020, 11/2021, 11/2023, 4/2025, 2/2026
	REVISION DATES: 10/2011, 4/2014

PRINCIPLE

A wet preparation of vaginal and urethral discharges, urine and prostatic secretions can demonstrate the presence of leukocytes, *Trichomonas vaginalis*, and yeasts. The presence of WBCs is one factor suggestive of an invasive reproductive tract infectious process, including pelvic inflammatory disease and cervical infection due to *Chlamydia trachomatis* or *Neisseria gonorrhoeae*.

Large numbers of WBCs are associated with *T. vaginalis* infection. Additionally, a wet mount of vaginal fluid can demonstrate the presence of specialized epithelial cells coated with bacteria known as "clue cells". This rapid test is useful in the timely detection of bacterial vaginosis and vaginitis. Bacterial vaginosis is a clinical syndrome characterized by a shift in the vaginal microbiota from the dominant microbiota of *Lactobacillus* spp. to a mixed microbiota of *Gardnerella vaginalis*, *Prevotella* spp., *Mobiluncus* spp., and *Mycoplasma hominis*. Budding yeasts and/or pseudohyphae of yeasts can also be identified in the vaginal fluid and are an indicator of yeast vaginitis

.

Recent data indicate that microscopic examination of a spun urine specimen performed in conjunction with microscopic examination of a vaginal fluid specimen improves the detection rate of *T. vaginalis*.

Several specimens may need to be examined for detection of the organisms. The sensitivity associated with wet mount examinations varies between 40% to more than 80%. Often the percentage detection from this procedure is quite low with limited sensitivity and specificity.

SPECIMEN COLLECTION, TRANSPORT, AND HANDLING

Urine

Collect urine specimen into a sterile, leak proof, wide mouthed container and store at 4 degrees C.

If fresh urine cannot be transported and processed for wet mount within 2 hours after collection, place in a sterile transport tube containing preservative (boric acid). Preserved urine may be indefinitely transported and stored prior to wet mount exam.

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Prostatic secretions and Urethral discharges

Prostatic secretions can be collected after prostatic massage into a sterile, leak proof, wide mouthed container and stored at 4 degrees C. Prostatic secretions and urethral discharges may also be collected on a swab placed in Amies' gel transport system.

Vaginal Fluid

Collect vaginal fluid/discharge from the posterior fornix using sterile cotton or Dacron swab.

Slides for wet mount must be immediately prepared and examined (within 15 to 20 min after collection) for WBC and trichomonad evaluation.

Vaginal swabs for wet mount that cannot be immediately examined should be placed in Amies' gel transport system.

REJECTION CRITERIA

Reject specimens that are not received in transport media if they are delayed in transport and received more than 2 hours after collection.

Smears prepared at the time of collection are acceptable for WBC evaluation for up to 24 hours after collection.

PROCEDURE

If specimen is transported in Amies' gel, suspend into 2 or 3 drops of saline before placing onto the slide.

Apply coverslip and examine by using the high dry objective (400X magnification).

Observe for and count leukocytes, epithelial cells (clue cells in vaginal specimens) in 10-20 fields to get an accurate determination of the specimen content.

Clue cells are squamous epithelial cells with bacteria attached to the top and sides.

Clue cells appear as granular cells with an undefined edge.

Observe for parasites that are motile, such as trichomonads. Use reduced illumination and look for the presence of actively motile organisms as the jerky motility begins to diminish, it may be possible to observe the undulating membrane.

Observe for budding yeast cells and pseudohyphae.

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REPORTING RESULTS

Report number of WBCs per HPF.

Report on the presence of *T. vaginalis*.

Report on the presence of budding yeasts and pseudohyphae.

Report on the presence of clue cells.

If the vaginal specimen is negative for parasites and was not processed within 10-20 minutes, report "Unable to determine the presence of Trichomonas vaginalis because of delay in transport." (Use "DELAYTRICH") coded response in L.I.S.

INTERPRETATION

Vaginal infections with *T. vaginalis* are usually accompanied by >30 WBCs/HPF.

For vaginal specimens, the sensitivity of testing by wet mount by wet mount for WBCs is not as important as the examination for clue cells, yeasts, and *T. vaginalis*, although *T. vaginalis* is more common in specimens with WBCs.

The presence of budding yeast is associated with candidiasis.

The presence of clue cells is indicative of bacterial vaginosis.

QUALITY CONTROL

Positive controls are not needed for wet mounts as no reagents are added but evaluate competency with an ongoing program using positive and negative smears showing WBCs, clue cells, and trichomonads. This is generally accomplished by viewing a collection of photographs.

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LIMITATIONS

This examination must be performed within 10-20 minutes after sample collection; if not, organisms lose motility and may not be identified.

Several specimens may need to be examined for detection of *T. vaginalis*. The sensitivity associated with wet mount examinations varies between 40% and more 80%. Often the percent detection from this procedure is quite low with limited sensitivity and specificity.

WBCs are often confused with trichomonads that are no longer moving, which can be avoided by careful examination for the characteristics of the parasite.

Activated leukocytes disintegrate easily, decreasing the sensitivity of the assay with delays in transit.

If there is a question in reading the test, the cells, but not yeasts, will dissolve with the addition of KOH.

REFERENCES

Garcia, Lynne S. editor in chief. Clinical Microbiology Procedures Handbook, Third Edition. Washington, DC: ASM Press, 2010. Print.

Garcia, Lynne S. Diagnostic Medical Parasitology. Washington, DC: ASM Press, 2007. Print.

Tille, Patricia M. Bailey & Scott's Diagnostic Microbiology, Thirteenth Edition.

St. Louis, Missouri: Elsevier Mosby. 2014. Print.

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Approval Signatures

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Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator, VCMC & SPH	3/3/2026
Policy Owner	M. Anwar Molani: Medical Director, Laboratory Services	3/3/2026
Policy Owner	Erlinda Roxas: Director, Laboratory Services	3/3/2026
Policy Owner	Linda Conboy: Supervisor-Microbiology, Laboratory Services	3/2/2026

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Owner	Linda Conboy: Supervisor-Microbiology, Laboratory Services
Policy Area	Laboratory Services - Microbiology

L.MIC 6.1 Blood Parasite Detection

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EFFECTIVE DATE 3/28/2000	REVIEW DATES: 9/2010, 9/2011,5/2013, 12/2015, 12/2016, 12/2017,1/2019, 11/2021, 11/2023, 4/2025, 2/2026
	REVISION DATES: 7/13/2009, 12/2011, 8/2013, 2/2016, 8/2017, 12/2020, 6/2023

PRINCIPLE:

During some stages in their life cycle, *Plasmodium spp*. (malaria), *Babesia spp*., *Trypanosoma spp*., *Leishmania donovani*, and the filaria are detectable in human blood. *Plasmodium* and *Babesia* species are found within the RBCs; trypanosomes and microfilariae, the larval stage of filariae, are found outside the RBCs; and *Leishmania* amastigotes are occasionally found within monocytes. Species identification of all blood parasites are usually made from either or both of two types of stained blood films; a thin film and a thick film. These films can be made from whole or anticoagulated blood or from the sediment of a variety of procedures designed to concentrate trypanosomes and microfilariae in the blood.

Microscopic examination of stained blood films is best accomplished by beginning with a thorough search of both the thin and thick films with low power magnification for microfilariae. If larvae are found, magnification at a higher power will reveal the finer morphological details necessary to make a definitive identification. Other blood parasites require examination with oil immersion magnification of both the thin and thick films.

All species of parasites found in a blood specimen should be reported to the attending physician as soon as possible. Notification of appropriate public health and infection control should be

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made after confirmation by the pathologist on duty.
The laboratory must be proactive in obtaining the patient's history.

The patient's travel history and date of return to the United States can suggest the likelihood of infection and the possible species involved. The interval between exposure to an infective bite and the development of symptoms is typically 7 to 12 days for *Plasmodium falciparum*, *Plasmodium vivax* and *Plasmodium ovale* and up to 40 days for *Plasmodium malariae*. In general, malaria appearing more than one month after return from an area in which the disease is endemic is relatively unlikely due to *Plasmodium falciparum,* unless the patient received antimalarial agents which might have suppressed parasitemia.

A prior history of malaria in the patient suggests the possibility of relapse.
Knowledge of the fever pattern when the specimen was obtained in relation to a paroxysm is helpful. In a regularly periodic Plasmodium *falciparum* infection, the circulation parasitemia can be very low and difficult to detect between paroxysms.

SPECIMEN COLLECTION:

Blood Specimen: Well mixed EDTA blood specimen

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Use of anticoagulants: Blood samples for malaria are preferably collected without anticoagulants, but if anticoagulants must be used for other testing, **films for reliable staining of malaria parasites should be made immediately or within 1 hour of collection.** EDTA is recommended by most parasitologists for use with malaria parasites.

Collection Guidelines:

On admission or when a parasitic infection is first suspected.

If no parasites are found in the first sample, blood is collected every 6 to 12 hours until a diagnosis is made, or infection is no longer suspected (usually 3 to 5 days). ***Infection with a blood parasite cannot be ruled out by a single blood sample.***

If either trypanosomes or microfilariae are suspected, each sample should be concentrated by an appropriate technique to detect a low parasitemia.

The examination of blood for malaria should be considered a stat request. Preparation and examination of smears and reporting of results should be performed on a stat basis.

Blood films for parasites should be made on clean, standard, glass microscope slides. All slides, even new "precleaned" ones, should be dipped in alcohol and polished with a lint free towel or Kimwipe to remove any grease or dirt before the preparations are made.

Staining of Blood Films: All blood films, regardless of the stain which will be used, should be

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stained as soon as possible after they are thoroughly dry. Prolonged storage may cause erratic staining.

MATERIALS REQUIRED:

Six Clean glass slides (precleaned with 70% alcohol and wiped fry with gauze or Kimwipe)

Hematology Slide Stainer with Wright Stain

Buffered water of pH 7

All Hydrion buffer salts are directly traceable to NIST standards and certified to +/- 0.02 pH units at 25C.

Graduated cylinder, 100ml

Coplin jar

Diff-Safe Blood Dispenser

Wooden applicator stick

Blood parasite Control Slide (Commercial)

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QUALITY CONTROL:

A known positive Control slide should be stained for each run each day of use.
The buffered water used for thick smear should be clear with no visible contamination.

A collection of known slides should be available as a study tool and for comparison.
with patient samples.

PROCEDURE:

Thin Blood Film: The thin blood film can be stained within a few minutes and will afford a quick diagnosis of malaria if the patient has a high degree of parasitemia.

The thin film is identical to a differential WBC count film. It provides a good area for examining the morphology of parasites and RBCs and is used to confirm the identity of parasites that cannot be identified in thick films. A thin film must be used to differentiate *Plasmodium ovale* from *Plasmodium vivax* and *Babesia* species from the ring forms of *Plasmodium falciparum*. The thin film is also better for identifying *Trypanosoma cruzi*, because these organisms become distorted in thick films. The thin film, however, is less sensitive than the thick film in light parasitemia.

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Procedure

Place a minimum of three cleaned glass slides on a horizontal surface.

The thin smear preparation is identical to a CBC review preparation.

Place a small drop of blood (10-15mcl) of specimen onto the center of the slide about ½ in. from the end.

Holding a second clean glass slide at a 40-degree angle, touch the angled end to the drop of blood.

Pull the angled slide back into the blood and allow the blood to almost fill the end area of the specimen slide.

Quickly and steadily move the angled slide toward the opposite end of the specimen slide until the blood is used up.

Visually, the thin film should be rounded, feathered, and progressively thinner toward the middle of the slide.

Label the slide and allow it to air dry.

Thick Blood Film: The thick blood film will afford a diagnosis of lighter infection. The thick film essentially condenses into an area suitable for examination about 20 times more blood than the thin film and therefore is more likely to demonstrate a low parasitemia. RBCs are lysed during the staining, making the preparation so that only parasites, platelets, and WBCs remain visible.

The thick film is recommended for the routine detection of all parasites when the diagnostic stages occur in the blood, and it can be used, in most instances, for identifying to the species level all microfilariae, the African trypanosomes, and all *Plasmodium spp*. except *P. ovale*.

Procedure:

Place a minimum of three clean glass slides on a horizontal surface.

Place a drop (30 to 40mcl) of blood onto the center of the slide about ½ inch from the end.

Using either the corner of another clean glass slide or an applicator stick, spread the blood into a circle about the size of dime or nickel.

The thick smear should be round to oval and approximately 1 inch diameter.

You should barely be able to read newsprint through the wet or dry film.

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Allow thick smears to air dry in a horizontal position. If thick smears are prepared correctly, they should dry in approximately 15-30 minutes.

Dissolve the contents of one pH Buffer Capsule (pH 7.0) into 100 ml of deionized water in a sterile cup. Add buffered water (pH 7.0 to 7.2) in a Copeland jar and place thick film in buffered water for 10 minutes. Then remove it from the water and place it in a vertical position (thick film down) to air dry.

Do not attempt to speed the drying process by applying any type of heat, because heat will fix the RBCs and they will not lyse in the staining process.

Staining

Place all thin and thick prepared smears and one Malaria Stain Control (unstained) on the hematology Slide Stainer to be stained (using the Wright-Giemsa stain).

Follow the normal staining procedure for routine CBC smears.

Do not pre-treat smears with methanol first.

EXAMINATION OF SMEARS

All Smears for Blood parasites require that two CLS perform the screen for Blood parasites.

If Plasmodium organisms are present, the cytoplasm stains pale blue and the nuclear material stains red.
Schuffner's stippling in RBC's infected by malaria species usually does not stain or stains very pale red with Wright's stain.
Nuclear and cytoplasmic colors that are seen in the malarial parasites will also be seen in the trypanosomes and any intracellular leishmaniae that are present.

The sheath of microfilariae may or may not stain with Wright's stain, while the body will usually appear pale to dark blue**.**
Examine thin and thick smears under the microscope, scanning a minimum of 300 oil immersion fields.

Consult morphology atlases in hematology and microbiology (parasitology)

Under HIGH DRY, some morphology may be seen.

Examine a minimum of 300 oil immersion (x1,000) fields before reporting no parasites found.

Examine the entire smear under low power (100X for the presence of microfilariae. Remember the

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sheath may not be visible (*W. bancrofti*).

On thin smears, disregard artifacts outside the RBCs.

Examine Control Slide on 100X OIL and record results in electronic record.

REPORTING RESULTS:

Report Malaria Screen in Cerner General Lab Module

Results for thin and thick smears are entered directly into the Gen Lab Results entry.

Use drops down window to select and document result and enter Slide QC Information and acceptability

Verify your results and place label next to microscope in microbiology for secondary smear evaluation.

VCMC laboratory is CAP accredited as a screening facility for blood parasites.

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Results are reported as Plasmodium sp./Babesia sp. seen, Trypanosomes seen, Microfilaria seen, or no blood parasites seen.
If you cannot rule out Plasmodium falciparum, talk to the physician and share this information. The patient may be redrawn in 5 to 6 hours. Plasmodium falciparum will only have the ring stage after 5 to 6 hours, whereas the other Plasmodium spp. will have other stages present.

Call all positive results according to the Critical Result Policy as soon as possible.

Confirmation should be made by the pathologist on duty.

As per the state requirement, send positive smears to Ventura County Public Health Lab for confirmation.

LIMITATIONS:

One negative result does not rule out infection. If malaria is a possible diagnosis, after the first set of negative smears, it is recommended that additional samples be taken at 6 to 8-hour intervals until diagnosis is made or infection is no longer suspected (usually 3-5 days).

Prepare slides within 60 minutes of collection. If the smears are prepared from anti-coagulated blood that is more than 1 hour old, morphology of the parasites may not be typical, and the film may wash off the slide during the staining procedure.

Excess stain on the film may be confusing and make the detection of the organisms difficult.

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REFERENCES:

Leber, Amy L., Clinical Microbiology Procedures Handbook, 2016, 4nd ed., ASM Press, Washington, D.C., pp 9.8.1 to 9.8.3

All Revision Dates

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Approval Signatures

Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator, VCMC & SPH	3/3/2026
Policy Owner	M. Anwar Molani: Medical Director, Laboratory Services	3/3/2026
Policy Owner	Erlinda Roxas: Director, Laboratory Services	3/3/2026
Policy Owner	Linda Conboy: Supervisor-Microbiology, Laboratory Services	3/2/2026

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Owner	Linda Conboy: Supervisor-Microbiology, Laboratory Services
Policy Area	Laboratory Services - Microbiology

L.MIC 6.2 Assessing Percent Parasitemia of Positive Malarial Smear

COPY

EFFECTIVE DATE: 6/14/2006	REVIEW DATES:10/25/2007, 9/5/2008, 7/6/2009, 9/17/2010, 9/9/2011, 5/19/2013, 12/17/2015, 12/2017, 1/2019, 12/2020, 11/2021, 11/2023, 4/2025, 2/2026
	REVISION DATES:

PRINCIPLE

It is important to report the level of parasitemia when blood films are examined and found to be positive for malaria parasites. Because of the potential for drug resistance in some of the *Plasmodium* species, particularly *Plasmodium falciparum*, it is important that every positive smear be assessed and the parasitemia reported exactly the same way for follow-up specimens as for the initial specimen. This allows the parasitemia to be monitored after therapy has been initiated.

In cases where the patient is hospitalized, monitoring should be performed at 24, 48, and 72 hours after initiating therapy.

Generally parasitemia will drop very quickly within the first 2 hours; however, in cases of drug resistance, the level may not decrease but actually increase over time.

SPECIMEN

Stained thick or thin blood films that have been examined a minimum of 300 oil immersion fields per blood film to determine that the film is positive for malaria parasites.

EQUIPMENT

Microscope, binocular w/ mechanical stage; low-power (10 X), high dry power (40 X), and oil immersion (100 X) objectives; 10 Z oculars; calibrated ocular micrometer, light source equivalent to a 20-W halogen or 100-W tungsten bulb; blue and white ground-glass diffuser filters.

QUALITY CONTROL

Slides stained on Hematology Slide Stainer. Defer to Hematology QC.

PROCEDURE

Thin blood per 100 RBCs counted (0.5%, 1.0%, etc.).

Thick or thin blood film: counting 100 WBCs (or more), report the number of parasites per 100 WBCs on the smear.

This figure can be converted to the number of parasites per microliter of blood; divide the number of parasites per 100 WBCs by 100, and multiply that figure by the number of WBCs per microliter of blood.

Depending on the parasitemia, 200 or more WBCs may have to be counted, so the denominator may vary (it may be 200 or even more).

Using this method, blood for both the peripheral smears and cell counts must be collected at the same time.

REPORTING RESULTS

Using the thin blood film method, report the percentage of parasite-infected RBCs per 100 RBCs counted. This can be entered in the comment section of the Plasmodium result

Example: *Plasmodium falciparum*, parasitemia -= 0.5 %

Using the thick-thin blood film method, report the number of parasites per microliter of blood.

Example: *Plasmodium falciparum*, parasitemia = 10,000 per mcl of blood

PROCEDURAL NOTES

It is critical that the same reporting method be used consistently for every subsequent set of blood films so that the parasitemia can be tracked for decrease or possible increase, indicating resistance.

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Remember, drug resistance may not become evident for several days; the parasitemia may even appear to be dropping before it begins to increase again.

It is very important that any patient with *P. falciparum* infection be monitored; drug resistance has also been reported for *Plasmodium vivax* infection.

It is critical to remember that mixed malarial infections occur, many of which will include *P. falciparum*.

LIMITATIONS OF THE PROCEDURE

A light infection may be missed in a thin film, whereas the increased volume of blood present on a thick film may allow the detection of the infection, even with a low parasitemia.

If the smears are prepared from anticoagulated blood that is more than 1 hour old, the morphology of both parasites and infected RBCs may not be typical.

It is important that good-quality blood films be examined and counted according to directions; poorly prepared and/or stained blood films will lead to incorrect assessments of the parasitemia (both too low and too high).

Follow-up counts are critical in monitoring the patient, and it is critical to understand the types of malaria resistance.

COPY

REFERENCE

Isenberg, Henry D. et al, **Clinical Microbiology Procedures Handbook**, 2nd edition, Volume 2, ASM, Washington, D.C., 2004, pages 9.8.7 to 9.8.7.3.

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Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator, VCMC & SPH	3/3/2026

Policy Owner	M. Anwar Molani: Medical Director, Laboratory Services	3/3/2026
Policy Owner	Erlinda Roxas: Director, Laboratory Services	3/3/2026
Policy Owner	Linda Conboy: Supervisor-Microbiology, Laboratory Services	3/2/2026

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L.MIC 6.3 AFB Culture Handling, Processing, and Transport

COPY

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	REVISION DATES: 1/2017

PRINCIPLE:

Tuberculosis (TB) is a major global public health problem. The disease is the second biggest killer of adults due to an infectious disease after HIV. Early and accurate diagnosis of TB is critical to preventing disease transmission and expediting patient management.

COLLECTION:

It is suggested that three sputum samples be collected at 8–24-hour intervals and should include at least one first morning specimen. First morning sputum should be collected in a sterile, leak-proof plastic sputum collection device.

Bronchial alveolar lavage (BAL) specimens should be sent in sterile leak-proof containers. Specimens that cannot be processed within one hour of the time of collection should be refrigerated during transport and storage.

Urine should be collected in sterile leak proof cups. Twenty-four-hour urine collections are not suitable for culture.

Biopsy specimens should be sent in sterile containers in sterile isotonic saline.

CSF specimens should be sent in screw top collection tubes.

Aspirate should be in a sterile screwcap container; parafilm container for safety.

Body Fluids should be in a sterile screw cap container; parafilm container for safety

Gastric lavage specimens should be sent in a sterile leak proof container.
Swab specimens are not recommended for specimen collection because mycobacteria will adhere to the fibers.
Stool should be in a sterile leak-proof container. The amount needed is 2gm.

UNACCEPTABLE SPECIMENS:

Specimen Type	Unacceptable Specimens
Abscess contents, aspirated fluid	Dry Swab
Blood & Bone Marrow	Blood collected in EDTA, which greatly inhibits mycobacterial growth even in trace amounts. Coagulated blood. Specimen submitted in formalin.
Gastric Lavage	Specimen that has not been neutralized in calcium bicarbonate.
Lymph node	Specimen submitted in formalin
Skin lesion material	Dry swab
Sputum	24-hour pooled specimens; saliva
Stool	Frozen specimen
Tissue Biopsy	Submitted in formalin
Urine	24-hour pooled specimens; urine from catheter bag; specimens of <40ml unless larger volume is not obtainable
Wound material	Dry swab

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TRANSPORT

Specimens should be transported to the laboratory as soon as possible. If transportation is delayed by more than one hour, except for CSF and tissue specimens, should be refrigerated at 2-8 °Celsius.

If gastric lavage specimens cannot be processed within 4h of collection, add 100 mg of sodium carbonate to the container and mix. This will neutralize the acidity of the specimen.

Blood specimens should be collected in a blood culture bottle found in the microbiology department and submitted to reference laboratory.

TRANSFER TO VENTURA COUNTY PUBLIC HEALTH LAB

Specimens are picked up and transported to Ventura County Public Health Lab by courier daily.

All specimens received before 7am are to be packaged for the 7am courier for same day processing on Monday, Tuesday, Thursday, and Friday. AFB smears are available within 24 hours of collection.

Orders are entered in LIS *C AFB (Acid Fast Bacilli Culture)*
Specimen must be labeled with following:
- Patient's name (last, first)
- Chart number
- Date & time of collection
- Source of specimen

Use Cerner procedure to Transfer Specimen to Public Health Lab
- Transfer Specimens App
- Click New
- Click Manual Build
- Location from: VCMC Tracking L Location to: PHL Ventura Tra
- Scan accession number. Press Save
- Select Transfer. Batch Status Report will print to default printer
- Place specimen in plastic biohazard specimen bag, making sure that the container lid is secure to avoid leakage. (VCPH Lab will not accept leaking specimens). Parafilm may be used for additional protection.
- Place SHARED SPECIMEN sticker on specimen if specimen is to be used at VCPH for AFB and FUNGUS cultures. Place labels and one copy of Sent Batch Status Report in the front pocket of the bag.
- Place a copy of Batch Status Report in binder labeled **Microbiology Send outs Public Health**.
- Place specimen in the send out refrigerator in the designated box for VCPH specimens at the Main Lab.

COPY

REFERENCES

Leber, Amy L, Clinical Microbiology Procedures Handbook, 4th edition, 2017

All Revision Dates

3/3/2026

Attachments

Micro 6.3 REF MYCOBACTERIOLOGY SPECIMEN SET UP GUIDE.XLS

Approval Signatures

Step Description	Approver	Date

Hospital Administration	Jason Arimura: Associate Hospital Administrator, VCMC & SPH	3/3/2026
Policy Owner	M. Anwar Molani: Medical Director, Laboratory Services	3/3/2026
Policy Owner	Erlinda Roxas: Director, Laboratory Services	3/3/2026
Policy Owner	Linda Conboy: Supervisor-Microbiology, Laboratory Services	3/2/2026

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Status **Active** PolicyStat ID **20035826**

Origination	3/3/2026
Last Approved	3/3/2026
Effective	3/3/2026
Last Revised	3/3/2026
Next Review	3/2/2028
Owner	Linda Conboy: Supervisor-Microbiology, Laboratory Services
Policy Area	Laboratory Services - Microbiology

L.MIC 6.4 Fungal Culture Handling, Processing and Transport

COPY

EFFECTIVE DATE: 7/14/2009	REVIEW DATES: 11/2010, 11/2011, 12/2015, 12/2015, 1/2017, 12/2017, 1/2019, 12/2020, 11/2021, 11/2023, 4/2025, 2/2026
	REVISION DATES: 7/2015,12/2015

PRINCIPLE:

Suitable specimen selection, proper specimen collection, and rapid specimen transport must be performed to ensure the successful isolation of the etiologic agent of fungal infection.
It is essential for the laboratory to have guidelines regarding minimum specimen volumes, and appropriate specimen transport.

COLLECTION AND TRANSPORT:

Refer to Fungal Specimen Collection and Transport Chart for guidelines established by the Ventura County Public Health Department.

Additional Notes

Almost all specimens for fungal cultures should be held and transported at room temperature. The only exceptions to this are urines and respiratory specimens.

If a specimen needs to be share for both fungal and AFB cultures, then they should be kept refrigerated.

TRANSFER TO VENTURA COUNTY PUBLIC HEALTH LAB

Specimens are picked up and transported to Ventura County Public Health Lab by courier daily. Orders are entered in LIS *C FUNGUS*

Specimen must be labeled with following:

- Patient's name (last, first)
- Chart number
- Date & time of collection
- Source of specimen

Use Cerner procedure to Transfer Specimen to Public Health Lab

- Transfer Specimens App
- Click New
- Click Manual Build
- Location from: VCMC Tracking L Location to: PHL Ventura Tra
- Scan accession number. Press Save
- Select Transfer. Batch Status Report will print to default printer
- Place specimen in plastic biohazard specimen bag, making sure that the container lid is secure to avoid leakage. (VCPH Lab will not accept leaking specimens). Parafilm may be used for additional protection.
- Place SHARED SPECIMEN sticker on specimen if specimen is to be used at VCPH for fungus and AFB cultures. Place labels and one copy of Sent Batch Status Report in the front pocket of the bag.
- Place a copy of Batch Status Report in binder labeled **Microbiology Sendouts Public Health**.
- Place specimen in the sendout refrigerator in the designated box for VCPH specimens at the Main Lab.

COPY

REFERENCES:

Leber, Amy L, Clinical Microbiology Procedures Handbook, 4th edition, 2017

Hannah, Carol, **Fungal Specimen Collection and Transport Chart**, Ventura County Public Health Department, August 2016

All Revision Dates

3/3/2026

Attachments

Micro 6.4 REF Mycology Set up Guide.xls

Micro 6.4 REF Mycology VCPH requirements.xlsx

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Approval Signatures

Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator, VCMC & SPH	3/3/2026
Policy Owner	M. Anwar Molani: Medical Director, Laboratory Services	3/3/2026
Policy Owner	Erlinda Roxas: Director, Laboratory Services	3/3/2026
Policy Owner	Linda Conboy: Supervisor-Microbiology, Laboratory Services	3/2/2026

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Policy Area	Laboratory Services - Microbiology

L.MIC 7.03 Unloading & Preliminary Work Up of BacT/Alert Positive Bottles

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The BACT/ALERT VIRTUO instrument provides automated loading and unloading of Culture Bottles.
The following specimen types can be used in the system:
Blood
Sterile body fluids
The disposable Culture Bottles contain a liquid emulsion sensor that is monitored continuously using solid state photo detectors. The bottles contain media and atmosphere that promote the recovery of a wide variety of microorganisms.
The system supervises the reading of the Culture Bottles and contains decision-making algorithms to determine which samples are positive or negative. If no microbial growth is present after a specified maximum test time, the sample is determined to be negative and unloads to the waste container. Positive bottles automatically unload to the bottle retrieval area.

UNLOADING OF POSITIVE BACT/ALERT BOTTLES

Unloading Positive Bottles Automatically
Positive Bottles indicates the result is positive. All identified positive bottles are automatically removed from the cells and transfer to the bottle retrieval area to stop incubation
Fully remove bottles from return chute
After the positive bottles are removed from the bottle retrieval area, the positive bottle counts update, and the unload events record in the audit log
The bottle status changes to Unloaded after the bottle is removed from the bottle retrieval area

WORK UP OF THE BACT/ALERT POSITIVE BOTTLES

LABELS AND WORKCARD
Print a set of media labels for each bottle to be worked up.
Print a BC worksheet for each accession number being worked up. This is recommended for the off shifts to facilitate morning review the following day.
Once the bottle is out of the instrument, prepare to perform the work-up in the Biological Safety Cabinet. **NOTE:** All work up must be performed in the Biological Safety Cabinet, Gloves and protective clothing must also be worn.

MEDIA SELECTION AND INOCULATION

Positive Aerobic Bottle
Media to be used: BAP, CHOC, MAC
Place the large media label on the BAP and the smaller label on each remaining plate. Indicate "aerobic" (AER) or "anaerobic" (ANA) and write the date of subculture on the pre-printed labels.
Wipe rubber septum top with 70% alcohol pad prior to obtaining blood sample.
Introduce venting needle into the blood culture bottle.
Place a drop of the blood culture onto each of the above media and streak each for isolation using a sterile inoculating loop or needle. Refer to Micro 4.2 *Streak Plate Methods*
Incubate aerobic plates at 5% CO_2

Positive Anaerobic Bottle
Media to be used: BAP, CHOC, MAC, and BRU. BAP, CHOC, MAC may be inoculated and incubated as for positive aerobic bottle above.
Place the large media label on the BRU.
Indicate "anaerobic" (ANA) and write the date of subculture on the pre-printed labels.
Wipe rubber septum top with 70% alcohol pad prior to obtaining blood sample.
Introduce venting needle into the blood culture bottle.
Place a drop of the blood culture onto the above media and streak each for isolation using a sterile inoculating loop or needle. Refer to Micro 4.2 *Streak Plate Methods*
Incubate anaerobic plates under anaerobic conditions

SMEAR PREPARATION

Label a clean glass slide with the accession number, patient's last name, indicate whether the bottle was aerobic or anaerobic, and the date.
Place a drop of the well-mixed blood from the bottle onto the glass slide (without touching the slide). Spread the inoculum on the glass slide with a sterile applicator stick or the inoculating loop thinly to allow drying and reading when gram stained. A 22-mm square area just above the frosted end of the slide is preferred.
Dispose of the airway unit in a Sharps container.

Handling Unconfirmed Positive Bottles

If a Gram stain of a positive bottle reveals no microorganisms, make a wet mount of the blood

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culture to rule out organisms that do not stain with Gram Stain or to observe motility that would suggest the presence of an organism.
Subculture the bottle **and reload it within two hours** to continue testing in the instrument.
Place the bottles upright on the conveyor belt. The convey will begin moving and will feed the bottle into the bottle indexer.
When a bottle previously called positive is reloaded, a message states that the bottle result may reset to negative to date and may be flagged as unconfirmed positive. Select an option:

- **OK** to continue.
- **Cancel** to cancel the action. The bottle result remains positive

If growth appears on the subculture, access the **Edit Bottle Record** screen, and change the bottle test result to **Positive.**
NOTE: If a reloaded positive bottle signals positive a second time that bottle cannot be reloaded

INPUT RESULTS OF GRAM STAIN IN WORKCARD

No Previous Positive Results
Document results in LIS under Order Results Entry
Under the Entry Field, enter your observations by entering <obs>
Select < Add >
An Add Sub Media window will open. Under the Media field, enter < slide >
Press < OK
Add gram stain observation under the description of the slide. If it is mixed, you can document multiple morphologies on the same line.
Press <OK>

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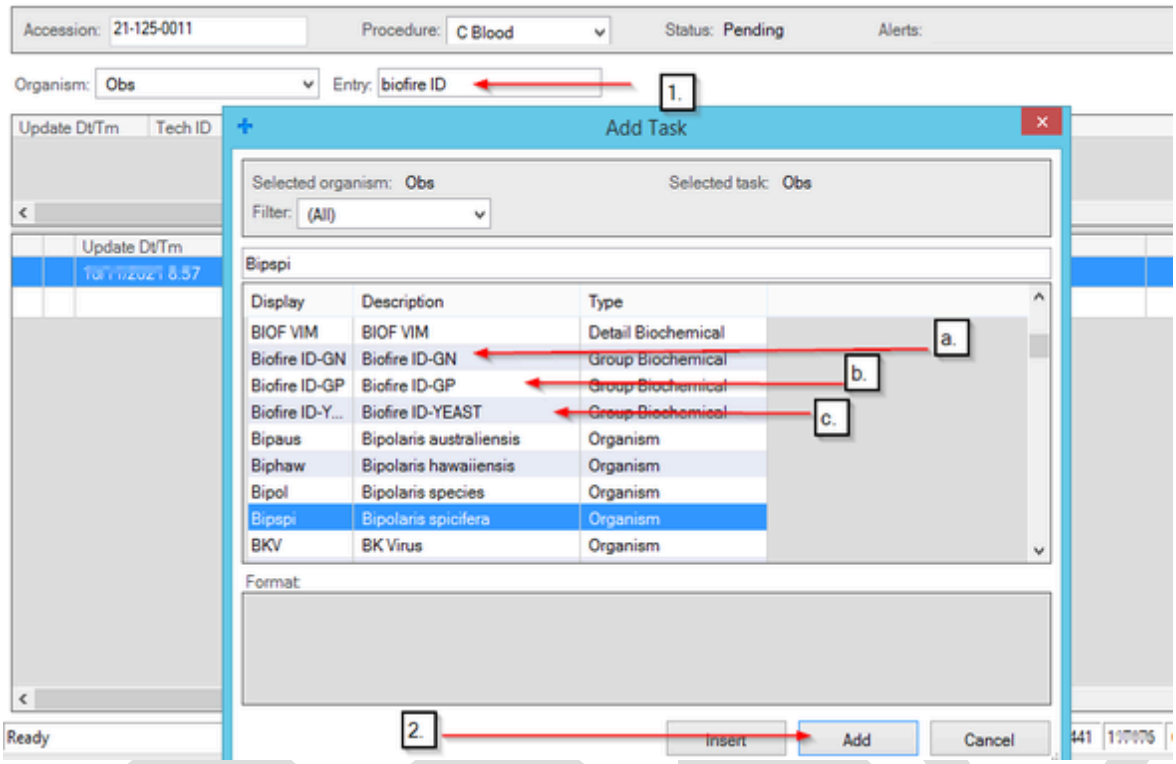
DIRECT IDENTIFICATION FROM THE BLOOD CULTURE BOTTLE BY PCR
This is performed using the BioFire. Refer to Micro 2.4 *BioFire Blood Culture Identification 2 (BCID2) Panel* for instructions for use.
Note: The blood culture bottle must be subcultured to solid media to allow for confirmation with the oganism identification from the analyzer.
Order Direct Identification
Enter <Biofire ID> in enty field. Select one of three options depending on the gram stain observation.
Biofire ID-GN for gram negative observation
Biofire ID-GP for gram positive observation
Biofire ID-Yeast for yeast observation
Press < Add >



.

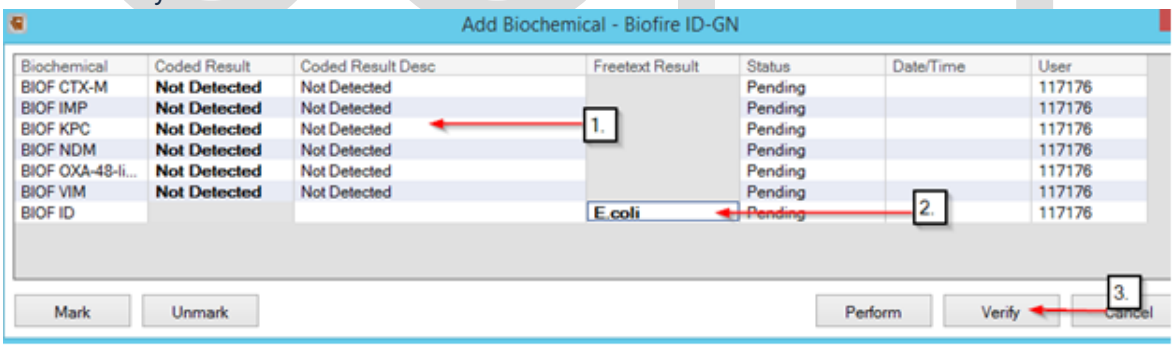
Enter Results of Blood Culture Identification

Double click on the line that has the Biofire ID order. This will open a result window.

Enter the Resistance Genes into the work card as listed on BioFire Report.

Enter the organism identification from the BioFire Report.

Enter < Verify >



Note: The BCID 2 panel identifies of the most common organisms isolated from blood cultures. Report the gram stain when the BCID2 does not provide a result.

REPORTING PRELIMINARY BLOOD CULTURE RESULTS

Preliminary result with Blood Culture Identification Result (from BioFire)

Once an identification has been determined, a preliminary report must be submitted, and the organism identification and applicable resistant genes must be called.

Enter <pre> under the entry field. Press <enter> on your keyboard.

If there is an existing negative Preliminary Result, line feed the NGX result prior to entering the positive result.

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In the first cell enter the organism's name using REF Micro 2.3 *Abbreviations for computer entry.*
In the adjacent cell, enter <Det>.
In the row below, enter resistant gene using REF Micro 2.3 *Abbreviations for computer entry.*
The resistant gene if present must be reported on the report and during the critical call. It helps to guide appropriate therapy.
In the row below, enter <IDC> to document critical call result.
Tap on the adjacent cell to activate it and then press <Free Text>. This will open another window where you can free text your call to a physician or licensed care giver taking care of the patient. Proper documentation includes caregiver's first and last name, classification, location, and date and time.
Press OK
In the cell below, add <CRP>
Confirm the entries on the preliminary report by reviewing the Chart View on the bottom left of the window.
If acceptable, press <Verify> to complete the report process.

Preliminary result with Gram stain Result only

In cases when the organism identification yields no identification, the direct observation of the gram stain must be documented and called to the physician/licensed care giver in charge of the patient.
Enter <pre> under the entry field. Press <enter> on your keyboard.
If there is an existing negative Preliminary Result, line feed the NGTD result prior to entering the positive result.
In the first cell, enter the gram stain morphology GPC, GNR, GPR, GNDC, or Yeast.
In the adjacent cell, if applicable, enter <GPC1> if suggestive of Staphylococcus or <GPC2> if suggestive of Streptococcus sp.
In the next row below, enter <IRC> to document critical call result.
Tap on the adjacent cell to activate it and then press <Free Text>. This will open another window where you can free text your call to a physician or licensed care giver taking care of the patient. Proper documentation includes caregiver's first and last name, classification, location, and date and time.
Press OK.
In the cell below, add <CIP>
NOTE: If there is a change of shift before the Blood Culture Identification has completed, gram stain result must be entered and called before endorsing the blood culture to the following shift**.**

Previous positive

Check in L.I.S. to see if the patient has had other positive blood culture within the last 24 hours.
If the bottle being worked up has the same accession number as one previously worked up, document your results on the work card as stated in Input Gram stain Results in Work card. Gram stain results do not need to be called if the results are consistent with those previously called. **If the results are different, results will need to be called as usual protocol.**
If the bottle being worked has a **different** accession number from one previously worked up, submit a preliminary report with gram stain result only.
A BioFire Identification is performed once per patient per admission unless the gram stain observation is different from previous set(s). The results will need to be called because the

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significance of having more than one draw being positive may demonstrate clinical relevance.

FOLLOW-UP WORKUP OF POSITIVE BLOOD CULTURE MEDIA

Examine all inoculated media after 18 to 24 hours of incubation.
Media and incubation requirements:

BAP, CHOC, MAC: 35°C in 5% CO2
Gram-negative rods growing on MAC
Note: The presence of these isolates in blood cultures is most associated with septic shock.
Process and report as quickly as possible
Perform spot indole and oxidase.
Place on MS Prime for Identification and perform AST.
Haemophilus or other fastidious Gram-negative rods that do not grow on MAC
Do beta-lactamase test
Do catalase, oxidase, and rapid urea if organism is growing on both BAP and CHOC. Rule out Brucella.
Place on MS Prime for Identification and perform AST if indicated.
Staphylococci
Perform catalase test. Should be positive. Perform Staph latex. If positive, Perform PBP2a as indicated
Confirm that it is not sticky or bright yellow. If lemon-yellow and coagulase negative,, call it a *Micrococcus* sp. If it is sticky, rule out possible *Rothia mucilaginosa* (Stomatococcus mucilaginosus).
Place on MS Prime for Identification
Perform AST if Staphylococcus aureus or coagulase negative Staphylococcus isolated from multiple sets.
Note: Isolation of *S.lugdanensis* is more often associated with endocarditis and poor outcome than isolation of other coagulase-negative staphylococci; thus it should be differentiated from other species.
If Staphylococcus aureus and oxacillin resistant, identify as methicillin resistant Staphyloccocus aureus (MRSA).
If Staphylococcus aureus and oxacillin susceptible, identify as methicillin susceptible Staphylococcus aureus (MSSA).
Streptococci and other catalase-negative cocci.
Place on MS Prime for identification
Streptococcus pneumoniae. Set up AST and D test
Enterococci. Place on MS Prime for identification. Perform AST
Viridans Streptococcus. Perform AST by physician request.
Gram positive rods
Do catalase test.
Catalase positive.
Small rods with small zone of hemolysis and bile esculin positive, Check CAMP test. *Listeria monocytogenes* is positive.
Large rods. Check for spores and motility.

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Note: *Bacillus cereus* is hemolytic and motile; Bacillus anthracis is nonhemolytic and nonmotile.
If present in only one culture of several collected, limit workup of diphtheroid unless the physician indicates that the isolate may be significant.
Note: *Coynebacterium jeikeium* is associated with catheter-related sepsis.
Potential anaerobic microorganisms
Sub to Brucella agar and incubate anaerobically for 6 days.
Yeasts
Sub to SabDex. Place on MS Prime for Identification.
If there is no growth on initial subculture:
Hold the aerobic plates for 4 days before discarding.
Hold anaerobic plate(s) for 6 days
Subculture to BAP and incubate micro aerobically at 42C when gram stain is suggestive of Campylobacters.
If no organisms were seen on gram stain, hold plated media for 2 days before reporting as negative.
Hold positive culture isolates for 7 days for further studies.

REPORTING BLOOD CULTURE MEDIA RESULTS

Negative bottles are reported automatically from instrument to Cerner at 12 hours, 1d, 2d, 3d, 4d, and Final at 5 days.
Positive cultures
Immediately report Gram stain results of all positive cultures, or additional organisms found in previously positive cultures, to the physician or licensed caregiver, with as much interpretive information as possible, such as Gram -positive cocci in clusters or pleiomorphic Gram-negative bacilli, to help physicians make better empiric antimicrobial choices.
Follow immediately with a written or computer-generated report including the following.
Number of positive cultures compared with total number of specimens collected for a specific patient.
Note: There is no justification for telling the physician that one or both bottles in the set are positive, because the number of positive bottles in a set does not reliably differentiate contamination from true infection.
Date and time of collection
Date and time positive result is reported.
Name and location of person taking report. Readback confirmation
For single positive cultures with microorganisms generally considered skin contaminants (coagulase-negative staphylococci, viridans group streptococci, corynebacteria, and Propionibacterium, perform only minimal identification and do not perform AST.
For subsequent positive cultures, it is not necessary to repeat biochemical testing if the microorganism has the same Gram and colony morphology as the first isolate. Perform a few spot tests (catalase, coagulase, indole, PYR, etc.) to verify that it is the same species. Report as "Probable [genus and species]; refer to previous culture."

INTERPRETATION OF BLOOD CULTURE RESULTS

Probable Contaminants

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Growth of Bacillus spp., Corynebacterium spp., Propionibacterium acnes, or coagulase negative staphylococcus in only one of several cultures/draws. (Mixed skin flora suggests contamination)
Growth of multiple organisms from only one of several cultures (polymicrobial bacteremia is uncommon).
The clinical presentation and/or course is not consistent with sepsis (physician-based, not laboratory-based criteria).
The organism causing the infection at a primary site of infection is not the same as that isolated from the blood culture.
Probable Pathogen
Growth of the same organism in repeated cultures obtained either at different times or from different anatomic sites.
Growth of certain organisms in cultures obtained from patients suspected of endocarditis, such as enterococci, or gram-negative bacilli in patients with clinical gram negative sepsis.
Growth of certain organisms such as members of Enterobacteriaceae, **Streptococcus pneumoniae,** gram negative anaerobes, and **Streptococcus pyogenes.**

BACTERIA COMMONLY ISOLATED FROM BLOOD CULTURES

Coagulase negative staphylococci
Staphylococcus aureus
Enterococcus spp.
Viridans streptococci
Beta-hemolytic streptococci
Streptococcus pneumoniae
Escherichia spp.
Klebsiella spp.
Pseudomonas spp.
Enterobacter spp.
Proteus spp.
Anaerobic: Bacteroides & Clostridium spp.

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FUNGUS COMMONLY ISOLATED FROM BLOOD CULTURES

Candida albicans
Candida tropicalis
Candida glabrata
Candida parapsilosis
Histoplasma capsulatum
Cryptococcus neoformans
Candida lusitaniae
Candida krusei

TYPES OF INFECTIONS

INTRAVASCULAR: include infective endocarditis, mycotic aneurysm, suppurative thrombophlebitis, and IV, catheter-associated bacteremia. Organisms are in bloodstream at a fairly constant rate.
Agents of Infective Endocarditis

Viridans streptococci
Nutritionally deficient streptococci
Enterococci*
Streptococcus bovis
Staphylococcus aureus*
Coagulase negative staphylococci
Enterobacteriaceae
Pseudomonas sp. (drug abusers)
Haemophilis sp., (H. aphrophilus)
Unusual gram negative bacilli (Actinobacillus, Cardiobacterium, Eikenella)
Yeast
*Most common in native valve endocarditis in non-drug-abusing adults
Common Agents of IV-Catheter-Associated Bacteremia
Staphylococcus epidermidis
Other coagulase negative staphylococci
Staphylococcus aureus
Enterobacteriaceae
Pseudomonas aeruginosa
Candida spp.
Corynebacterium spp.
Other gram-negative bacilli
EXTRAVASCULAR
Most common portals of entry:
Genitourinary tract
Respiratory tract
Abscesses
Surgical wounds
Biliary tract

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ORGANISMS COMMONLY ASSOCIATED WITH BLOODSTREAM INVASION FROM EXTRAVASCULAR SITES OF INFECTION

Haemophilus influenzae, type b Meninges, epiglottitis, periorbital region
Streptococcus pneumoniae Meninges, sometimes lung
Neisseria meningitidis Meninges
Brucella spp. Reticuloendothelial system
Salmonella typhi Small intestine, regional lymph nodes of the
intestines, reticuloendothelial system
Listeria Meninges

IMMUNOCOMPROMISED PATIENTS

Organ transplantees, elderly, malignant disease, those undergoing chemotherapy
Gram postive aerobic bacteria: Staphylococcus aureus, Enterococcus spp.
Gram negative aerobic bacteria: Enterobacteriaceae, Pseudomonas aeruginosa
AIDS

Mycobacteria spp.
Bartonella henselae
Corynebacterium jeikeium
Shigella flexneri
Unusual Salmonella spp.
Histoplasma capsulatum
Cryptococcus neoformans

LIMITATIONS OF THE BACT/ALERT VIRTUO

Patient specimens determined positive by BacT/Alert Virtuo may contain organisms that are positive by smear that will not grow on routine subculturing media. These specimens should be subcultured on special media when such organisms are suspected. Also, positive specimens may contain organisms that are not seen with routine smear methods and may require both specialized smears and/or specialized media for detection and recovery.
It is possible that certain rare, fastidious microorganisms will not grow in the aerobic or anaerobic culture bottle growth medium. If rare, fastidious organisms requiring specialized media and conditions are suspected, then alternative methods for recovery should be considered.
On rare occasions organisms may be encountered that grow in the aerobic or anaerobic culture bottle growth media but do not produce sufficient carbon dioxide to be determined positive. The presence of antibiotics in samples or oxygen starvation in anaerobic culture are examples that may result in this situation.
Certain strains of *H. influenzae, N. meningitidis, N. gonorrhoeae,* and *P. anaerobius* may be sensitive to the anticoagulant (SPS) which may result in lack of growth or low production of CO2 by these strains if an insufficient amount of blood sample is inoculated into the culture bottles,
Aerobic and Anaerobic BacT/Alert culture bottles used to culture non-blood specimens (normally sterile body fluids) may require added blood or other supplements to support growth, particularly for recovery of fastidious organisms such as *Haemophilus influenzae* and *Neisseria gonorrhoeae.*
Infrequently, false positives may occur due to a very high number of white blood cells being present in the blood sample. This will result in smear and subculture negative samples.
Organisms are often few and may appear intermittently in the bloodstream, several consecutive blood samples should be collected from each patient.
Prompt removal of positives as they are signaled by BacT/Alert Virtuo is strongly recommended to avoid possible non-viable cultures due to autolysis or other reasons. Certain strains of *Streptococcus pneumoniae* may be particularly prone to autolysis if they are not removed promptly after being signaled positive.

TROUBLESHOOTING

Refer to the **BacT/Alert Virtuo Training Manual**, accessible on the main screen of the instrument.
Refer to Resolving Alarms and Alerts; Section 8.1 Troubleshooting
Refer to Reboot the Instrument; Section 9.1 Performing System Maintenance
Only a BioMerieux representative can shut down the instrument. Users can reboot using the small display on the instrument.
If the system becomes inoperable, Refer to Micro 7.04 *Blood Cultures Conventional Handling.*

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QUALITY CONTROL

Certificates of Conformance are electronic certifying that samples were tested by standard procedures including the methods and control cultures specified in the CLSI approved standard. No additional QC is required. One certificate is printed per lot #/shipment and place in the Blood culture certificate Binder. Place date of receipt on the certificate.
Regulatory agencies (e.g., CAP) do not require routine QC checks by the user of commercially purchased blood culture bottles.
Contamination
Determine if a culture has been collected from an intravascular catheter and whether a peripheral collection accompanied the line collection for adults. Educate clinicians on the need to collect both, to properly evaluate the culture results.
Monitor positive blood culture results regularly for skin contaminations.
For purposes of determination of contamination rate, consider only skin contaminants from venipuncture as significant. These consist of the following:
Coagulase-negative staphylococci (excluding pediatric and line collections)
Bacillus species
Corynebacterium species (diphtheroids)
Propionibacterium species
Exclude positive cultures as skin contaminants if more than one blood culture from the same patient is positive is positive for any of the microorganisms listed above, provided that for coagulase-negative staphylococci the antibiograms are consistent with the isolates being the same strain.
Include as skin contaminants all positive cultures, even if both bottles are positive if only one culture was collected.
Calculate the contamination rate by dividing the number of cultures containing skin contaminants by the total number of cultures collected by venipuncture.
Additional training of staff involved with blood collection and processing if the contamination rate exceeds the expected rate for the institution. The rate should generally not exceed 3%, although many institutions have a goal to decrease the rate below 1% for cultures collected by venipuncture. When rates are high separate calculations can be done for each phlebotomist and for each collection location.
Validate true-positive blood culture rates.
Calculate the true-positive culture rate by dividing the number of cultures positive by the total number of blood cultures received.
The rate should be in the 6 to 12% range. If it is too low, too many cultures might have been drawn; if it is too high, not enough cultures may have been collected.
Perform statistical analysis periodically to determine if the length of incubation is sufficient or can be decreased without loss of clinically meaningful information.
Tabulate the number of cultures positive on days 4 through 7.
Delete those positives that are considered skin contaminants, as defined above.
Delete those positives that are positive in another culture collected within 24 hours before or after the delayed positive culture.
For the remaining positive cultures, determine from chart review if they were considered

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contributing to true bacteremia.
Review completed results with the infectious disease service to determine a reasonable incubation period for cost-effective detection of bacteremia.
Use statistics to determine if bottles in use are appropriate for detection of local pathogens.
Monitor compliance with volume and number of bottles submitted and number of cultures collected from catheter lines without an accompanying peripheral culture.

REFERENCES

Forbes, Betty A. et al, **Bailey & Scott's Diagnostic Microbiology**, 12th edition, C.V. Mosby, St. Louis, 2007, page785.

Leber, Amy L et al. **Clinical Microbiology Procedures Handbook,** 4th ed., 2016, pp 3.4.1-3.4.21

Clinical and Laboratory Standards Institute, M47-A, Vol. 27, No.17, 2007

Miller, Michael J, **Specimen Management in Clinical Microbiology**,, 2nd*ed., ASM, 1999, pp.*53-56, 144.

VCMC Administrative Policy, Procedure: Critical Test Results, Policy No. 100.030, 2019.

COPY

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Approval Signatures

Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator, VCMC & SPH	3/2/2026
Policy Owner	Linda Conboy: Supervisor-Microbiology, Laboratory Services	3/1/2026
Policy Owner	M. Anwar Molani: Medical Director, Laboratory Services	2/24/2026
Policy Owner	Erlinda Roxas: Director, Laboratory Services	2/24/2026

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Next Review	3/1/2028
Owner	Linda Conboy: Supervisor-Microbiology, Laboratory Services
Policy Area	Laboratory Services - Microbiology

L.MIC 7.04 Blood Cultures-Conventional Handling

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PRINCIPLE:

This procedure is intended for the handling of blood cultures not drawn in Bact/Alert blood culture bottles or Bact/Alert bottles with a delay in load time of more than 24 hours. It is important to maintain incubation conditions to allow recovery of microorganisms and maintain rotation or agitation of the media if at all possible, for a minimum of five days. At least one blind subculture must be performed on visually negative bottles.

SPECIMENS

- Blood: venous, catheter, arterial
- Bone marrow should be reserved for culture for specific pathogens such as Brucella, Salmonella, Listeria, fungi, and mycobacteria; it adds little to the detection of most other bacteria. Because of the complex nature of the collection procedure, it is more likely to result in a contaminated bacterial culture than a diagnostic one.

SPECIMEN COLLECTION & TRANSPORT

Refer to Blood Culture Collection procedure, Micro 7.01 for collection and transport guidelines.

MANUAL PROCESSING IN LABORATORY

1. The target fill-to line on the bottle label can be used to assist in estimating a sample volume of approximately 10mL. Alternatively, the 5 mL graduations on the bottle label can be used to assist in estimating the sample volume. Low blood volumes (<10 mL) will be documented in LIS and a comment added to report that reads, **Results may be questionable due to suboptimal volume. Optimal volume is 10 mL per bottle.**

2. Incubate in regular incubator at 35°C for 5 days.
3. Mix by gentle inversion daily to enhance growth for some organisms such as *Pseudomonas aeruginosa*. Examine the cultures at least twice daily for the first two days for hemolysis, turbidity, gas production, pellicle formation, "puffballs," and clotting, which are indicative of microbial growth. Then at least daily for the remainder of the 5 days.
4. Macroscopically negative aerobic cultures are stained and/or sub cultured onto a chocolate agar plate after first 12 hours of incubation and then again at 72 hours to detect most pathogens missed by visual inspection.
5. Subculture anaerobic bottle onto a chocolate agar plate and a reduced brucella agar plate after first 12 hours of incubation and then again at 72 hours to detect most pathogens missed by visual inspection.
6. Hold the subcultures for 2 days before reporting as negative.

REPORTING NEGATIVE BLOOD CULTURE RESULTS

1. PRELIMINARY: Report at day two as: No growth to date. Culture held for 5 days.
2. FINAL: Report at day five as: No growth at 5 days.

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HANDLING OF POSITIVE BLOOD CULTURES

1. Refer to *Micro 7.03 Unloading & Preliminary work up of BacT/Alert Positive Bottles*.

REFERENCE

BacT/Alert® FA Plus Package Insert, Ref 410851, 9303398 F, April 2017

Forbes, Betty A., PhD et al, **Bailey & Scott's Diagnostic Microbiology,** 10th edition, Mosby, St. Louis, 1998, page 295.

Leber, Amy L. et al., Clinical Microbiology Procedures Handbook, 4th edition, 2016 American Society of Microbiology (ASM), Section 3.4

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11/21/2016, 12/16/2017, 12/4/2019, 11/2/2020, 11/2020,9/2022, 11/2023, 4/20
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L.MIC 7.05 Blood Culture for Malasezzia furfur

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PRINCIPLE:
Malassezia furfur is the etiologic agent for pityriasis (tinea versicolor), a superficial infection characterized by pale or dark patches of skin. Catheter related sepsis due to this organism is commonly seen in neonates and adults receiving prolonged intravenous lipids. ***M. Furfur*** is part of the normal skin flora in over 90% of adults.

SPECIMEN COLLECTION:
Collect 0.5 ml (infant) to a few ml (adult) of blood from the potentially infected catheter port. The specimen may be placed in a green (heparinized) tube for transport. The Isolator (Wampole Laboratories) can also be used.

REAGENTS:
Blood Agar Plate and/or noninhibitor fungal medium (SAB DEX)
Olive Oil

PROCEDURE:

1. Collect 0.5ml (infant) to a few ml (adult) of blood from the potentially infected catheter port. The specimen may be transported to the laboratory in a heparinized tube.
2. Inoculate the media and streak for isolated colonies.
3. Add a drop of pure virgin olive oil (sterilization not necessary) the size of a dime onto the agar surface to provide essential nutrients.
4. Incubate at 30-37 C for seven days. ***M. Furfur*** grows poorly at 25 C.

RESULTS:

Growth of smooth, cream to yellowish brown colonies. Yeast-like cells (1.5-4.5um X2.0-6.5 um) are actually phialides with small collarettes. The cells of this genus are unique in being round at one end and bluntly cut off at the other. Hyphal elements are usually absent, but sparse rudimentary forms may occasionally develop.

LIMITATIONS:

M.furfur can have its lipid requirement supplied by oleic acid or Tween 80**. Malassezia sympodialis** cannot. This serves to distinguish **Malassezia furfur** from the seldom encountered **M. sympodialis**.

REFERENCES:

Garcia, Lynn, ed., Clinical Microbiology Procedures Handbook, 2nd ed, update, 2007, ASM, Washington D.C. p.3.4.1.17.

Larone, Davise, Medically Important Fungi, 4th ed., 2002, ASM, Washington D.C., p.136.

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L.MIC 7.06 Blood Culture Contamination Rate Quality Assurance

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PRINCIPLE:

According to the standards published by the American Society of Microbiology, the rate of blood culture contamination should not exceed 3%. Bates et al reported in 1991 that the average inpatient with a contaminated blood culture accumulated $4385 in excess charges and stayed in the hospital 4.5 additional days, compared to an otherwise similar patient without a contaminated blood culture. Thus, an institution that processes blood cultures from 10 new patients per day will free up 82 bed days and reduce expense by $100,500 during the course of a year if the local blood culture rate could be reduced by 0.5%.
Costs related to false positive blood cultures are associated with increased charges for IV antibiotics and microbiology testing.

PROCEDURE:

1. The phlebotomist will follow the directions of the procedure for sterile phlebotomy according to their training.
2. Special consideration will be given to letting the disinfectant dry. The disinfectant must be allowed to dry for 30-60 seconds before phlebotomy is performed.
3. Make sure the initials are clearly written on the Bacti Alert bottles. When you receive a blood culture, make sure that the correct person is listed under "Collected by..."
4. The Blood Culture Contamination Rate will be checked at least monthly (or when requested by Lab Management) by using the Explorer Option of the Cerner Path Net: Microbiology L.I.S.
5. The Microbiology Lab will notify each phlebotomist whenever the individual's

contamination rate is above 3.0%.

6. The phlebotomist will be required to watch the training DVD, be instructed in correct technique by the assigned phlebotomy trainer and be observed performing the technique correctly by the phlebotomy trainer. The phlebotomy trainer will fill out the Blood Culture Phlebotomy Documentation of the Training Log.

CALCULATIONS:

1. The Blood Culture Contamination Rate will be checked at least monthly (or when requested by Lab Management) by using the Explorer Option of the Cerner Path Net: Microbiology L.I.S.
2. There will be a separate Blood Culture Contamination Rate report run for Ventura County Medical Center and Santa Paula Hospital.
3. The report will list the phlebotomist, the total blood cultures drawn in the designated time period, the contaminated draws (determined by the search for the phrase in the laboratory report of "Blood Culture Contaminated"), and the percentage of contamination.
4. The report will list each accession number of the contaminated blood culture, the unit where the blood culture was collected, the date of collection and the MRN of the patient.
5. The total laboratory blood culture contamination rate is determined by adding the total number of contaminants drawn by the laboratory staff and dividing by the total number of blood cultures drawn by all members of the laboratory staff. There is a roster that is maintained that shows the current laboratory staff.

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LIMITATIONS:

1. The report includes the blood cultures that have been completed. Thus, the search dates for the report excludes blood cultures drawn in the last seven days. (eg. September 1, 2013 to September 30, 2013 and search performed on October 7, 2013).
2. The Microbiology staff must use the comment "MBC" in the result of a presumed contaminant. There are criteria in place which states when a blood culture isolate is a probable contaminant.

REFERENCES:

Garcia, Lynne S., **Clinical Microbiology Procedures Handbook**, 3rd ed., 2010, ASM Press, Washington D.C., pp. 3.4.1.6-3.4.1.7.

Tille, Patricia M. PhD. MLS (ASCP), **Bailey and Scott's Diagnostic Microbiology**, 13th ed., 2014, Elsevier Mosby, St. Louis, Mo., p. 873.

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L.MIC 7.07 Handling of Probable Contaminants

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PRINCIPLE

1. The ultimate clinical decision as to whether an isolate is a contaminant or pathogen rests upon the physician.
2. The number of positive culture bottles in one set from a single venipuncture has no significance.
3. Multiple organisms from one culture suggest contamination.
4. Skin flora are usually contaminants. These usually include coagulase negative staphylococcus, Bacillus sp. (not Bacillus anthracis), viridans Streptococcus, and Corynebacterium sp. (diphtheroids).
5. Significant bacteremia usually occurs within 12 hours of draw.
6. This procedure is to provide a system of documenting after consultation with the physician when an isolate may appear to be a contaminant.

EVALUATION OF CONTAMINANTS

1. Probable contaminant: One blood culture, when more than one culture obtained or if multiple positives separated by negatives.
2. Probably significant: More than one culture with same morphological type within 24 hours.
3. Questionable significance: Only one culture obtained (need more cultures).
4. Different organisms recovered from the aerobic and anaerobic bottles suggests improper filling of bottles; e.g., two different venipunctures.

PROCEDURE

1. After you have determined that a blood culture isolate is a contaminant using the above evaluation criteria, report as per "Examples of Probable Contaminant Comments."
2. If indeterminate, call the physician taking care of the patient and explain the situation.

A. The total number of sets of blood cultures drawn and what organism was isolated.

B. Ask the physician if he/she is planning to treat the patient and if he/she will need antimicrobial susceptibility testing (if validated methods are available).

EXAMPLES OF PROBABLE CONTAMINANT COMMENTS

1. "Growth of coagulase negative Staphylococcus at_____day(s) incubation. This single blood culture suggests contamination."
2. "Growth of coagulase negative Staphylococcus sp. from the aerobic and anaerobic bottles of this blood culture set, suggesting improper inoculation of blood culture bottles."

REPORTING FORMATS

1. If you've determined that the culture isolate is a probable contaminant, report: (**Organism**), probable contaminant; susceptibilities not performed. Organism on hold until (date 7 days from report) in case susceptibilities are needed.
2. After consulting physician to verify that no further work-up is needed, document: **(Organism)**. No antimicrobial susceptibilities performed after consultation with Dr._____, (date), (time). Isolate on hold until (date 7 days from report) in case susceptibilities are needed.
3. **When a physician calls and request susceptibilities on a probable contaminant, perform the susceptibilities but do not remove the CBC comment in the report**
4. In the case of viridans streptococcus that is isolated in a single set only, report as "Viridans Streptococcus, susceptibilities not performed. Organism on hold until (date 7 days from report) in case susceptibilities are needed. Clues that may help to differentiate contamination from bacteremia include identity of the organism, number of positive culture sets, number of positive bottles within a set, and clinical and laboratory data.

REFERENCE

Schreckenberger, Paul C., Ph.d.,**Lowering Laboratory Costs: Practical Guide for the Testing and Work-up of Specimens in Clinical Microbiology**, Hardy Diagnostics Education Seminar, January 9, 2004, Torrance Memorial Medical Center, Torrance, CA, page 9-11.

REVIEW DATES: 8/2005, 5/2006, 9/2007, 9/2008, 7/2009, 9/2010, 9/2011, 2/2014, 12/2015, 1/2019, 1/2021,11/2023, 4/2025, 2/20

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Policy Area	Laboratory Services - Microbiology

L.MIC 7.10 CULTURE OF SUSPECTED CONTAMINATED BANKED BLOOD, PLASMA AND OTHER INFUSED FLUIDS

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PRINCIPLE

The clinical manifestations associated with bacterial contamination mimic those seen in a hemolytic transfusion reaction unrelated to infection. After immunological and other non-infectious sources are ruled out, bacterial contamination should be considered.
The use of a closed system for blood collection in sterile disposable bags, implementation of rigid standards for blood bank operations, and more stringent attention to skin disinfection have contributed to the reduction of bacterial contamination. Although bacterial contamination of blood products is rare, it remains a significant concern.

SPECIMEN

Whenever clinical circumstances lead to culture of a blood unit, the recipient patient's blood should be cultured simultaneously. Since intravascular therapy has been implicated as the source of sepsis, the catheter and fluid should be cultured as well.
Volume: 20ml of blood or blood product from the suspect unit

MATERIALS REQUIRED
Aerobic and anaerobic blood culture bottles. For each unit of blood or blood component to be cultured, have two sets of blood culture bottles. A set is one aerobic and one anaerobic bottle.
Gram Stain Reagents
Alcohol
Iodophor
Needle and 20 ml syringe

PROCEDURE

1. Wear gloves and use a Biological Safety Cabinet at all times when handling blood or blood products.
2. Cleanse the rubber septum of each blood culture bottle and the ports of the blood bag with alcohol and/or iodophor, scrubbing with the antiseptic for at least one minute.
3. Using a needle and syringe, aseptically remove approximately 20ml of blood or blood product from the suspect unit.
4. Inoculate approximately a 3-5ml sample into each of the four blood culture bottles. If less than 20ml of blood is available for culture, dispense equal amounts into the blood culture bottles. Reserve approximately 0.5 to 1 ml of blood for Gram Stain.
5. Prepare a slide for Gram Stain. Place a couple of drops of the specimen onto a glass slide without touching the slide.
6. Use and applicator stick to make a thin smear for Gram Stain. If organisms are observed, directly inoculate plated media (Chocolate Agar and Blood Agar) and incubate at 35 C in CO2.

Incubate one set of blood culture bottles at room temperature (25 C)
At 48 hours, perform a blind subculture onto a Blood Agar, Chocolate Agar and a Primary Anaerobic Set Up.
Incubatethe second set of blood culture bottles in a continuous monitoring system (Virtuo) at 35 C. If bottles are flagged as positive, use the Gram Stain and subculturing methods as described above.

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RESULTS

Report Gram Stain results to Blood Bank as soon as possible.
If the slide shows to be positive for organisms, the Blood Bank department will notify the physician and the floor.

REPORTING

Report final results to the Blood Bank Department

REFERENCE

Isenberg, Henry D., ed., **Clinical Microbiology Handbook**, 2nd edition, American Society of Microbiology Press, Washington D.C., 2004, pp 13.13.1-13.13.4.

REVIEW DATES:
7/2008, 9/2010, 9/2011, 2/2014, 12/2015,12/2016, 1/2019, 1/2020, 1/2021, 1
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L.MIC 7.12 Cystic Fibrosis Culture

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PROCEDURE: **CYSTIC FIBROSIS CULTURE**		POLICY NO: Micro 7.12
DEPARTMENT: Laboratory AFFECTS: LABORATORY	EFFECTIVE DATE: 4/18/2004	REVIEW DATES: 8/2005, 5/2006, 9/2008, 9/2010, 2/2014, 12/2015, 1/2019, 1/2021, 11/2023,4/2025,2/2026
		REVISION DATES: 9/2007, 7/2009, 9/2011, 7/2012, 1/2018

PRINCIPLE

Chronic pulmonary infection, principally with *Staph. Aureus, Pseudomonas aeruginosa, Burkholderia (Pseudomonas) cepacia, Haemophilus influenzae* is the major cause of morbidity and mortality in cystic fibrosis. Sputum of cystic fibrosis patients are often overgrown with a mucoid strain of *Pseudomonas aeruginosa* that special efforts must be made in order to recover *Haemophilus influenzae, Staph. Aureus,* and *Burkholderia cepacia*. The specimen must then be specially pretreated and inoculated on a variety of selective media.

Correct identification must be made once the isolation is achieved. Misidentification can lead to misclassification of the CF patient. For example, *B. cepacia*, now well recognized as a serious pathogen for CF patients, can be spread from patient to patient. Infection control measures for patients with *B. cepacia* can be implemented appropriately if the identification is made accurately. Therefore, misclassification may have significant medical and psychosocial implications for the CF patient.

SPECIMENS

Bronchoalveolar lavage fluid (BAL) is the optimal specimen for assessing the microbiology of the lower respiratory tract. The procedure is invasive, expensive, and requires skilled personnel and has some risk for the patient so it is often not performed. Process specimen with mucolytic agent before plating.

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Sputum is often submitted from those patients capable of expectorating. Process specimen with mucolytic agent before plating.
Oropharyngeal (throat) Swabs are the optimal alternative specimen. Do not process with mucolytic agent before plating.

SPECIMEN HANDLING AND PROCESSING
Transport to Lab as soon as possible within same working day, preferably in less than 3 hours. Otherwise refrigerate prior to transport. Swabs do not need to be refrigerated.
If unable to process upon receipt, refrigerate specimen at 4-8°C.

SMEAR FOR GRAM STAIN (DONE ONLY ON HOSPITALIZED PATIENTS ONLY)
Prepare before processing specimen with mucolytic agent.
Bronchoalveolar Lavage: For evaluation of the presence of leukocytes and microorganisms.
Sputum: To ensure adequacy and quality of specimen. Make smear before processing with mucolytic agent.

MEDIA AND INCUBATION
BLOOD AGAR, incubate at 35 degrees C, in CO_2 for 4 days.
MACCONKEY, incubate at 35 degrees C, aerobic for 4 days.
MANNITOL SALT, incubate at 35 degrees C, aerobic for 4 days.
HORSE BLOOD AGAR, incubate 35 degrees C, anaerobically, for 4 days.
BURKHOLDERIA CEPACIA AGAR, incubate at 35 degrees C, aerobically for 4 days.

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NOTES ON SPECIALIZED MEDIA USED
MANNITOL SALT AGAR
Selective media for isolation of ***Staph aureus***.
Staph aureus grows luxuriantly, producing yellow colonies with yellow zones.
Subculture to blood agar plate before working up.
HORSE BLOOD AGAR
Selective media for isolation of *Haemophilus influenzae*.
Subculture isolates to chocolate agar plate **and** blood agar plate before working up. Gram stain all isolates that grow **only** on chocolate agar
BURKHOLDERIA CEPACIA Agar
Selective media for isolation of *Burkholderia cepacia*.
Growth of gray-white colonies surrounded by bright pink to red zone in medium may be presumptively identified as *Burkholderia* (*Pseudomonas*) *cepacia*.
Do not perform oxidase test on colonies from this medium. Subculture to blood agar and maconkey before working up. Colonies may be tiny and beta-hemolytic but are gram negative rods. All presumptive Burkholderia Cepacia isolates must be sent to reference laboratory for confirmatory identification by DNA sequencing.
For species confirmation of any isolate identified as belonging to the genus Burkholderia or to rule our Burkholderia spp. among nonenteric, nonfermenting, gram-negative bacteria isolated from CF sputum, isolate must be submitted to CFF Burkholderia cepacia Research Laboratory and

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Repository in Ann Arbor, Michigan.

PRINCIPLE OF COPAN MUCOLYTIC AGENT:

Copan's SL solution is a ready to use mucolytic agent for sputum samples with the principle active ingredient being DTT (Dithiotreitol). SL solution quickly liquefies sputum specimens without affecting the morphology, growth or microscopic staining of pathogens in the sputum. It enables the emulsification of sputum and mucus resulting in a homogenous suspension allowing for easier, more consistent and reproducible planting and streaking of specimens. The Sputum Dipper, exclusive to Copan, allows for easy transfer of sputum samples from specimen container to SL solution tube.

Copan SL Solution Kit: 12X80mm polypropylene screw-cap tubes with internal conical shape filled with 0.5 ml SLsolution (DTT). Sterile Sputum Dippers for sputum sample transfer.

How to use Copan SL solution

1. Peel open one sputum dipper
2. Open the plastic pack containing the tube of SL solution. Remove one tube and unscrew the cap.
3. By means of the Sputum Dipper, transfer the sputum sample into the opened tube. Break the sputum dipper into the tube by exerting s slight pressure against the tube surface near the breaking point
4. Re-cap the tube of SL solution
5. Vortex the tube for 30 seconds at 2000/2500 rpm or until it is liquefied. Leave the mixture at room temperature for 15 minutes. Prolonged contact time up to 6 hours does not inhibit bacteria and fungi survival into the sample.
6. Aseptically remove aliquots of the liquefied sputum and inoculate onto appropriate bacteriology culture medium

NOTE: Best results are obtained with a biological sample: SL solution ratio of 1:1

LIMITATIONS

- In the laboratory, wear latex gloves and other protection commensurate with universal precautions when handling clinical specimens.
- Condition, timing, and volume of specimen collected for culture are significant variables in obtaining reliable culture results.
- Copan SL solution is not tested for acid resistant bacterial cultures.
- Performance testing with Copan SL solution was conducted using laboratory strains spiked into SL solution tubes and not human specimens.
- Proper specimen collection from the patient is extremely critical for successful isolation and identification of infectious organisms.

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WASTE DISPOSAL

- Unused reagents may be considered as non hazardous waste and disposed of accordingly.
- Dispose of used reagents as well as any other contaminated disposable materials following procedures for infectious or potentially infectious products.

EXAMINATION OF CULTURE

1. Examine for *Pseudomonas aeruginosa, Staph aureus, Haemophilus influenzae, Burkholderia cepacia and Achromobacter xylosoxidans*
2. Subculture *Pseudomonas aeruginosa* at least once before performing a disk diffusion antimicrobial susceptibility tests.
3. Isolate and identify any other potential lower respiratory pathogens if they are significant and predominant. Hold susceptibilities upon request.

REPORTING AND IDENTIFICATION

1. Follow established protocol for bronchial washings, sputa, and tracheal aspirates when reporting normal flora and identifying all potential pathogens. Specimens from CF patients should be screened carefully for *Hemophilus influenzae,Staph aureus, Pseudomonas aeruginosa*, and *Burkholderia cepacia and Achromobacter xylosoxidans*
2. If *Pseudomonas aeruginosa* is isolated, note if mucoid strain on report: e.g., 4+ *Pseudomonas aeruginosa,* mucoid strain.
3. Of the four organisms sought, if not present please note on report after listing those that were present. For example: No Haemophilus influenza or Burkholderia cepacia isolated.

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ANTIMICROBIAL SUSCEPTIBILITY TESTING

1. Follow established guidelines for susceptibility testing of *Staphylococcus, Pseudomonas aeruginosa, Achromobacter xylosoxidans* and *Burkholderia cepacia*.
2. When performing susceptibilities on *Pseudomonas aeruginosa*, perform the Kirby-Bauer disk method. This is the only method approved by the Cystic Fibrosis Association.
3. Pseudomonas aeruginosa isolates need susceptibilities performed once per year. It is not necessary to perform MIC each time it is isolated unless suspected to be a different strain. (ex. mucoid/non mucoid)
4. Add colistin, 10 mcg disk to prevent misidentification of *Burkholderia cepacia*. *Pseudomonas aeruginosa* are susceptible, whereas *Burkholderia cepacia* are resistant.
5. Susceptibility testing of *Haemophilus sp* and *Burkholderia cepacia* isolates must be referred to reference laboratory.
6. Follow established CLSI guidelines for reporting antibiotics on *Staphylococcus,,Achromobacter xylosoxidans* and *Pseudomonas aeruginosa*.

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1. Mucolyse Product Insert, December 1994
2. Cystic Fibrosis Procedure, 1/4/88, Miller Memorial Medical Center, Long Beach, CA.
3. Forbes, Betty A., et al, **Bailey & Scott's Diagnostic Microbiology**, 10th edition, the C.V. Mosby Co., St. Louis, 1998, page 312.
4. Consensus Conferences: Concepts in Care: "Microbiology and Infectious Disease in Cystic Fibrosis," Cystic Fibrosis Foundation, Vol. V, Section I, May 17018, 1994, pp. 2-3
5. COPAN SLsolution Product Circular, P108 REV.00DATE2010.12 www.copanusa.com
6. ASM 2011 Workshop, Peter Gilligan, University of North Carolina, "Understanding the Increasing Complexity of the Microbiology of Chronic Infection in Cystic Fibrosis," May 21, 2011.
7. Journal of Clinical Microbiology, September 2003, JCM.41.9.4009-4015.2003
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Policy Owner	M. Anwar Molani: Medical Director, Laboratory Services	3/1/2026

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Policy Area	Laboratory Services - Microbiology

L.MIC 7.13 Ear Cultures

COPY

PRINCIPLE

Anatomy
The ear is divided into three anatomic parts: the external, middle, and inner ear.
The middle ear is part of a continuous system that includes the nares, nasopharynx, auditory tube, and the mastoid air spaces. These structures are lined with respiratory epitheliim.

The normal flora of the external ear canal are rather sparse, similar to the flora of the conjunctival sac qualitatively except **Streptococcus pneumoniae**, **Propionibacterium acnes**, **Staph aureus**, and enteobacteriaceae are encountered more often. **Pseudomonas aeruginosa** is found on occasion. **Candida spp** (non-**Candida albicans**) are also common.
Diseases

Otitis externa is similar to skin and soft tissue infections elsewhere. Local trauma, the presence of foreign bodies, or excessive moisture can lead to otitis externa. Also, an infection from the middle ear can extend by purulent drainage to the external ear. Two major types of otitis externa: acute or chronic.

Acute localized disease in the form of a pustule or furuncle and typically caused by **Staph aureus**. Erysipelas caused by group A streptococci. Swimmer" ear (acute diffuse) is related to maceration (softening of tissue) of the ear from swimming and/or hot, humid weather. Gram negative bacilli, especially **Pseudomonas aeruginosa** are involved. A severe, hemorrhagic external otitis caused by **Pseudomonas aeruginosa** is very difficult to treat and has occasionally been related to hot tub use.

Chronic otitis externa results from the irritation of drainage from the middle ear of patients with chronic, suppurative otitis media and a perforated eardrum. Malignant otitis externa is a necrotizing infection that spreads to adjacent areas of soft tissue, cartilage, and bone. If allowed to progress and spread into the central nervous system or vascular channel, a life-threatening situation may develope. **Pseudomonas aeuginosa** and anaerobes are frequently associated with this process.
Malignant otitis media is seen in patients with diabetes who have blood vessel disease of the tissues overlying the temporal bone in which the poor local perfusion of tissues provides an opportunity for invasion by bacteria. Certain viruses may infect the external auditory canal, the soft tissue of the ear, or the tympanic membrane; influenza A virus is a suspected, but not an established, cause, Varicella zoster virus may cause painful vesicles within the soft tissue of the ear and the ear canal. **Mycoplasma pneumoniae** is a cause of bullous myringitis (a painful infection of the eardrum with hemorrhagic bullae); the ear canal itself may be involved as well.

Otitis media
Anatomic or physiologic abnormalities of the auditory tube can predispose individuals to develop otitis media. The auditory tube is responsible for protecting the middle ear from nasopharyngeal secretions, draining secretions produced in the middle ear into the nasophayrnx, and ventilating the middle ear so that air pressure is equilibrated with that in the external ear canal. If any of these functions becomes compromised and fluid develops in the middle ear, infection may occur.

The mastoid is a portion of the temporal bone (lower sides of skull) that contains the mastoid sinuses . Mastoiditis is a complication of chronic otitis media in which organisms find their way into the mastoid sinuses.

COPY

SPECIMEN COLLECTION

External Ear
Insert a sterile swab into ear canal until resistance is met. Rotate swab and allow fluid to collect on swab. A swab of exudate collected after the external ear is cleansed with a mild germicide such as 1:1000 aqueous solution of benzalkonium chloride can reduce the contaminating skin flora.
Tympanocentesis fluid
CLean the external canal with mild detergent.
Using a syringe aspriation technique, the physician will obtain fluid from the eardrum
Send the specimen in a sterile container or in the syringe capped with a Luer-Lok with the needle removed. DO NOT SUBMIT SYRINGE WITH NEEDLE.
If the eardrum is ruptured, collect exudate by inserting a sterile swab through an auditory speculum.

Material from the ear,especially that obtained after spontaneous perforation of the eardrum or by needle aspiration of middle ear fluid (tympanocentesis), collected by otolaryngologist using sterile equipment.

Mastoid specimens are generally taken on swabs during surgery. Actual bone is preferred. Specimen should be transported anaerobically.

SPECIMEN TRANSPORT AND HANDLING

Submit promptly to the laboratory for processing. When using swabs, ESwabs are preferred.
Submit aspirates in a sterile container or in the original syringe capped with a Luer-Lok to prevent leakage.
Label specimens wiht demmographic information, date and time of collection, and site of collection.

GRAM STAIN

Make smear using method for swab specimens or liquid specimen, whichever is applicable.

COPY

MEDIA

Routine: BAP, CHOC, MAC.

INOCULATION

If only one swab is submitted swab plated media, and then make smear for Gram stain last.

If two swabs are submitted and anaerobic culture has been ordered, break one swab into THIO broth and swab plated media with second swab. After plates are inoculated, make a smear for Gram stain from second swab.

INCUBATION

Incubate BAP, CHOC, and MAC, at 35 degrees Celsius in CO2 incubator for a minimum of 48 hours.

For cultures of invasively collected ear fluid samples, incubation may be extended to 4 days, if the results are negative.

MAJOR INFECTIOUS CAUSES OF EAR DISEASE

Otitis Externa
Acute causes: **Staph aureus**, **Strep pyogenes**, **Pseudomonas aeruginosa**, other Gram negative bacilli
Chronic: **Pseudomonas aeruginosa**, anaerobes

Otitis Media
Acute: **Strep pneumoniae**, **Hemophilus influenzae**, **Strep pyogenes**, RSV, Influenzae virus
Chronic: Anaerobes

CULTURE EXAMINATION

COPY

External Otitis
Observe plates for growth at 24 and 48 hours.

If no visible growth at 24 hours is observed, re-incubate. Examine plates daily for 48 hours before discarding.

Culture with growth.
Semi-quantitate growth on plated media.

Gram stain each morphotype, if applicable

Since only one pathogen is generally responsible for otitis externa, mixed culture of Gram-negative rods should be minimally identified.

Identify all organisms and perform AST, if appropriate. In the case of Proteus sp., evaluate on MAC, where they generally do not swarm, to be sure they are the predominant microorganism before performing AST.

Identify yeasts, if predominate or pure, and molds, if present. *Aspergillus* and *Candida albicans* have been implicated in chronic illness.

Otitis Media

Observe plates for growth for 4 days. Anaerobic cultures may be indicated.

Normal skin microbiota (coagulase-negative staphylococci, viridans streptococci, and corynebacteria) can be reported as organisms representing skin flora unless they are the only predominant species in the culture and are present in large numbers.

REPORTING RESULTS

Report new results and update results whenever available as preliminary results.

Report quantity along with organism name.

INTERPRETATION

A positive external ear culture with a predominant Gram-negative rod, beta-hemolytic streptococci, or *S. aureus* generally indicates infection with that agent.
A positive middle ear culture with *S. pneumoniae, M. catarrhalis*, and *A. otitis* generally indicates infection with that organism.
A negative culture cannot rule out otitis media. In chronic infections, a pathogen is often not isolated.

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LIMITATIONS

False-negative results can result from overgrowth of the culture with normal cutaneous microbiota.
False-positive results can be caused by overinterpretation of the culture results.
A. otitidis is difficult to culture and may not be detected.

REFERENCE

Forbes, Betty, et al, Diagnostic Microbiology, 10th edition, The C.V. Mosby Co., St. Louis, 1998, pages 346-348.

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Policy Owner	M. Anwar Molani: Medical Director, Laboratory Services	2/28/2026
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Policy Area	Laboratory Services - Microbiology

L.MIC 7.14 Eye Cultures

COPY

PRINCIPLE

ANATOMY

Ocular infections can be divided into those that involve the external structures and those that involve internal sites.

External structures include eyelids, conjunctiva, sclera, and cornea. The eyeball is comprised of three layers: from the outside are the sclera, the choroid, and the retina. The sclera is a tough, white fibrous tissue (white of eye). The anterior (toward the front) portion of the sclera is the cornea, which is transparent and has no blood vessels. The conjunctiva, a mucous membrane, lines each eyelid and extends onto the surface of the eye itself.

The large interior space of the eyeball is divided into two sections: the anterior and posterior cavities. The anterior cavity is filled with a clear and watery substance called aqueous humor. The posterior cavity is filled with a soft, gelatin-like substance called vitreous humor.

Infections can also occur in the eye's lacrimal (tears) system, which include the lacrimal gland, lacrimal canaliculi, and lacrimal sac.

DISEASES

Blepharitis: Inflammation of the margins of the eyelids. Symptoms include irritation, redness, burning sensation, and occasional itching.

Conjunctivitis: Inflammation of the conjunctiva. Symptoms vary according to the etiologic agent but most have swelling of the conjunctiva and inflammatory exudates.

Keratitis: Inflammation of the cornea. Although there are no specific clinical signs to conform infection, most patients complain of pain and usually some decrease in vision, with or without discharge from the eye.

Keratconjunctivitis: Infection involving both the conjunctiva and cornea. Ophthalmia neonatorum is an acute conjunctivitis or keratoconjunctivitis of the newborn caused by either Neisseria gonorrhoeae or Chlamydia trachomatis.

Endophthalmitis: Infection of the aqueous or vitreous humor. This infection is usually caused by bacteria or fungi, is rare, develops suddenly and progresses rapidly, often leading to blindness. Pain, especially while moving the eye, and decreased vision, are prominent features.
Lacrimal Infections
Canaliculitis: A rare, chronic inflammation of the lacrimal canals in which the eyelid swells and there is a thick, mucopurulent discharge.

Dacryocystis: Inflammation of the lacrimal sac that is accompanied by pain, swelling, and tenderness of the soft tissue in the media canthal region.
Dacryoadenitis: Acute infection of the lacrimal gland. These infections are rare and can be accompanied by pain, redness and swelling of the upper eyelid, and conjunctival discharge.

SPECIMEN TYPES

Swab of purulent material from the surface of the lower conjunctivitis
Corneal scrapings
Wound abscess material
Material from anterior and posterior chambers of the eye

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SPECIMEN HANDLING

Conjunctivitis: purulent material from the surface of the lower conjunctival sac and inner canthus (angle) of the eye is collected on a sterile swab for culture. Both eyes should be cultured separately.
Keratitis: An ophthalmologist should obtain scrapings of the cornea with a heat sterilized platinum spatula. Multiple inoculations with the spatula are made to BAP, CHOC, THIO, ANA, and fungus media.
Endophthalmitis: Material obtained by the ophthalmologist from the anterior and posterior chambers of the eye.
Lid infection material is collected on a swab.
For viral studies: Refer to Send Out Department for instructions.
For AFB and/or mycology studies: Refer to VCPH for processing.

GRAM STAIN

Make smear using method for swab specimens or liquid specimens, whichever is applicable.

MEDIA

Routine: BAP, CAP, and THIO broth if sterile tissue or anaerobic culture ordered

INOCULATION

If two swabs submitted, swab BAP, CHOC with second swab. After plates are inoculated, make a smear for Gram stain from second swab.
If only one swab is submitted, swish swab in THIO broth, then swab BAP and CHOC, and make smear for Gram stain.

INCUBATION

Incubate BAP and CHOC agar plates at 35 degrees at CO2

ORGANISMS IN INFECTION
Blepharitis: **Staph aureus**
Conjunctivitis: **Strep pneumoniae, Hemophilus influenzae, Staph aureus, Hemophilus aegyptius**, **Neissera gonorrhoeae**, **Strep pyogenes**
Keratitis (cornea): **Staph aureus**, **Strep pneumoniae**, **Pseudomonas aeruginosa**
Endophthalmitis (aqueous or vitreous humor): **Staph aureus**, **Staph epidermidis**, **Strep pneumoniae**, other Streptococcus spp., **Pseudomonas aeruginosa**, gram negative bacilli.
Lacrimal Infections
Canaliculitis (chronic inflammation of the lacrimal canals in which eyelid swells, and thick mucopurulent discharge is present: **Actinomyces**, **Propionibacterium propionicum**
Dacryocystis (inflammation of lacrimal sac): **Strep pneumoniae**, **Staph aureus**, **Strep pyogenes, Hemophilus influenzae**
Dacryoadenitis (acute infection of lacrimal gland): **Strep pneumoniae**, **Staph aureus**, **Strep pyogenes**

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CULTURE EXAMINATION

24-h old
Examine all plated media for growth.
If no visible growth is observed, re-incubate.
Examine plates and broth daily for 72 hours before discarding.
Culture with growth
Semi-quantitate growth on plated media.
Gram stain each morphotype, if applicable.
Notify physician of results.
Identify all organisms and perform AST, if appropriate.
Organism Identification
Definitively identify all isolated unless the patient's physician says otherwise.
If an organism is determined by the physician to be a probable contaminant. A complete identification may not be needed.
Refer to AST Manual for appropriate procedures.
Perform beta-lactamase (Cefinase) when applicable.

48-h and older
Examine culture daily for 3 days. Anaerobic cultures may be indicated.

REPORTING RESULTS

1. Report new results and update results whenever available as preliminary report.

REFERENCES

Forbes, Betty, et al, **Diagnostic Microbiology,** 10th edition, The C.V. Mosby Co., St. Louis, 1998, pages 340-343.

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L.MIC 7.15 Genital Cultures

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PRINCIPLE:

Specimens from genital sites are sent to the clinical microbiology laboratory for detection of microorganisms from females presenting with clinical syndromes such as cervicitis, vulvovaginitis, urethritis, bacterial vaginosis, salpingitis, endometritis, or genital ulcers
and from males exhibiting urethritis, epididymitis, prostatitis, or genital ulcers.
For surgically collected specimens and those from normally sterile sites, a routine wound and abscess culture, will detect most bacterial pathogens if selective media for Neisseria gonorrhoeae are included.
To diagnose vulvovaginitis and bacterial vaginosis, routine bacterial cultures are not helpful.
Accurate diagnosis of genital infections depends on the separation of microbial pathogens from the normal genital flora.

SPECIMEN COLLECTION:

1. Observe universal precautions.
2. Special care must be taken to collect specimens likely to yield the pathogen and exclude normal flora. Appropriate specimens from the female and male genital tract are listed in Tables 1 and 2, respectively. Vaginal tract specimens that arrive on swabs are often contaminated with vaginal flora and should be examined selectively for primary pathogens Conversely, any growth from a specimen that was collected with a syringe should be considered significant and should be identified and reported as significant.
3. Proper handling, transport, processing, and planting of specimens with selective, nonselective, and enriched media and the provision of specific environmental conditions will facilitate the recovery of such fastidious genital tract pathogens as **Neisseria gonorrhoeae**, actinomycetes, and **Haemophilus ducreyi**.

Table 1. Appropriate female genital specimens

SITE	***SPECIMEN***
Amniotic fluid	Catheter aspirate; amniocentesis; swab from caesarean section
Bartholin gland	Duct aspirate in syringe or on swab
Cervix	Swab of endocervical canal
Endometrium	Transcervical aspirate obtained via telescoping catheter
Fallopian tubes	Abscess aspirate; culdocentesis swab obtained during pelvic surgery
Genital ulcer	Dry or moistened swab of ulcer base; bubo aspirate
IUD	IUD; associated secretions & pus
Urethra	Discharge on swab; swab from posterior vaginal vault or vaginal orifice
Vagina	Discharge on swab; swab from posterior vaginal vault or vaginal orifice
Vesicle	Vesicular material in syringe or on swab

Table 2. Appropriate male genital specimens

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SITE	***SPECIMEN***
Epididymis	Calcium alginate swab of urethra
Genital ulcer	Dry or moistened swab or ulcer base; biopsy sample or curettings of ulcer base; bubo aspirate
Penile discharge	Discharge on swab
Prostate	Expressed prostatic secretions on swab or in cup
Urethra	Expressed exudate on swab or calcium alginate swab from distal urethra
Vesicle	Vesicular material in syringe or on swab
Testicle	Syringe containing (abscess) aspirate; aspirate on swab

Rejection Criteria

1. Reject specimens not received in transport medium, since the agents of genital infections lose viability easily.

MATERIALS

1. Media
    A. BAP, CHOC, MTM, and CNA (for vaginal culture)

PROCEDURE

A. Direct smear

- Prepare a Gram stain from the swab after plate inoculation.
- Stain slide and, for women in childbearing years, observe for evidence of BV from vaginal specimens, for yeasts, and for evidence of other bacteria associated with WBC's.

A. Incubation
Incubate plates at 35C in CO2.for 18 to 24 hours.
Hold negative plates up to 72 hours.

B. Interpretation of Culture MediaFor each genital culture, examine the BAP, CHOC, and CNA agar plates, after 24 and 48 hours of incubation.Hold the MTM agar for 72 hours prior to reporting as negative.Perform each of the following steps when applicable in the examination of a genital culture.

1. Correlate varieties and quantities of colonial morphotypes with direct-smear Gram stain (if done) results. Consider the presence of epithelial cells and/or WBCs to determine the significance of growth.
2. Identify the following pathogens if present
    a. Examine non-lactose fermenting, Gram –negative rods for *Shigella spp*. or other enteric pathogens, especially from pediatric patients.
    NOTE: DO not examine cervical or vaginal specimens for other *Enterobacteriacea*, as these microorganisms are normally found in the female genital tract.
    b. *Streptococcus pyogenes*
    c. *S. agalactiae*
    d. *Listeria monocytogenes*
    e. *N. gonorrhoeae*
    f. *Candida albicans*. Mention other yeasts. *Candida glabrata* has been implicated as a cause of vulvovaginitis.
3. Identify the following only if the specimen was invasively collected or there is heavy growth, and they are the predominant microorganisms in the culture.
    a. *Haemophilus* spp.
    b. Gram-negative rods
        1. Enteric Gram-negative rods (exception: *Enterobacteriaceae* are part of the normal microbiota of the vagina and should not be reported).
        2. Psuedomonas spp. and other non-glucose-fermenting, Gram-negative rods.
    c. *Staphylococcus aureus*

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d. *Streptococcus pneumonia*

e. *Neisseria meningiti*

f. *G. vaginalis*

a. For vaginal specimens, do not use selective medium to isolate this organism, because the importance of its isolation is determined by the quantity compared to that of lactobacilli in the culture. *G. vaginalis* grows well on both CNA and CHOC.

b. When present in quantities less than the normal microbiota, it should be included as part of normal vaginal microbota. However, children report its presence regardless of the quantity present.

c. It is the predominant microorganism from the female vaginal tract and is isolated in 3 to 4+ quantities, report its presence.

d. Identification

1. Colonies appear pinpoint and transparent, with no greening of the agar.
2. Gram-variable to Gram negative small, pleomorphic coccobacilli that do not elongate into filaments or chains.
3. Catalase negative. Other 'coryneform' bacilli that are genitourinary and skin commensals (i.e., *Actinomyces pyogenes*, *Arcanobacterium haemolyticum*) are also catalase-negative and may be confused with *G. vaginalis*.

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C. Susceptibility Testing

1. Antimicrobial susceptibility testing should be performed on all aerobic bacterial isolates from pelvic or amniotic fluid or tissue specimens that are primary pathogens.
2. N. gonorrhoeae isolated from any genital site should be referred for antimicrobial susceptibility testing.

D. Reporting

1. From surgical specimens and those from normally sterile sites, report the pathogens isolated. For cultures with mixed microbiota, limited identification may be indicated.
2. If no pathogen is isolated but normal microbiota is present, report as "Normal vaginal pathogens isolated" (MNVP) and as "Normal skin flora isolated" (MMNSK) for male urethral specimens.
3. If specific pathogens are requested, report "No [pathogen name]
4. Positive reporting

A. Quantitate pathogens

B. Notify physician of pathogens of serious significance in pregnant females (e.g., *L. monocytogenes*) or communicable diseases (e.g. *Neisseria gonorrhoeae*).

A. Hold positive culture plates for 7 days should further testing be indicated.

Guidelines for performing genital cultures on children

FOR CHILDREN, Smears lack the specificity for accurate **N. gonorrhoeae** diagnosis for children. For this reason, **do not perform gram stain on prepubescent children**.

Add the mneumonic "MVAGKID"for all genital cultures on children. It states.

"Cultures taken from children must be chosen and performed with the utmost care, since a positive report can have far reaching psychosocial and medico-legal implications. In the United States, culture identification is the only definitive method of diagnosis from a legal standpoint.

Cultures (not nucleic acid tests) must be performed in all medico-legal cases and with specimens from prepubescent children."

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BACTERIAL VAGINOSIS

Vulvovaginitis is caused by *Candida albicans* and other Candida species, *Trichomonas vaginalis*, and a syndrome (bacterial vaginosis) in which the normal predominance of lactobacilli has been replaced by a predominance of anaerobic gram negative bacilli and curved rods. Two or more of these infections may coexist so that the presenting signs and symptoms may not always be typical. Vaginosis is a synergistic infection in which many organisms play a role.

Diagnosis of bacterial vaginosis is best accomplished with clinical criteria along with a Gram stain of the vaginal discharge using the Nugent scoring system. Bacterial Vaginosis is associated with an increased risk of several pathological conditions, including postoperative infections, postabortion pelvic inflammatory disease and clinical chorioamnionitis with increased rate of neonatal sepsis.

Specimen collection:

Bacterial vaginosis involves an overgrowth of multiple bacteria and is probably a synergistic infection in which many organisms play a role. The diagnosis of bacterial vaginosis is often a clinical diagnosis based on demonstrating three of the following four criteria:

1. A "thin" (but profuse) vaginal discharge
2. A pH of greater than 4.5

3. An odor usually described as "fishy"
4. The demonstration of "clue cells"

Swabs submitted for vaginal culture and evaluation for bacterial vaginosis consist of secretions obtained from the mucosal membrane of the vaginal vault. The swab is placed in appropriate transport and is acceptable up to 24 hours from time of collection

Perform gram stain for evaluation of BV score

Enumerate and report WBCs, RBCs, pathogenic morphotypes (e.g. gram-neg diplococci), and Yeast from Grading Table. Enter P or A for Clue Cells. **Enter BV Score from Interpretation Table.**
Quantitation of Bacterial Morphotypes

# / OIF	0	0-1	1-5	5-30	>30
Grade	0	1+	2+	3+	4+
		SCORE	TALLEY		
Med to lrg gram pos rods	4	3	2	1	0
Small gram-neg or –var rods	0	1	2	3	4
Curved gram-neg or –var rods	0	1	1	2	2

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BV-SCORE and Interpretation – Add Scores from the above Quantitation to arrive at BV-SCORE.

Total	Computer Entry	Report Interpretation
0 - 3	0, 1, 2 or 3	Morphotypes consistent with normal vaginal microbiota.
4 – 6	4, 5, or 6	Mixed morphotypes consistent with transition from normal vaginal microbiota.
7 - 10	7, 8, 9 or 10	Mixed morphotypes consistent with bacterial vaginosis.

Interpretation of culture for bacterial vaginosis

1. The presence of yeast may be significant. Quantitate and report the presence of yeast species.
2. The presence of **Neisseria gonorrhoeae** must always be considered significant. Identify, quantitate, report and submit isolate to Ventura County Public Health Laboratories.
3. **Listeria monocytogenes** may be recovered from the mother's vagina in cases of neonatal **Listeria** infection. Identify, quantitate, report as significant and call attending physician.
4. **Streptococcus pyogenes** is a significant pathogen in children
5. **Streptococcus agalactiae** is a significant pathogen.

6. For the recognition of toxic shock syndrome (TSS), isolation of S. aureus is difficult and not sufficient for the diagnosis. Further characterization of the strain is necessary to confirm the diagnosis. If TSS is suspected, submit specimen to reference laboratory for testing.

Results

Microbiology Specimen comment to be added in cases of vaginal/cervical cultures for BV:
"MVAG" Routine bacterial cultures are not helpful to diagnose vulvovaginitis and bacterial vaginosis. Bacterial vaginosis involves an overgrowth of multiple bacteria and is most likely a synergistic infection in which many organisms play a role. The diagnosis of bacterial vaginosis is bases on demonstrating three of the following four criteria:

1. A "thin" (but profuse) vaginal discharge
2. A pH of greater than 4.5
3. An odor usually described as "fishy"
4. The demonstration of "clue cells"

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Gram stain using the Nugent scoring system:

WBCs: Enumerate (if any)
RBCs: Enumerate (if any)
YEAST: Enumerate (if any)
Clue cells: Present or Absent
BV Score: *DO NOT ENUMERATE INDIVIDUAL ORGANISM TYPES*
0-3: Morphotypes consistent with normal vaginal microbiota.
4-6 Mixed morphotypes consistent with transition from normal
7-10 Mixed morphotypes consistent with bacterial vaginosis.

Preliminary Report
"MNVP"
No Neisseria gonorrhoeae, Strep pyogenes (group A), Strep agalactiae (group B), or Listeria sp. Isolated to date.

Final Report:
"MNVPF"
No Neisseria gonorrhoeae, Strep pyogenes (group A), Strep agalactiae (group B), or Listeria sp. Isolated.

QUALITY CONTROL

A. Verify that media meet expiration date and QC parameters per CLSI document M22-A3.

INTERPRETATION

A. The presence of any microorganism from a normally sterile site is generally considered significant.
B. Isolation of sexually transmitted disease pathogens (e.g., *N. gonorrhoeae* and *H. ducreyi*) is considered clinically significant from any genital site. Isolation of certain organisms such as *S. pyogenes* and *Clostridium perfringens* from soft tissue as well as endometrial tissue or transvaginal fluid samples should also be considered clinically significant.
C. The presence of other pathogens may or may not be a cause of disease and must be evaluated with consideration of relative amounts and symptoms or other conditions (e.g. pregnancy) in the patient.

LIMITATIONS

A. Many agents of disease are difficult to culture, and the lack of isolation may not indicate that the pathogen is not the cause of disease.
B. BV is best diagnosed by Gram stain using Nugent's criteria.
C. Due to the poor sensitivity of wet-mount examination, another method should be used for the diagnosis of *T. vaginalis* infection.

COPY

REFERENCE

Leber, Amy L et al., Clinical Microbiology Procedures Handbook, 4th ed., ASM Press, Vol 1, 2016 p 3.9.1-3.9.12

Schreckenberger, Paul C., **Lowering Laboratory Costs: Practical Guidelines for the Testing and Work-up of Specimens in Clinical**

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Policy Owner	M. Anwar Molani: Medical Director, Laboratory Services	3/1/2026
Policy Owner	Erlinda Roxas: Director, Laboratory Services	2/28/2026

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L.MIC 7.17 Gonococcus Screen

COPY

PRINCIPLE

Neisseria gonorrhoeae is an agent of sexually-transmitted disease. It may cause cervicitis, pelvic inflammatory disease (endometritis, salpingitis, localized or generalized peritonitis, fallopian tube or ovarian abscesses), epididymitis, prostatitis, and synovitis. Therefore, it is important to be able to isolate this organism using selective medium.

Endocervical discharge, male urethral discharge collected and transported onCopan ESwab system at room temperature.
Transport to lab as soon as possible; i.e., preferably within 12 hours of collection. Recovery is compromised if not cultured within 72 hours.

MATERIALS NEEDED

Modified Thayer Martin (MTM) Agar Plate
Inoculating loop, sterile
Biological Safety Cabinet
Oxidase reagent
Gram stain reagents
Vitek NH ID Card
Nutrient agar slant
Chocolate agar
CO_2 incubator, 35 degrees Celsius

INCUBATION

Incubate MTM plate at 35°C, in 5 to 10% CO_2 incubator for 72 hours

EXAMINATION OF CULTURE

Examine MTM plates for clear, translucent colonies typical of Neisseria gonorrhoeae at 24 hours, 48 hours, and then at 72 hours of incubation.
When **Neisseria gonorrhoeae**-like colonies are evident, perform oxidase test and Gram stain.
Neisseria gonorrhoeae are oxidase positive and are Gram-negative diplococci.

If there is sufficient growth, perform Vitek NH ID card identification and subculture to nutrient agar slant to rule out other gonococcus look-alikes.

If there is not enough growth to perform the Vitek NH ID, subculture to chocolate agar plate, Thayer Martin plate and also to a nutrient agar slant.

Expected Results:

Neisseria gonorrhoeae are Gram-negative diplococci, oxidase positive, and does not grow on nutrient agar after 4 days of incubation in CO_2.

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REPORTING RESULTS

Adult: If positive for gonococcus, report Neisseria gonorrhoeae isolated.

Notify physician, Infection Control (if in-house patient), and Ventura County Public Health Department, Communicable Diseases Office by FAX.

Child or from extragenital sources. TWO confirmatory tests that use distinct identification methods are required :

If negative for gonococcus, report "No gonococcus isolated."

If specimen is overgrown by normal flora microorganisms, add comment: Please submit another specimen. Culture was grossly overgrown to the extent that **Neisseria gonorrhoeae** could not be detected."

If specimen is overgrown with yeast, report "Culture overgrown with yeast; unable to isolate **Neisseria gonorrhoeae**; please submit another specimen."
Overabundance of yeast cells lower the pH of the medium and thus inhibit the growth of **Neisseria gonorrhoeae**.

REFERENCE

Forbes, Betty et al, **Bailey & Scott's Diagnostic Microbiology,** Mosby, St . Louis, 1998, pages 364-374.

Isenberg, H.D., 2004, **Clinical Microbiology Procedures Handbook**, 2nd ed., ASM Press, Washington D.C.

Remel, NET, REF R211173, product circular, July 26, 2010

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Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator, VCMC & SPH	3/2/2026
Policy Owner	Linda Conboy: Supervisor-Microbiology, Laboratory Services	3/1/2026
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Policy Owner	Erlinda Roxas: Director, Laboratory Services	2/23/2026

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L.MIC 7.18 Sinus Cultures

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PRINCIPLE

ANATOMY

The sinuses, like the mastoids, are unique, air-filled cavities within the head. The sinuses are normally sterile. These structures, as well as the eustachian tube, the middle ear, and the respiratory portion of the pharynx, are lined by respiratory epithelium. The clearance of secretions and contaminants depends on normal ciliary activity and mucous flow.

DISEASES

Acute sinusitis usually develops during course of a cold or flu and tends to be self-limited, lasting one to three weeks. Acute sinusitis is difficult to distinguish from primary illness. Symptoms include purulent nasal and postnasal discharge, a feeling of pressure over sinus area of the face, cough, and a nasal quality to the voice, and often a fever.
Acute sinusitis often progresses to the chronic state in which bacterial colonization occurs and the condition no longer responds to antibiotics. Ordinarily, surgery or drainage is required for successful management. Complications include flare-ups, local extension into the orbit, skull, meninges, or brain.
Most acute sinusitis is believed to be bacterial complications of viral cold. 5-10% result from infection originating from a dental source. The maxillary sinuses are close to the roots of the upper teeth so that dental infections can extend into these sinuses.

SPECIMEN COLLECTION

Maxillary sinus aspiration by puncture or surgically obtained need to placed in transport media or in syringe with sterile cap.

Sinus drainage is unacceptable because of probable contamination with aerobic and anaerobic normal respiratory flora.

GRAM STAIN

Make smear using according to the consistency of the specimen.

MEDIA

Routine: BAP, CHOC Agar, MAC, and ANA set up

INOCULATION

Inoculate the plated media. Lastly make a smear for Gram stain.

Inoculate ANA media as per anaerobe protocol.

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INCUBATION

Incubate BAP, CHOC, and MAC agar at 35 degrees Celsius in CO2 incubator.

Incubate ANA media in anaerobe jar or GasPak Pouch system at 35 degrees Celsius.

CULTURE EXAMINATION

24-hour evaluation

Examine all plated media for growth.

If no visible growth is observed, re-incubate.

Examine plates and daily for 6 days before discarding.

Culture with growth

Gram stain the broth if positive for growth.

Semi-quantitate growth on plated media.

Gram stain each morphotype, if applicable.

Identify all organisms and perform AST, if appropriate.

Organism Identification

Definitively identify clinically significant isolates.

Identify as per Lab protocol.

Susceptibility

Refer to AST Manual for appropriate procedures.

Perform beta-lactamase (Cefinase) on applicable isolates.

48-hour evaluation and older

Examine aerobic culture daily for 4 days. Examine anaerobes 6 days.

REPORTING RESULTS

Report new results and update results whenever available as preliminary results.
Report quantity along with organism name.

REFERENCE

Forbes, Betty, et al, Diagnostic Microbiology, 10th edition, The C.V. Mosby Co., St. Louis, 1998, pages 348-349.

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Policy Owner	M. Anwar Molani: Medical Director, Laboratory Services	2/23/2026
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L.MIC 7.20 Catheter Tip Cultures

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PRINCIPLE:

More than 3 million central venous catheters are used annually in the United States. Central venous catheters are used to administer fluids, blood products, medications, antibiotics, nutrition and for hemodynamic monitoring. One major consequence of these devices is colonization of the catheter by either bacteria or fungi, which can lead to serious bloodstream infections. The most common etiologic agents for IV catheter associated bloodstream infections are organisms found on the skin. Certain strains of **Staph. Epidermidis** appear to produce a biofilm or "slime" that consists of complex sugars that are believed to help the organism adhere to the catheter's surface.

Culture of intravascular catheter tips is performed to determine the source of a bacteremia and should be performed only when concurrent blood cultures are obtained. Laboratory confirmation of central catheter infection requires recovery of the same organism from a patient's blood and from cultures of the catheter tip and/or intracutaneous catheter segment.

SPECIMEN COLLECTION:

A. It is recommended to obtain two blood cultures, one through the catheter and one from a peripheral site at the time the catheter is submitted for culture.
B. Clean the skin with 70% alcohol prior to catheter removal.
C. Carefully remove the catheter from the patient with a sterile instrument, taking care to avoid contact with exposed skin. Holding the distal end over a sterile container, cut the tip with a sterile scissors, dropping the last 2 to 3 inches into the container.
D. Avoid drying by sealing the tube and submit to the laboratory as soon as possible.

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E. Rejection criteria

1. Catheter tips should not be placed in saline or transport medium.
2. Submit catheter tips only if there are signs of infection, i.e. fever, signs of sepsis, or documented bacteremia in which the source is not apparent. Patients suspected of having a central line infection should also have blood cultures done.
3. For ventricular-peritoneal shunts, peritoneal or spinal fluid is preferred to the catheter tip. If the tip is submitted, culture it, but request submission of fluid.

MEDIA:

BAP and CHOC
Olive oil- Decant olive oil into a sterile container for use, but there is no need to sterilize the oil.

PROCEDURE:

Semiquantitative method
Using a sterile forceps, remove catheter tip from transport tube.
Lay catheter tip on BAP or CHOC

Roll the tip back and forth across the entire surface of a BAP and CHOC using sterile forceps and exerting slight downward pressure.

If the tip is too long, using sterile scissors, cut the end closest to the top of the tube (proximal end) prior to rolling on the plates.

If the specimen is from the total parenteral nutrition or is the catheter tip from a hyperalimentation, culture also for **Malassezia furfur.**

1. Using a sterile pipette, add a small drop of olive oil to the initial area of roll after the inoculation of the blood plate.
2. Do not allow the oil to spread beyond a small area of the plate.

Incubate plates at 35 C in CO2.
Certain types of catheter tips require prolonged incubation. Cultures from central line and vascular catheter tips should be held for up to 4 days, mainly to look for yeasts, including **M. furfur,** which grow as pinpoint colonies in 3 days.
Anaerobic cultures from central nervous system shunt tips (e.g., ventriculoperitoneal and ventriculoatrial shunts) should be incubated for up to 14 days in order to recover important slow growing pathogens such as **Propionbacterium acnes.**

Read the semiquantitative plates at 24, 48, 72 and 96 hours.
Count each type of colony isolated, comparing growth on each medium. Only enumerate the

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growth on the BAP.
Identify to at least the genus level any of the following.
Each organism present with colony counts of >15 CFU, including gram positive rods.
For counts of <15 CFU, identify only significant pathogens (e.g. **Candida albicans,** group A streptococci, and gram negative rods).
Save plates with growth for 1 week for comparison in case blood cultures become positive.

Antimicrobial susceptibility testing should be performed on all significant isolates from vascular catheters or grafts and CNS shunts **when the same organism is identified from the patient's blood.**
Since catheter tip infections are due to the formation of a biofilm on the device, different morphotypes of the same organism may be recovered from the blood and the device. These morphotypes may have different antibiotic susceptibility profiles, and antibiotic therapy should be directed against the more resistant isolate.

REPORTING RESULTS:

The semiquantitative technique is reported to distinguish infection from contamination, with counts of >=15 CFU considered significant. Growth of more than 15 CFU is considered significant; i.e. it implicates the catheter tip as the likely source of a bacteremia **if a similar isolate is detected in a blood culture.**

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For any morphotype with a count of >15 CFU

1. Enter the number of CFU isolated for each organism: i.e., 18 CFU followed by the organism name, at least to the genus level.
2. For gram positive rods, report as "Coryneform rods; not otherwise specified"
3. If different morphologies of coagulase negative staphylococci are present, report "[number] CFU of coagulase negative staphylococci (mixed morphologies)."

If any morphology is <15 CFU

1. Report significant pathogen by name
2. Group together mixed skin microbiota organisms (i.e., coagulase negative Staphylococcus, diphtheroids, non-Candida albicans yeasts, Acinetobacter or viridians group streptococci) as, e.g., "25 CFU mixed skin microbiota."
3. Report minimal identification of pure cultures of skin microbiota as, e.g. staphylococci or gram positive rods

If organisms are too numerous to count, report as ">100CFU."

Report preliminary reports as "No growth at days.

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Report final negative cultures as, e.g., "No growth at 4 days.
If gram negative rods or Staph aureus is isolated and no blood culture was submitted, add the following note to the report: **"Submit blood cultures to diagnose catheter related sepsis."**

INTERPRETATION:
The presence of >15 CFU suggests the catheter as a potential source of bacteremia, which occurs with about 10% of colonized catheters.
Different bacterial morphotypes isolated from the blood and the catheter may only be recognized by variations in their antibiogram profiles. The antimicrobial therapy is directed against the most resistant morphotype isolated from either site. Antimicrobial susceptibility testing should be performed on isolates both from blood and from the catheter tip segments submitted to the lab for culture.

LIMITATIONS:
Semi quantitative catheter tip cultures are estimated to have a sensitivity of 85% in diagnosis of catheter related bacteremia, but the specificity to diagnosis of catheter related sepsis is low.
Blood cultures collected from peripheral sites are helpful in confirmation of the diagnosis of catheter related sepsis.
Infections of the catheter hub lumen may be missed by culture of only the tip.
Efforts to diagnose catheter related sepsis using unpaired quantitative blood cultures drawn from the catheter are less sensitive than tip cultures.
Catheter cultures may be helpful in determination of the cause of fever.
Siegman-Igra et al. suggest that antimicrobial treatments of patients with positive catheter tip cultures but negative blood cultures increases medical costs unnecessarily, because of the low specificity of catheter tip cultures. **For this reason, susceptibility testing of single catheter tip isolates in the absence of concomitant blood cultures is not indicated. If concomitant blood cultures are positive, antimicrobial testing of the blood isolate and the catheter tip isolated is appropriate.**

REFERENCES:

Forbes, Betty A et **al., Bailey & Scott's Diagnostic Microbiology,** 12th ed., 2007, Mosby, St. Louis, pp.781-789

Garcia, Lynne S., ed., **Clinical Microbiology Handbook,** 2nd ed., 2007 update, ASM Press, Washington D.C., pp. 3.6.1 to 3.6.5.

Murray, Patrick, et al., **Manual of Clinical Microbiology,** 9th ed, Volume 1, ASM Press, Washington D.C., 2007, p310.

Siegman-Ifra Y., A.M Anglim, D.E. Shaprio, K.A. Adal, B.A. Strain, and B.M. Farr, 1997, Diagnosis of vascular catheter related bloodstream infection: a meta-analysis, **J. Clinical Microbiology.** 35:928-936.

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Policy Owner	Erlinda Roxas: Director, Laboratory Services	2/23/2026

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L.MIC 7.22 Quantitative Cultures of Wound TIssues

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PRINCIPLE:

Tissues from acute wounds such as those from trauma and burn patients, and duodenal aspirates are the specimen types that may be used for quantitative microbiological analysis.

The presence of bacteria in tissue in significant amounts is one of several factors that have been associated with delayed healing and has also been correlated with infection.

Patients that were grafted when the wound biopsies were determined to be less than or equal to 10 to the fifth CFU's per gram of tissue had a 94% survival; those that had higher counts had less than 20% graft survival.

Beta hemolytic Streptococci has continually proven to be clinically significant at numbers that are much lower. The gold standard is to not execute a skin graft or close a wound in the presence of beta hemolytic Streptococci, regardless of the numeric assessment.

Quantitative cultures for anaerobic bacteria are problematic and thus less meaningful. Anaerobic microorganisms tend to live in microbial synergy with other organisms in the culture and do not grow well when diluted.

SPECIMEN COLLECTION:

Tissues

Submit 2 by 1 cm or larger tissue samples collected after cleansing and/or surgical debridement to yield the most useful information. This will yield approximately 500mg (0.5gm) of tissue, depending on the density.
Submit as soon as possible without transport medium, but keep moist in a sealed, sterile container.

Swab collection

Follow standard wound collection procedure.
Use only an alginate swab for qualitative culture.

REJECTION CRITERIA

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If insufficient specimen is received for quantitation, process the specimen for qualitative culture only.
Do not process dry swabs.

MEDIA:

Media:
BAP
CHOC
MAC
Thio or saline for dilution

PROCEDURE:

Tissues

Weigh the tube or petri dish containing the tissue on an analytical balance.

Remove the tissue by using aseptic technique and place it in either a different sterile petri dish or in 5 ml of sterile 0.85% NaCl or THIO. Use THIO only if anaerobic culture is performed..

Weigh the original tube or petri dish and subtract to determine the weight of the tissue in grams or

milligrams.

Homogenize the tissue in a disposable tissue grinder using small amount of saline from a. 5 ml of sterile 0.85% NaCl tube. After grinding, return contents of grinder to the 5 ml of sterile 0.85% NaCl tube. This is the ORIGINAL HOMOGENATE. This is a 1:5 dilution of tissue.

Plate 100ul (BLUE PIPETTE) of the original homogenate on the center of a BAP, CHOC, MAC. Label plates "10^{-1}" for amount of dilution of the original homogenate (which is a 1:5 dilution of the specimen).

Remove 0.5ml from a 5ml sterile 0.85% sterile NaCl tube and discard.

Make 1:10 dilution of the original homogenate by placing 0.5ml (YELLOWPIPETTE) of the homogenate into 4.5ml of sterile 0.85% saline.

Plate 100ul (BLUE PIPETTE) of the 1:10 dilution onto the center of BAP, CHOC and MAC. Label plates "10^{-2}". Evenly distribute the inoculums with the disposable bent rod.

Place 10ul (BLUE LOOP) of the 1:10 dilution on a BAP, CHOC, and MAC. Label the plates "10^{-3} dilution. Evenly distribute the inoculums with the disposable bent rod.

Place 1ul (GREEN LOOP) of the 1:10 dilution on a BAP, CHOC and MAC. Label the plates "10^{-4}" dilution. Evenly distribute the inoculums with the disposable bent rod.

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Repeat inoculations onto anaerobic media, if desired.

Incubate aerobic plates at 35 C in 5% CO_2 for 18-24 h. Use an anaerobic atmosphere for anaerobic plates.

Swabs

Place a swab in 5ml of 0.85% sterile NaCl solution. Vortex and remove remaining swab material (Swab should dissolve). This is the original homogenate to be used for "10^{-1}" and to make the 1:10 dilution (see #7)
As in procedure above, inoculate and process as with tissue.

Gram stains

Prepare Gram stain of tissue specimens by spreading 10ul aliquot of the homogenate on a 1 X 1 cm area of a glass slide.

Allow to dry, fix with methanol and Gram stain.

Examine 10 fields under 100 X oil immersion objective.

Organisms are visible in Gram stain when at least 10^5 organisms per gram of tissue are present in the specimen.
Examination of cultures: tissue and swabs

Read at 24, 48,72 hours.

Determine the number of organisms per gram of tissue by counting the colonies on the plate that grew between 30 and 300 colonies.

NOTE: Only use the MAC if overgrowth on the BAP or CHOC precludes accurate counting of gram-negative bacilli.

Calculate the total number of organisms by using the colony count times the dilution factor (use 5 as the factor for the homogenate dilution and the dilutions labeled on the plates for the subsequent dilution) divided by the original weight of the tissue.

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CALCULATIONS:

Example of calculation: tissue weighed 0.3gm
Count was 50 on plate labeled 10^3

$$\frac{50 \text{ CFU X } 5 \text{ (homogenate dilution) x } 10^3 \text{ (plate dilution)}}{0.3\text{gm}} = 2.5 \times 10^5 \text{ organisms}$$

$$\frac{}{0.3\text{gm}} = 8.3 \text{ X } 10^5 \text{ CFU/gm}$$

Report total count "per gram of tissue" or "per swab"
Work up pathogenic organisms for identification and AST according to wound culture procedure when count >10^5 organisms per gram. Special considerations must be made case by case for counts of <10^5 per gram depending on the identity of the isolates.

QUALITY CONTROL:

Verify that media meet expiration date and QC parameters per current CLSI M22 document.

Validate the method of quantitation using known cultures at various colony counts.

REPORTING RESULTS:

Report direct results of smears of tissues with enumeration of each morphotype (e.g. 0-1/OIF of gram-positive cocci in pairs)
Report wound cultures as total number of organisms per gram of tissue.
See wound procedure for reporting predominant species and performing AST

INTERPRETATION:

The probability that tissue from a traumatic wound or burn is infected or will fail to heal can be predicted from cultures showing >10^5organisms per gram of tissue.
Colony counts of approximately 10^5 CFU/gm of tissue were found to be equivalent to colony counts of 10^3 CFU/ml of specimen obtained on a moist **alginated** swab.

LIMITATIONS:

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These tests should only be done under certain circumstances and after consultation with the physician or clinical service.
Loops are not as accurate as pipettes to deliver the inoculums.
Spreading with a loop is not as accurate as spreading with a bent rod.
The lack of isolation of a pathogen does not mean that the laboratory was unable to detect the agent. Other inflammatory diseases can have the same presentation as infectious diseases, including the presence of PMN's on the Gram stain.

REFERENCES:

Bowler, P.G., Duerden, B.I., and Armstrong, D.G., **Wound Microbiology and Associated Approaches to Wound Management**, Clinical Microbiology Reviews, Volume 14, No. 2, April 2001, pp.244-269.

College of American Pathologists, Q&A – March 2005. www.cap.org.

Leber, Amy L et al., **Clinical Microbiology Handbook**, 4th edition, ASM Press, Washington D.C., 2016 3.13.2.1-3.13.2.4

Heggers, John P., PhD, Assessing and controlling wound infection, **Clinical Plastic Surgery**, 30 (2003), 25-35

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Hospital Administration	Jason Arimura: Associate Hospital Administrator, VCMC & SPH	3/2/2026
Policy Owner	Linda Conboy: Supervisor-Microbiology, Laboratory Services	3/1/2026
Policy Owner	M. Anwar Molani: Medical Director, Laboratory Services	2/23/2026
Policy Owner	Erlinda Roxas: Director, Laboratory Services	2/23/2026

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L.MIC 7.24 Candida auris Surveillance Screen

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PURPOSE

Candida auris is an emerging health care-associated pathogen that represents a serious multi-drug resistant (MDR) global threat. Though the organism often presents fewer virulence factors than Candida albicans, C. auris may persistently colonize the skin and hospital environment, making its transmission within and between health care settings more difficult to control. C. auris fungemia results in a wide range of mortality rates (from 32%-66%), depending upon the patient's overall condition, underlying disease, geographic region, access to medical care, and age.

Patients or residents of health care facilities can be asymptomatically colonized with C. auris, meaning they have it on their body but without causing an infection. They can subsequently spread the fungus to other patients through contaminated surfaces (e.g., bed rails, bedside tables), shared mobile medical equipment (e.g. glucometers, ultrasound machines) or the hands or clothing of health care personnel. Screening patients for C. auris is an important way to prevent spreading health care facilities. Screening identifies patients with C. auris so that special precautions can be taken to prevent spread and to help guide infection prevention and control strategies in health care facilities.

PRINCIPLE

Hardy Diagnostics HardyCHROM™ Candida + auris is recommended as a medium for the primary, selective isolation and differential identification of Candida species. The medium allows for the differentiation of C. albicans, C. tropicalis, C. krusei, and C. auris based on colony morphology, color, and positive UV fluorescence. Chloramphenicol is added as an inhibitory agent against the growth of most bacteria, which may be present in the sample.

HardyCHROM™ Candida + auris is a selective and differential medium containing chromogenic substrates. After degradation by specific enzymes, the substrates release different colored compounds. Certain species or groups of organisms can then be differentiated with a minimum number of confirmatory tests. Colonies

of C. albicans will appear green to dark metallic green. Colonies of C. tropicalis will appear medium blue to dark metallic blue with a blue halo. Colonies of C. krusei will appear flat, often rough or crenated, and pink to medium pink in color. Colonies of C. auris will appear white with a characteristic teal to teal green "bullseye" center. Other species will appear pink, often with a darker mauve center (e.g. C. glabrata and other species). Other yeasts may appear from white to pink. Most typical yeast colonies tested for fluorescence at 48 hours using a UV lamp at 365nm will be negative, except for C. auris which will be positive at 48-72 hours.

Yeast colonies growing on the Candida + auris plate can then be isolated on Sabouraud Dextrose Agar (SabDex) and tested by Vitek MS Prime MALDI-TOF to confirm identification.

SPECIMEN COLLECTION, TRANSPORT, AND HANDLING

Site of collection is axilla/groin, both with a single swab.

Specimens received for testing must be labeled with patient demographics, date, time of collection, collector, and site of collection.

Collect patient skin swabs using ESwab collection and transport system containing 1.0 mL of Amies buffer. Eswabs are documented to be stable for up to 96 hours.

Carefully remove ESwab from its packaging without touching the soft tip. **Use the same swab to**:

Swipe all sides of swab tip back and forth 5 times over left axilla skin surface. Target the crease where the arm meets the body. Repeat on the right.

Swipe all sides of swab tip back and forth 5 times over left groin skin surface (inguinal crease in the skin where the leg meets the pelvic region). Repeat on the right.

After the specimen is collected, the swab should be placed into the tube containing the Amies buffer and stored at 4°C–25°C and transported to the laboratory for processing within 2 hours.

Minimum requirements identifying patient risk groups that necessitate Candida auris Screen:

Patients coming from high acuity post-acute care facilities including long-term acute care hospitals and ventilator-capable skilled nursing facilities admitted to the Intensive Care Units.

Patients with high risk and admitted to other locations. Patients with risk factors for acquiring C. auris include:

Mechanical ventilation

Indwelling medical devices, including central lines, feeding tubes, urinary catheters, etc.

Receipt of complex or high acuity medical care

Frequent or long healthcare stays, especially at high-risk facilities

MATERIALS AND SUPPLIES

HardyCHROM™ Candida + auris

On receipt, **store plates in the dark at 2-8°C in original sleeve wrapping and original cardboard box until time of inoculation**. Prolonged exposure to light (>4 h) may result in reduced recovery and/or coloration of

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the QC organisms or patient isolates. Plates may be used up until the expiration date.

Media should appear opaque and white in color and should not be used if there are any signs of deterioration (shrinking, cracking, or discoloration), contamination, or if the expiration date has passed.

Sabouraud Dextrose Agar for isolation

Vitek MS Prime MALDI-TOF

QUALITY CONTROL

Upon receipt, examine plates for signs of deterioration (drying, cracking) or contamination.

Tests each lot of commercially manufactured media using appropriate quality control microorganisms and quality specifications as outlined in the CLSI document M22-A3 Quality Assurance for Commercially Prepared Microbiological Culture Media Inoculation Method B.

QC Organism	Incubation Time/Temp	Results
Candida albicans ATCC® 10231	24-48hr 35°C	Growth; smooth, emerald, green to dark metallic green colonies; negative UV fluorescence
Candida auris CDC B11903	24-48hr 35°C	Growth; smooth, white colonies with teal to teal-green bullseye" center; positive UV fluorescence
Escherichia coli ATCC® 25922	24-48hr 35°C	Partial to complete inhibition; negative UV fluorescence

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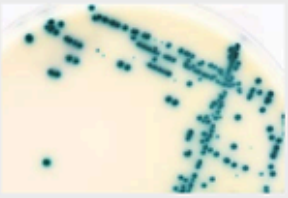
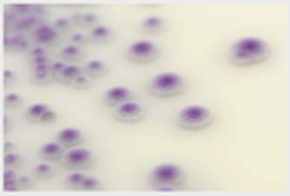
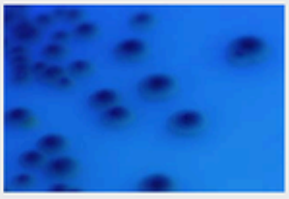
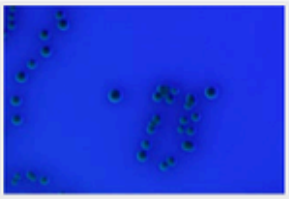
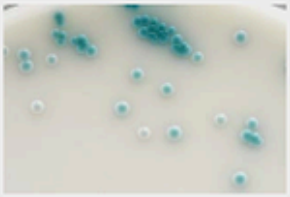
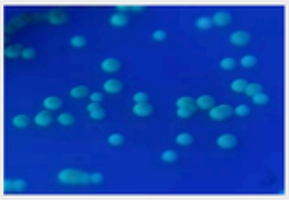
PROCEDURE

Allow plates to warm to room temperature. The agar surface should be dry prior to inoculating.

Roll the swab over a small area of the agar surface. Streak for isolation with a sterile loop.

Incubate plates in an inverted position, protected from the light, aerobically at 35ºC for up to 72h.*

Organism	48hr Reaction	48hr Appearance	48hr Fluorescence
Candida albicans	Medium, smooth, green to dark metallic green colonies; negative Fluorescence		
Candida tropicalis	Medium, smooth, medium blue to dark metallic blue colonies, with a blue halo; negative Fluorescence		
Candida krusei	Large, flat, spreading, often rough or crenated, pink to medium pink colored colonies; negative Fluorescence		
*Candida glabrata**	Medium, smooth, pink colonies, often with a darker mauve center; negative Fluorescence		
*Candida auris***	Medium, smooth white colonies with a teal to teal-green "bullseye" center; positive Fluorescence		

- In instances where C. auris is suspected, it is recommended to extend the incubation period to at least 72 hours.

** Full color development may take up to 72 hours for slow growing strains or for strains from mixed specimens.

EXAMINATION OF CULTURE MEDIA

Examine plated media for macroscopic evidence of growth at 24 hours.

If no visible growth is observed on the culture media and re-incubate

a. Read aerobic plates daily for up to 72h.

Colonies of C. auris will appear as smooth, white colonies with teal-to-teal green "bullseye" center. Most typical yeast colonies tested for fluorescence at 48 hours using a UV lamp at 365nm will be negative, except for C. auris which will be positive at 48-72 hours.

Yeast colonies suspicious Candida auris will be subbed to a SabDex Agar plate and tested by Vitek MS Prime to confirm identification.

REPORTING RESULTS

Positive culture result is to be reported as Candida auris isolated.

Positive culture result is to include the following text, ***C. auris isolated. Please check infection control policy regarding contact isolation. ***. (MCACOM)

Positive culture results must be called to a licensed caregiver and documented (MCAURCALL).

Hold positive culture for 7 days.

Negative cultures are to be reported as No Candida auris isolated (MNCA).

LIMITATIONS

Minimize exposure (>4 h) of HardyCHROM™ Candida + auris to light both before and during incubation, as prolonged exposure may result in reduced recovery and/or coloration of isolates. Keep plates within the original sleeve wrapping in the dark for the entire storage and incubation period.

Other rare Candida species, as well as non-clinical yeast species, may exhibit fluorescence under UV light, but will not exhibit the characteristic white colonies with teal-to-teal green "bullseye" centers at 48 to 72 hours indicative of C. auris.

C. haemulonii, which has been commonly misidentified for C. auris, exhibits fluorescence under UV light but produces white colonies at 48 hours. C. haemulonii will eventually produce light pink or mauve colonies when incubated for longer than 48 hours. Colonies will be positive for UV fluorescence

Surveillance testing determines the colonization status at a given time and could vary depending on patient treatment, patient status or exposure to high-risk environments. Monitoring colonization status should be done according to hospital policies.

Results from HardyCHROM™ Candida + auris should be used as an adjunct to nosocomial infection control efforts to identify patients needing enhanced precautions. The test is not intended to identify patients with C. auris infection. Results should not be used to guide or monitor treatment for Candida auris infections. This device can be used to identify patients for isolation or removal from isolation to control nosocomial transmission of Candida auris.

REFERENCES

1. Centers for Disease Control and Prevention. (n.d.). *Screening for C. auris*. Centers for Disease Control and Prevention. https://www.cdc.gov/candida-auris/screening/index.html
2. Marathe, A., Y. Zhu, V. Chaturvedi, S. Chaturvedi, *Utility of CHROMagar™ Candida Plus for Presumptive Identification of Candida Auris from surveillance samples*. Mycopathologia, November 2022 187:527-534.
3. HardyCHROM™ Candida + auris, Instructions for Use, Hardy Diagnostics, IFU-000801[F], 2020

COPY

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3/2/2026

Approval Signatures

Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator, VCMC & SPH	3/2/2026
Policy Owner	Linda Conboy: Supervisor-Microbiology, Laboratory Services	3/1/2026
Policy Owner	M. Anwar Molani: Medical Director, Laboratory Services	2/23/2026
Policy Owner	Erlinda Roxas: Director, Laboratory Services	2/23/2026

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Owner	Linda Conboy: Supervisor-Microbiology, Laboratory Services
Policy Area	Laboratory Services - Microbiology

L.MIC 7.25 Methicillin Resistant Staphylococcus Aureus Admission Screening by Culture

COPY

PRINCIPLE

CHROMagar MRSA is a selective and differential medium for the qualitative direct detection of nasal colonization by methicillin resistant *Staphylococcus aureus* (MRSA) to aid in the prevention and control of MRSA infections in healthcare settings. The test is performed on anterior nares swab specimens to screen for MRSA colonization.

MRSA are a major cause of nosocomial and life-threatening infections. Infections with MRSA have been associated with a significantly higher morbidity, mortality and costs than methicillin-susceptible Staph *aureus* (MSSA). To control the transmission of MRSA, the Society for Healthcare Epidemiology of America (SHEA) has recommended guidelines, which include an active surveillance program to identify potential reservoirs and a rigorous infection control program to control the spread of MRSA. SB1058 has now mandated MRSA surveillance for those hospital patients deemed at risk.

BBL CHROM agar MRSA medium permits the direct detection and identification of MRSA through the incorporation of specific chromogenic substrates and cefoxitin. MRSA strains will grow in the presence of cefoxitin and produce mauve-colored colonies resulting from hydrolysis of the chromogenic substrate. Additional selective agents are incorporated for the suppression of gram-negative organisms, yeast and, some gram- positive bacteria.

BBL CHROM agar MRSA is not intended to diagnose MRSA infection nor to guide or monitor treatment of infection.

SPECIMEN COLLECTION AND HANDLING:

On admission, within 24 hours, a culture of the anterior nares will be performed on qualifying patients according to Senate Bill 1058
Transport nasal swab to the laboratory within two hours (inpatient) or within twenty-four hours (outpatient).
Do NOT refrigerate the specimen.

Minimum requirements identifying patient risk groups that necessitates MRSA admission Screen:

Patients readmitted within 30 days of discharge from any acute care hospital.

Patients received from Skilled Nursing Facility or Rehab facility.

Patients admitted to Intensive Care Units.

Patients scheduled for inpatient surgery have documented medical conditions that would increase susceptibility to infection.

Patients receive inpatient dialysis treatment.

Patients with a negative MRSA swab whom the licensed provider feels are at increased risk of invasive MRSA should be retested for MRSA prior to discharge.
MRSA Screening and Management for High Risk Surgeries
All patients scheduled for high-risk surgeries will be screened for MRSA colonization within 48 hours prior to surgery whenever possible. If patient is not screened prior, patient will be screened in pre-op and treated empirically pending results.
Additional screening may be performed at the discretion of the surgeon or based on patient risk factors (e.g., recent hospitalization, known MRSA history, or immunocompromised state).

MATERIALS AND STORAGE :

CHROMagar MRSA

On receipt, **store plates in the dark at 2-8°C in original sleeve wrapping and original cardboard box until time of inoculation**. Prolonged exposure to light (>4 h) may result in reduced recovery and/or coloration of the QC organisms or patient isolates. Plates may be used up until the expiration date.
INOCULATION

Allow the medium to warm to room temperature in the dark before inoculation (<4h)
Incubate plates aerobically at 35-37°C for 20-26 h in an inverted position
Product Deterioration*:* Do not use plates if they show evidence of microbial contamination, discoloration, drying, cracking or other signs of deterioration.

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PROCEDURE and INTERPRETATION

20-26 h incubation	Interpretation/Recommended Action
Mauve colonies morphologically resembling staphylococci	Perform gram stain, catalase, and coagulase tests. If gram positive cocci, catalase positive, and coagulase positive, Interpretation is to be reported as MRSA isolated. (MRSA ISO). Add 1) MMRSACOM 2) MMRSACALL
Non-mauve colonies detected	Negative-No MRSA detected (MNMRSA)
No growth	Negative-No MRSA detected (MNMRSA) A negative result does not preclude MRSA nasal colonization. If MRSA is suspected, an alternate method for confirming MRSA should be used.

Ancillary culture media (BAP or CNA agar),
Staphylococci typically produce moderately sized smooth mauve colonies on BBL CHROM agar MRSA medium. Mauve colonies which are very small to pinpoint are most often gram-positive rods, usually corynebacteria. If morphology is unclear, confirmatory tests such as gram stain and coagulase may be used.

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QUALITY CONTROL:
Check each lot/shipment for performance each lot/shipment by inoculating a plate with pure cultures of stable control organisms.

Read plates against a white background. Colonies of MRSA will appear mauve on the CHROMagar MRSA medium. Other organisms (non-MRSA) will be inhibited or produce colorless, white, blue, or blue/green colonies.

Test Strain	*Expected Results*
Staphylococcus aureus ATCC 25923	No growth
Staphylococcus aureus ATCC 43300	Growth with mauve colonies

LIMITATIONS

Minimize exposure (>4 h) of BBL CHROMagar MRSA to light both before and during incubation, as prolonged exposure may result in reduced recovery and/or coloration of isolates. Keep plates within the original sleeve wrapping and cardboard box for the entire storage and incubation period.

At 24h *Staphylococcus simulans, S. epidermidis, and methicillin-susceptible Staphylococcus aureus* may also produce mauve colored colonies requiring a confirmatory coagulase test for confirmation of MRSA. In clinical studies, approximately 5% (6/120) of the mauve- colored colonies detected at 24 h were coagulase-negative staphylococci and/or corynebacteria on the

BBL CHROMagar MRSA medium. If desired, a coagulase test and PBP2 may be performed on mauve-colored colonies to increase specificity.

Surveillance testing determines the colonization status at a given time and could vary depending on patient treatment (e.g. decolonization regime), patient status (e.g. not actively shedding MRSA) or exposure to high-risk environments (e.g. contact with MRSA carrier, prolonged hospitalization). Monitoring colonization status should be done according to hospital policies.

Results from CHROMagar MRSA should be used as an adjunct to nosocomial infection control efforts to identify patients needing enhanced precautions. The test is not intended to identify patients with staphylococcal infection. Results should not be used to guide or monitor treatment for MRSA infections. This device can be used to identify patients for isolation or removal from isolation to control nosocomial transmission of MRSA.

A CHROMagar MRSA negative result following a previous positive test result may indicate treatment eradication success or may occur due to intermittent shedding

Rare strains of MRSA have demonstrated sensitivity to the CHROMagar MRSA base. This sensitivity is unrelated to methicillin resistance but is due to a component in the base. As a result, these strains may appear as falsely susceptible to methicillin.
Incubation in CO2 is not recommended and may result in false negative cultures.

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REFERENCES

BD Diagnostics BBL CHROM agar MRSA, May 2006.

MRSA. Methicillin Resistant *Staphylococcus aureus:* Fact Sheet. CDC website, http://www.cdc.gov/ncidod/hip/Aresistlmrsafaq.htm.

Proportion of S. *aureus* Nosocomial Infections Resistance to Oxacillin (MRSA) AmongIntensive Care Unit Patients, 1989 .2003 (graph).
CDC website, http://www.cdc.gov/ncidod/hip/ARESIST/ICUIvII{SA.pdf

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Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator, VCMC & SPH	3/2/2026
Policy Owner	Linda Conboy: Supervisor-Microbiology, Laboratory Services	3/1/2026
Policy Owner	M. Anwar Molani: Medical Director, Laboratory Services	3/1/2026
Policy Owner	Erlinda Roxas: Director, Laboratory Services	2/28/2026

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Policy Area	Laboratory Services - Microbiology

L.MIC 7.26 Group B Streptococcus Cultures

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PRINCIPLE:

Group B Streptococcus (GBS) has been recognized as the leading cause of perinatal morbidity and mortality in the United States. The primary risk factor for early-onset GBS disease is maternal colonization with GBS. Colonization occurs in about 10%-30% of pregnant women. Intra partum antibiotic prophylaxis (IAP) is highly effective at preventing early-onset GBS disease among infants born to colonized women. Early-onset neonatal disease (during the first week of life) results from the transmission of GBS during labor or delivery from mother to infant. The disease is characterized by septicemia, pneumonia, or meningitis and can result in death or permanent neurological disease. In 1996 and 1997, the CDC issued guidelines that included culturing all women in risk groups at 35 to 37 weeks of gestation to identify carriers for whom treatment would most likely prevent disease. The rationale for this timing is that it is the colonization at the time of delivery that is associated with the disease. In 2002, CDC issued new guidelines stating the need for doing culture and providing more exact details for the culture techniques. A pre incubation step in a selective broth containing antimicrobials was included as part of the guidelines, because it is the most sensitive culture method.
Strep B carrot broth has sensitivity comparable to that of standard selective broth but improved test turnaround time because GBS can be directly reported based on the production of orange, red, or brick red pigment which is a unique characteristic of hemolytic GBS due to reaction with substrates such as starch, proteose, peptone, serum, and folate pathway inhibitors. At 24 hours, chromID Strepto B agar is inoculated from the broth as a selective chromogenic medium used to facilitate the observation of S. agalactiae based on the appearance of pale pink to red colonies.

SPECIMEN COLLECTION:

Collect specimen at 36 to 38 weeks' gestation. The optimum specimen for this test is a vaginal/rectal swab. Using a single swab or two separate swabs, swab the lower vagina followed by the rectum (i.e., insert swab through the anal sphincter).
Results may be compromised if only a vaginal swab is submitted.
If symptoms of sepsis or amnionitis are present; also submit amniotic fluid, blood, or urine for cultured.
Label the specimen and accompanying requisition with demographic information of the patient, collector, collection date and time, and source.

Specimen Handling and Transport

The laboratory should be notified if the patient is allergic to penicillin because testing for **clindamycin, inucible clindamycin resistance , and vancomycin** should be routinely performed in these cases.
Transport swabs as soon as possible. Although GBS isolates may remain viable in transport media for several days at room temperature, the ability to isolate this organism declines over 1-4 days, especially at increased temperatures.
Store at room temperature (25 degree C) or refrigerate (at 4 degree C).
Note: According to an alert from the CDC on 24 March 1997, gravely erroneous information and potentially fatal misdiagnosis can result from the use of direct antigen testing to detect GBS directly in urine of pregnant women and infants.

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MATERIALS:

Group B Carrot Broth
Modification of Granada medium that detects GBS based on a hemolytic strain's unique ability to react with substrates present in the broth.
Agar media
BAP
CHROMagar StrepB agar-chromogenic medium for the selective and differential screening of *S. agalactiae*
Columbia colistin-naladixic acid agar (CNA)
Identification methods
Gram stain
Catalase test
One of the following:
Latex test of streptococcal grouping

Other supplies/equipment
Incubator at 33-37 C
Disposable cards for serologic tests

QUALITY CONTROL:

Verify that media meet expiration date and QC parameters per current CLSI Document M22-A3.
Perform QC with each lot of both selective streptococcal broth and agar that contain antimicrobial agents (excluding CAN). Incubate aerobically overnight at 35°
Test a known positive and negative control for CAMP reaction each day of use.
Refer to the individual biochemical test procedures for further QC requirements

PROCEDURE:

INOCULATION:

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Inoculate StrepB Carrot Broth from the swab
Optional, in addition to the broth inoculation: inoculate CNA with swab immediately upon receipt if the patient is hospitalized.
Note: Dunne and Holland-Staley have shown that the addition of a selective direct plate to the broth culture increased detection by 15%, because *Enterococcus faecalis* can overgrow in the broth cultures and inhibit the growth of *S. agalactiae*.

INCUBATION:

Incubate broth at 35-37° C in ambient air for 18-24 hours
Observe for an orange color in the broth. This is representative of a positive result
Subculture to BAP only if there is an orange color change (indicating a positive result)
Subculture the broth to a BAP and CHROMagar StrepB after 18-24 hours *if* there is no color change.
Incubate plated media at 35C in ambient air for 18-24 hours **in the dark.** If no typical colonies are observed at 24 hours, prolong incubation up to 48 hours.

CULTURE EXAMINATION:

Observe Blood agar plate (and CNA if applicable) at 24 and 48 hours for large, gray, translucent colonies with a small zone of beta-hemolysis or no zone of hemolysis. On chromID StrepB agar,

Streptococcus agalactiae will appear as pale pink to red, round and pearly.
Perform catalase test
Perform Gram stain if catalase negative
Identify gram positive cocci in pairs and chains as **Strep agalactiae** if they are catalase negative and demonstrate one of the following reactions.
Identification on MS PRIME or Vitek GP card
Positive with group B streptococcal grouping antisera

Inducible Clindamycin Resistance

Testing for inducible clindamycin resistance should be performed on highly penicillin allergic women. Inducible clindamycin is performed by placing erythromycin and clindamycin disks 12mm apart. Only the results of clindamycin should be reported. Erythromycin should not be reported and is tested only for the purpose of determination of possible inducible clindamycin resistance.
Perform disk diffusion testing for susceptibility to clindamycin and erythromycin and vancomycin on request for highly penicillin-allergic patients. **Place disks 15-26 mm apart**.
If AST is not performed, hold positive cultures plates for 7 days in case susceptibilities are needed later.

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REPORTING RESULTS:

Negative results
A negative broth culture at 18-24 hours should be documented with a preliminary result of Culture pending. Final report to follow (MCP)
If the plated media is negative at 24 hours, report "No Group B Streptococcus isolated to date. Culture held 2 days." (MNBBSTD).
If the plated media is negative at 48 hours, report "No Group B Streptococcus isolated" (MNBBS). This is a final report.

Positive results
For positive carrot broth at 24 hours, report "Group B Streptococcus detected. Culturepending"
For positive carrot broth at 24h report "Group B Streptococcus detected".
For positive culture at 48-hours report "Group B Streptococcus isolated" and MAST10. Do not enumerate.
NOTE: If the patient has been admitted to the hospital, notify the physician or nurse of the positive results, and document the notification.

Penicillin allergic Patient
Routinely report clindamycin results for all patients with a severe penicillin allergy after determination of possible inducible clindamycin resistance as outlined below.
Report a zone size of >=19 mm with the clindamycin disk and no inhibition or flattening with the erythromycin disk as susceptible to clindamycin. Do not report erythromycin.
Report a zone size of >=17 mm with the vancomycin disk as susceptible to vancomycin.

INTERPRETATION:

A positive culture indicates colonization with the organism, which may or may not indicate infection.
Although 20% of women have genital colonization with GBS, vaginal-rectal colonization with group A streptococci is rare (<1%), so group A streptococci are not routinely screened for in late pregnancy. However, isolation of group A streptococci from vaginal-rectal cultures from prenatal women should be reported because of the risk of developing puerperal sepsis.
For women with sever penicillin allergy, clindamycin or vancomycin is used. Due to the increase in worldwide resistance to erythromycin, this agent should not be used for prenatal prophylaxis.

LIMITATIONS:

Although rare, a small percentage of GBS may not produce beta hemolysis. GBS detection with the Strep B Carrot Broth kit is only possible with beta-hemolytic colonies. For this reason, it is necessary to subculture to BAP and CHROMagar StrepB to rule out the possibility of the presence of a non-hemolytic GBS.
Certain species which are resistant to the antibiotics on the CHROMagar StrepB agar may develop and produce colonies of a characteristic color (e.g. S.pyogenes)
CHROMagar StrepB agar medium should not be exposed to light apart from during the inoculation and reading steps (maximum of 4 hours).

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REFERENCES:

CHROMagar StrepB agar, Biomerieux, REF 43 461, product circular, 2011/01
Clinical and Laboratory Standards Institute **, Performance Standards for Antimicrobial Susceptibility Testing**; 31st Informational Supplement, , M100-S31, January 2021

Dunne WM, Jr. Holland-Staley CA. 1998 Comparison of NNA agar culture and selective broth culture for detection of froup B streptococcus colonization in women. J Clin Microbiol, 36:2298-2300

Forbes, Betty A. **Bailey & Scott's Diagnostic Microbiology,** 13th ed., Mosby, St. Louis, 20014.

Hardy Diagnostics, **Strep B One Step Carrot Broth**, , REF Z140 product circular, 2016

Leber Amy L. **Clinical Microbiology Procedures Handbook**, Volume 1, Fourth Edition, ASM Press, Washington D.C., 2007, pp3.9.2.1-3.9.2.5.

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Hospital Administration	Jason Arimura: Associate Hospital Administrator, VCMC & SPH	3/2/2026
Policy Owner	Linda Conboy: Supervisor-Microbiology, Laboratory Services	3/1/2026
Policy Owner	M. Anwar Molani: Medical Director, Laboratory Services	2/28/2026
Policy Owner	Erlinda Roxas: Director, Laboratory Services	2/28/2026

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VENTURA COUNTY HEALTH CARE AGENCY

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Owner	Linda Conboy: Supervisor-Microbiology, Laboratory Services
Policy Area	Laboratory Services - Microbiology

L.MIC 7.27 Throat Culture for Gonorrhoeae

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PRINCIPLE

A good selective medium is essential for reliable isolation of gonococci from pharyngeal specimens, which contain a variety of microorganisms including saprophytic **Neisseria** spp. Methods for the identification of **Neisseria gonorrhoeae** from extra-genital sources, such as the oropharynx ,must be chosen and performed with the utmost care, since a positive report can have far-reaching psychosocial and medico-legal implications

SPECIMEN COLLECTION & TRANSPORT

Swabs of the tonsillar and posterior pharynges should be collected.
Refer to Specimen Collection & Handling Procedure Manual.

MATERIALS

Media
Modified Thayer-Martin Agar

Reagents
Gram stain reagents
Oxidase Reagent

VITEK NH CARD

PROCEDURE

Culture Evaluation

Examine the cultures after overnight incubation and after 48 and 72 hours. Return culture plates to the incubator as soon as possible to minimize autolysis of gonococci in the absence of CO_2.
Typical colonies are small, translucent, raised, gray, and mucoid with entire margins. When picked from the agar surface, they tend to come off as whole colonies. Pick typical colonies to perform a Gram Stain and an oxidase test.
If the Gram stain reveals gram-negative diplococci with flattened adjacent sides and the oxidase test is positive, proceed with confirmatory testing.
Subculture for isolation onto Chocolate Agar Plate, Thayer Martin Plates for VITEK NH ID testing and additional send out testing.

FROM EXTRAGENITAL SOURCES:

TWO confirmatory tests that use distinct identification methods are required. Isolate must be sent out for definitive identification.

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RESULTS

The culture report should include one of the following:

Presumptive **Neisseria gonorrhoeae** isolated. Specimen referred to reference laboratory for confirmatory identification.

"No **Neisseria gonorrhoeae isolated** .(MNGC)

"Specimen overgrown by normal microoorganisms. Please submit another specimen." Issue this report when the culture plate was grossly overgrown to the extent that underlying organisms could not be detected.

"Specimen contaminated with yeast cells." This can be added to reports of those with yeast cells, since yeast cells lower the pH of the medium and thus inhibit the growth of **Neisseria gonorrhoeae.**

"Unsatisfactory specimen. Please submit another specimen." Issue this report when dry swabs or

damaged specimens are received or when unacceptably long delays in specimen transport are evident (longer than 24 hour time lapse from collection time).

REFERENCES

1. Isenberg, Henry D. et al, **CMPH**, 1992, Volume I, ASM, Washington, D.C., pages 1.14.4 to 1.14.8.
2. Isenberg, H.D., 2004, **Clinical Microbiology Procedures Handbook**, 2nd ed., ASM Press, Washington D.C.
3. Remel, NET, REF R211173, product circular, July 26, 2010

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Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator, VCMC & SPH	3/2/2026
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Policy Area	Laboratory Services - Microbiology

L.MIC 7.28 Respiratory Tract Cultures

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PRINCIPLE

Infections of the lower respiratory tract are the sixth leading cause of mortality in the United States, with 2,000,000 to 3,000,000 cases per year, resulting in 500,000 hospitalizations. For community-acquired pneumonia (CAP) in adults and the elderly, Streptococcus pneumoniae is the cause in 6 to 10% of all cases and 60% of the bacterial cases, hence the utility of the pneumococcal vaccine to prevent this disease.

Culture of lower respiratory secretions can be helpful, but in reality, it is limited, with no agent isolated in 40 to 60% of cases. This lack of culture sensitivity may be due to the low sensitivity (50%) of sputum culture for S. pneumoniae, especially if specimens are not immediately processed. Many agents of pneumonia are difficult to grow (e.g., Legionella, Chlamydia pneumoniae, and Mycoplasma pneumoniae). In addition to the difficulty in culturing the pathogens, specimens are easily contaminated with upper respiratory secretions, which may obscure the presence of lower respiratory pathogens.
S. pneumoniae continues to be the most common agent of CAP but incidence of this infection is declining due to the widespread use the pneumococcal vaccine. Other important CAP agents include Klebsiella pneumoniae, Haemophilus influenzae, Moraxella catarrhalis, L. pneumophilia, M. pneumoniae, and C. pneumoniae. Additionally, methicillin resistant Staphylococcus aureus (MRSA) is being recognized as an increasingly important cause of CAP.

The sputum Gram stain has variability in sensitivity and specificity, depending on the specimen and the skill of the reader. The proper evaluation of the specimen by Gram stain is critical and is used to ensure that only appropriate specimens are processed.
Nosocomial pneumonia can be caused by many pathogens, including anaerobes, as in aspiration

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pneumonia. Gram-negative rods including Pseudomonas aeruginosa, K. pneumoniae, Escherichia coli and Acinetobacter baumannii, and S. aureus (especially MRSA) are common causes of ventilator-associated pneumonia (VAP), particularly in patients that have had a prolonged hospital course. Patients with severe CAP, immunocompromised patients with progressive pneumonia, or those with other types of nosocomial pneumonia (e.g., postoperative, or medial hypostatic) may also develop respiratory failure and require ventilator support. Diagnosis of the microbial pathogens causing VAP requires pulmonologists or intensivists to perform a bronchoalveolar lavage (BAL) for collection of samples from the alveoli of the lung, including protected brush specimens for anaerobic culture. Refer to Quantitative Cultures of BALs and PBS for detailed procedure.

SPECIMEN COLLECTION, TRANSPORT, AND HANDLING

Collection of sputa, ET tube aspirates, and auger suction specimens

Expectorated sputum

Do not have the patient rinse mouth and gargle with nonsterile water prior to sputum collection since this can introduce contaminating microbiota.
NOTE: Commensal mycobacteria from tap water can contaminate mycobacterial cultures but are rarely an issue for routine bacteriology.culturing. For specialized cultures (e.g., mycobacteria and legionellae), supply sterile saline or water to gargle prior to collection. Instruct the patient not to expectorate saliva or postnasal discharge into the container.
Collect expectorated sputum specimens into a sterile container with a screw cap that is tightly secured prior to transport.
The specimen should have a label that provides the sample type (i.e., ET tube aspirate, auger suction versus expectorated or induced sputa), date and time of collection, and the same patient demographic information as that provided on the requisition.

Induced sputum

NOTE: Induced sputa should only be tested for the presence of Mycobacterium tuberculosis or another Mycobacterium spp.
Using a wet toothbrush and sterile water or saline, brush the buccal mucosa, tongue, and gums for 5 to 10 min prior to the procedure. Do not use toothpaste.
Rinse the patient's mouth thoroughly with sterile water or saline.
Using an ultrasonic nebulizer, have the patient inhale approximately 20 to 30 ml of 3% NaCl.
Collect induced sputum specimens into a sterile container with a screw cap that is tightly secured prior to transport.
The specimen should have a label that provides the sample type (i.e., ET tube aspirate, auger suction versus expectorated or induced sputa), date and time of collection, and the same patient demographic information as that provided on the requisition.

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ET tube aspirates and auger suction specimen

Aspirate the specimen into a sterile sputum trap (i.e., Luken trap) and aseptically transfer the sputum sample to a sterile screw-cap container with the cap tightly secured before transport. Luken traps frequently leak.
Neonates, infants, and small children cannot provide an expectorated sputum sample, so a sample is collected from the upper airway using an auger. Frequently, a very small amount of secretions or sputum is obtained by this method, so the sample may be submitted in the catheter in a sterile container.
The specimen should have a label that provides the sample type (i.e., ET tube aspirate, auger suction versus expectorated or induced sputa), date and time of collection, and the same patient demographic information as that provided on the requisition.

Transport of sputa, endotracheal aspirates, and auger suction specimens

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Minimum volume of 1.0 ml is required. Since the samples are not placed into buffered transport media, it is important that they be received and handled by the laboratory as soon after collection as possible.
Store sputum specimens at 2 to 8 C until samples can be transported or processed by the laboratory
NOTE: A delay in processing of more than 2 h may result in a decreased ability to recover fastidious pathogens, such as S. pneumoniae and H. influenzae, and/or overgrowth of upper respiratory microflora.
Sputum samples should be placed into biohazard bags prior to transport to minimize contamination of the external environment if leakage occurs during transport.

MATERIALS

Direct tests
Gram stain
Primary media
BAP
CHOC
MAC or EMB
Other supplies/equipment
Incubator at 35 C with 5% CO2 or other CO2-generating system
Inoculating sticks and loops

QUALITY CONTROL

Verify that media meet expiration date and QC parameters per current CLSI M22 document.

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REJECTION CRITERIA BASED ON GRAM STAIN

Do not reject sputum and endotracheal aspirates for culture for Legionella or AFB or specimens from cystic fibrosis patients.

Examine 20 to 40 fields from sputum smears under low power and endotracheal smears under both low power and oil immersion using an 18- to 22-mm lens field of view. Average the number of cells in representative fields that contain cells.

Reject the following for culture, as poorly collected or not consistent with a bacterial infectious process.
Sputum: ≥10 SECs/low-power field (LPF),

NOTE: If the number of WBCs is 10 times the number of SECs and there is 3 to 4+ of a single morphotype of bacteria, accept the specimen for culture.

Tracheal aspirates from adults: ≥10 SECs/low-power field (LPF) or no organisms seen.

Tracheal aspirates from pediatric patients: No organisms seen.

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When rejecting the specimen for culture, report as follows in the gram stain:

Enter the mnemonic MSC into the gram stain report. This will populate the comment, "Smear contains ≥10 squamous epithelial cells per low power field, suggestive of poor quality; culture not performed. Please recollect if clinically indicated." Under the report entry field, enter REJECT into entry field and document caregiver notification.

Smear is negative for bacteria after examination of 40 fields; culture not performed. Contact laboratory if further studies are clinically indicated.

PROCEDURE FOR CULTURE

Processing and culture examination of sputa, auger suctions, and ET aspirate specimens

Inoculation and incubation

Process all specimens as soon after receipt as possible to maintain the viability of the primary pathogen(s).
Select the most purulent or blood-tinged portion of the specimen to microscopically examine.
Perform a Gram stain of the specimen as soon after receipt as possible to microscopically assess

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cellular and bacterial components.

For sputum samples collected from adults and older children (6+yr), if the specimen is inadequate for culture based on microscopic criteria and reading of smears), reject the sample and immediately phone the physician or nursing unit to collect another sample.
Process microscopically adequate sputum, auger suction, and endotracheal aspirate specimens in a BSL 2 cabinet since aerosols can result in laboratory-acquired infections.

Using a sterile swab, loop, or pipette, inoculate specimen to BAP, CHOC, and MAC (or EMB).
If sputum is mucoid, a mucolytic agent can be used to liquefy the sputum. Refer to Copan SL Solution kit procedure.

Incubate plates at 35 to 37 C in 5% CO2 for a minimum of 48 h.

Culture examination

Observe plates at 24 h.

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Incubate plates for an additional 24 to 48 h, which is useful to detect slow-growing, fastidious Gram-negative rods, such as Bordetella bronchiseptica or Pasteurella spp. or molds such as Aspergillus spp.

Even if there was growth at 24 h, plates should be examined again at 48h to detect additional isolates not found at 24 h.

The original specimen Gram stain should be used as a guide to interpret the culture.

Primary pathogen(s) grown in culture should be present in the original specimen Gram smear.

If one or more isolates grow on culture that were not reported from the original Gram stain, then the smear should be read a second time by a different person than the one who initially read the slide.

Follow Table 3.11.2–1, *Guidelines for reporting of primary pathogens for lower respiratory cultures*, for reporting bacterial morphotypes from the Gram stain that may be primary pathogens.
Identify the organisms that grow in significant amounts, defined as bacterial morphotypes that are potential primary pathogens that may or not be part of the normal respiratory microflora. Table 3.11.2–1 provides guidelines for the reporting of primary pathogens from these types of specimens.

Subculture to BAP and/or CHOC to obtain isolated colonies for accurate identification from mixed cultures.
Table 3.11.2-1

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Action	Organism(s)
Examine for and always report. No further workup unless specifically requested	1. . Streptococcus pyogenes 2. Group B streptococci in pediatric population 3. Francisella tularensis 4. Bordetella spp., especially Bordetella bronchiseptica 5. Yersinia pestis 6. Neisseria gonorrhoeae 7. Nocardia 8. Bacillus anthracis 9. Cryptococcus neoformans 10. Molds, not considered saprophytic contaminant
Always report, but do not try to find low numbers, unless they are seen in the smear.	1. Streptococcus pneumoniae, report AST 2. Haemophilus influenzae, report beta-lactamase
Report if present **in significant amounts, even if not predominant.** Significant growth is defined as follows. 1. Moderate to heavy growth of an isolate in the second or greater quadrant of the plate 2. Colonies in the first quadrant of the plate provided there is little or no other normal respiratory microflora on the plate (i.e., pure growth of a primary pathogen) and the Gram smear shows purulence (i.e., PMNs)	1. Moraxella catarrhalis 2. Neisseria meningitidis Report the following on inpatients only: 3. Pseudomonas aeruginosa, report AST 4. Stenotrophomonas maltophilia 5. Acinetobacter, report AST 6. Burkholderia, report AST
Action	Organism(s)
Report if present in **significant amounts and is the predominant organism in the culture,** particularly if smear suggests infection with morphology consistent with isolate. Significant growth is defined as follows.	1. Staphylococcus aureus, report AST 2. Beta-hemolytic streptococcus B (adults), C, or G, report with MAST comment

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1. Moderate to heavy growth of an isolate in the second or greater quadrant of the plate 2. Colonies in the first quadrant of the plate provided there is little or no other normal respiratory microflora on the plate (i.e., pure growth of a primary pathogen) and the Gram smear shows purulence (i.e., PMNs)	3. Single morphotype of Gram-negative rod (especially Klebsiella pneumoniae), report ID/AST 4. Corynebacterium if urea positive or from intubated patient. ID 5. Rhodococcus equi in immunocompromised patients. ID
Report as "Mixed Enteric Gram-negative rods."	More than one morphology of Gram-negative rods that grow on MAC and are oxidase negative and either indole positive, or lactose positive or spreading.
Report as "Mixed Glucose non-fermenting Gram-negative rods."	More than one morphology of Gram-negative rods that are either oxidase positive and grow on MAC (See exceptions above.)
Report as "Mixed normal oropharyngeal bacteria" Note: If enterococci and coagulase-negative staphylococci (with or without yeast) are the only organisms present, report as "Mixed Gram-positive microorganisms" or list individually with minimal identification, if 90% pure culture	Viridans streptococci and/or nonpathogenic Neisseria; diphtheroids, coagulase-negative staphylococci; Rothia, group F streptococcus; anaerobes; Haemophilus species (not H. influenzae); Eikenella; Actinobacillus; Capnocytophaga; Moraxella; enterococci; yeasts; and insignificant numbers of S. aureus organisms, Gram-negative rods, and N. meningitidis.

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Identification of primary pathogens of lower respiratory tract infection

The following species are important respiratory pathogens.

Streptococcus species

Examine for beta-hemolytic colonies and identify catalase-negative cocci in chains and pairs.
Use pyrrolidonyl-β-naphthylamide (PYR) test to identify Streptococcus pyogenes, which isreported in any amount.
Examine for colonies with a small zone of hemolysis and identify group B streptococcus inpediatric patients, if present, in any amount.
Identify other beta-hemolytic streptococci in significant amounts only if they are predominant.

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Do not report small colony types of beta hemolytic streptococci or group F streptococci, as they are part of the upper respiratory microbiota.
Examine alpha-hemolytic colonies for morphology consistent with S. pneumoniae. These will be inhibited by optochin. Quickly pick similar colonies. Perform antimicrobial susceptibility.

Fastidious Gram-negative rods (these microorganisms grow slowly or not at all on MAC).

Perform spot tests on significant numbers to differentiate them from normal respiratory microbiota.
H. influenzae organisms are coccobacilli that grow on CHOC but not on BAP, except with staphylococci or other microorganisms to demonstrate satelliting. Perform ALA (aminolevulinic acid) test to confirm identification and beta-lactamase test for penicillin susceptibility for H. influenzae isolates.
Do not identify most other fastidious Gram-negative rods, such as Eikenella, unless they are predominant and present in large amounts, since they are part of the normal upper respiratory microbiota and rarely cause respiratory disease.

Gram-negative diplococci

Examine colonies present in significant amounts that move when pushed. Confirm as Moraxella catarrhalis. Since more than 90% of M. catarrhalis organisms are beta-lactamase positive, testing is not helpful to treatment.
Examine CHOC for any oxidase-positive colonies that do not grow or grow poorly on BAP. Confirm identification of Neisseria gonorrhoeae and N. meningitidis. Do not perform AST
.

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Gram-negative rods that grow well on either MAC or EMB

Identify and perform AST on enteric Gram-negative rods, particularly Klebsiella pneumoniae, if there is only one morphology in significant amounts with no other pathogens in greater amounts.
For inpatients, regardless of the presence of other pathogens, examine for significant numbers of Pseudomonas aeruginosa, Acinetobacter, Burkholderia, and Stenotrophomonas organisms because they are typically resistant to multiple antimicrobials and can be implicated in nosocomial epidemics.
If more than one type of other Gram-negative rods is present in equal numbers, perform minimal testing to be able to describe the organisms e.g., indole, oxidase, odor, and morphology on MAC, colony pigment.

Staphylococcus

Identify S. aureus if present in significant amounts.
Perform AST if the Gram stain shows predominant cocci in clusters associated with WBCs and no other pathogen in significant amounts.
Identify coagulase-negative staphylococci, without species identification or AST, only if they are in 90% pure culture. Otherwise include in respiratory microbiota.

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Do not report Enterococcus unless the culture is 90% pure. Otherwise include in respiratory microbiota.

Gram-positive rods

Rule out Nocardia in any amount and Rhodococcus equi (mucoid and urease positive) from immunocompromised patients.

Examine for large, spore-forming, Gram-positive rods. If present, identify Bacillus anthracis and Bacillus cereus.

Limit identification of Corynebacterium, using an Identification system for Gram-positive rods, to those present in numerous and predominant amounts and when either of the following is true.

Generally, do not pursue other Gram-positive rods, as they are unlikely to cause pneumonia.

Identify molds unless the organism is consistent with a laboratory or environmental contaminant (e.g., Penicillium).

NOTE: Biphasic fungi (Histoplasma capsulatum and Coccidioides immitis) can be isolated from plates held for 48 h, even as the yeast-phase colony morphology. Use caution in examination of older cultures.

Yeast

Rule out Cryptococcus and do not identify other yeasts further.

NOTE: Candida organisms are not a cause of pneumonia, except possibly in oncology (e.g., leukemia) or lung transplant patients or in neonates. Even in those cases, growth of Candida in lower respiratory specimens, regardless of species, does not correlate with disease. Yeasts are normal inhabitants of the mouth.

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REPORTING RESULTS

Report "No mixed normal flora of the oropharynx" if there is no growth on any plates.

- NOTE: This may be indicative of antimicrobial inhibition of normal microbiota.

Positive reporting

Report preliminary and final results as "Mixed normal flora of the oropharynx" if no pathogens are isolated.

Report all pathogens and susceptibility tests performed using Table 3.11.2–1 as a guide.

Provide updated or final report, notifying appropriate persons of clinically or epidemiologically important results.

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INTERPRETATION

A positive culture with S. pneumoniae or H. influenzae generally indicates infection with that organism, although carriage of these organisms may lead to false-positive results.

A positive culture with a predominant Gram-negative rod or S. aureus generally indicates infection with that agent if the smear suggests an infectious process involving the corresponding morphology.

A negative bacterial culture does not rule out lower respiratory infection. The primary pathogen is frequently not recovered from patients with pneumonia, either because they have already been started on antimicrobial therapy when samples are taken or because they have infection with another type of organism. (e.g., virus, parasite, fungus, mycoplasma, or mycobacterium) that will not be recovered by bacterial culture.

LIMITATIONS

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Some primary pathogens of pneumonia do not grow in routine bacterial culture.

Laboratories should refer to additional support services for the analysis of clinical specimens. to detect these pathogens (e.g., Legionella, viruses, fungi, mycoplasmas, and mycobacteria).

False-negative bacterial cultures usually result from improper collection, prior antimicrobial therapy, and/or delayed transport of lower respiratory specimens to the laboratory.

False-positive results are usually caused by contamination of the specimen by normal respiratory flora and its subsequent growth on culture and overinterpretation by the laboratory. Contamination of a lower respiratory sample may also occur by leakage during transport.

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Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator, VCMC & SPH	3/2/2026
Policy Owner	Linda Conboy: Supervisor-Microbiology, Laboratory Services	3/1/2026
Policy Owner	M. Anwar Molani: Medical Director, Laboratory Services	2/28/2026
Policy Owner	Erlinda Roxas: Director, Laboratory Services	2/28/2026

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Owner	Linda Conboy: Supervisor-Microbiology, Laboratory Services
Policy Area	Laboratory Services - Microbiology

L.MIC 7.29 Quantitative cultures of BAL and PBS

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PRINCIPLE

Patients with severe community acquired pneumonia (CAP), pneumonia in the immunocompromised patient, cystic fibrosis patients and acute episodes in chronic obstructive pulmonary disease may develop respiratory failure and require ventilator support.
Diagnosis of the microbial pathogens causing VAP (ventilator associated pneumonia) requires pulmonologists or intensivists to perform invasive respiratory sampling which includes bronchoscopic techniques (i.e., bronchoalveolar lavage [BAL], protected specimen brush [PSB and nonbronchoscopic techniques (i.e. blind bronchial sampling [mini-BAL]
PBS is the preferred sample for anaerobic culture, since both bronchial wash and BAL samples and transbronchial biopsy samples are contaminated by respiratory anaerobic microbiota.

Quantitative cultures increase the specificity of the diagnosis, but the sensitivity (82-91%) for BAL specimens is dependent on the threshold chosen for a positive result. Many authors report a colony count of ≥10^4 CFU/ml for BAL specimens (>=10^3 CFU/ml for PBS) to be consistent with bacterial pneumonia, whereas counts below 10^4 (10,000) CFU/ml for BAL (10^3 CFU/ml for PBS) specimens likely indicate contamination with oronasal microbiota. This theory has been validated in numerous clinical studies, and quantitative culture of BAL fluid specimens has become the reference method for the diagnosis of pneumonia by BAL.
There are two methods of performing quantitative cultures: the serial dilution method and the calibrated-loop method. We perform the calibrated-loop method.

After incubation the colonies are counted and multiplied by the appropriate dilution factor to determine the number of bacteria present in 1 ml of fluid.

SPECIMEN COLLECTION, TRANSPORT, AND HANDLING

Specimen collection is performed by a trained physician.

Collection of BAL: Collect BAL fluid by carefully wedging the tip of the bronchoscope into an airway lumen and instilling as large a volume of 0.85% sterile, non-bacteriostatic saline as possible per aliquot (25 to 30 ml for adults and 5 to 10ml for children). Several aliquots MAY be used in the same lung location to wash the alveoli to collect enough fluid to perform all of the required tests. The sample returned contains secretions of distal bronchioles and alveoli. The initial fluid is discarded as contaminated, and the rest is submitted for culture and staining.

Blind Bronchial Sampling (mini-BAL): The Mini-BAL collection is collected by a sterile long suction catheter inserted through the ET and blindly advanced into the distal airways till resistance is felt. The catheter is wedged in that position. 20 ml of Sodium Chloride 0.9% is instilled through the catheter and aspirate collected in a sterile polypropylene collector tube container by suction. After these proceedings, the probe is delicately removed using turning movements.

Collection of PBS: Instill a brush to collect cellular material from the airway wall. This is the best specimen for viral and cytology studies.

Only a PBS is acceptable for anaerobic bacterial culture. Obtain by inserting a telescoping double catheter plugged with polyethylene glycol at the distal end (to prevent contamination of the bronchial brush) through the biopsy channel of the bronchoscope.
Place the PBS in a sterile vial containing 1ml of nonbacteriostatic saline.

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Specimen transport.

Submit to laboratory in sterile, leak-proof containers.
Label with specimen source and tests requested for each specimen type.
Specimens should be placed in biohazard bags prior to transport to minimize contamination of the external environment if leakage occurs during transpor
t.
Bronchial wash specimens, BAL specimens, lung aspirates should be delivered immediately to laboratory.
For specimens delayed in transit more than 2 hours without refrigeration, indicate on the report that the delay in transit may compromise culture results (MPD)

A delay in processing of more than 1 to 2 hours may result in a decreased ability to recover fastidious pathogens, such as *S. pneumonia and H. influenza,* and/or overgrowth of upper

respiratory microbiota.

Rejection criteria

BAL specimens and PBS specimens should never be rejected since the patient has undergone an invasive procedure in order to have them collected.

Bronchial wash samples should not be cultured quantitatively. They should be set up same as sputum.

BAL fluid is preferred to bronchial washings for bacterial culture. Bronchial washings are acceptable for mycobacterial, *Legionella*, and fungal cultures.

NOTE: The difference between BAL fluid and bronchial washings is not apparent from the appearance of the specimen. The BAL sample is from the distal respiratory bronchioles and alveoli. Bronchial washings sample the major airways, which is the same area sampled by an endotracheal aspirate. They can be used for fungal, *Legionella,* or acid-fast bacillus (AFB) culture but are contaminated with upper airway secretions and are not appropriate for quantitative bacterial culture if BAL fluid is also available.
Bronchial brush specimens not collected with catheter protection are best submitted for viral culture and not bacterial culture, since they contain cellular material.

PBS is the preferred sample for anaerobic culture, since both bronchial wash and BAL samples and transbronchial biopsy samples are contaminated by respiratory anaerobic microbiota.

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MATERIALS

Primary media
BAP, CHOC and MAC
Other supplies
100 mcl pipette with sterile tips (BLUE MLA Pipette)
1-mcl loop (GREEN URINE LOOP)
10mcl loop or (BLUE LOOP)
Sterile bent plastic disposable rods to spread inoculum
Incubator at 35°C with CO_2

QUALITY CONTROL

Calibrated pipettes as needed.

PROCEDURES

Inoculation

Process all bronchial wash and BAL specimens immediately upon receipt in order to maintain viability of primary pathogen(s).
Process bronchial was and BAL specimens in a BSL-2 cabinet, since aerosols can result in laboratory-acquired infections.
Use a cytocentrifuge to prepare BAL and PBS specimens for Gram stain.
Label a BAP, MAC, and CHOC for each dilution (10 CFU/ml, 100 CFU/ml, and 1000 CFU/ml
Using a micropipette, place 100 mcl (using BLUE PIPETTE) of bacterial culture onto the center of the BAP, MAC, and CHOC agar plate without touching the agar.
Each colony from this plate = 10 CFU/ml.
Using a 10 mcl loop (BLUE LOOP), place 10 mcl bacterial culture onto the center of the agar plate without touching the agar Each colony from this plate = 100 CFU/ml.
Using a 1mcl loop (GREEN LOOP), place 1 mcl bacterial culture onto the center of the agar plate without touching the agar Each colony from this = 1,000 CFU/ml.
For all dilutions, spread the inoculum over the surface of each plate evenly by using a sterile disposable plastic rod with the spreader technique.
Using your sterile spreader, gently rub across the agar surface while rotating the plate with the other hand. See the diagram below for an example.
It is important that you spread the sample across the whole agar plate, so it makes counting colonies easier.
Continue spreading until the liquid is absorbed by the agar.
With your free hand turn the plate while spreading the culture.
Move the spreader back and forth to cover the entire plate.
Begin with the most dilute inoculum (1:1000) and proceed to the least dilute (1:10) using the same sterile rod for each place.
After completing the spread, dispose of the spreader in the waste beaker.

Incubation

Incubate the plates in 35° C CO2 incubator. Evaluate daily for 48-72 hours.

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The remainder of the specimen may be centrifuged for culture of viruses, mycobacteria, Legionella, and fungi and for smears for viruses, Pneumocystis, AFB, and fungi, upon request.

Identification of primary pathogens

Examine for beta-hemolytic colonies

Evaluate for the presence of *Streptococcus pyogenes* or Group B streptococcus in any amounts
Identify other beta-hemolytic streptococci in significant amounts only if they are predominant.
Do not report small colony types of beta hemolytic streptococcus or Group F streptococci, as they are part of the upper respiratory microbiota.

Examine alpha-hemolytic colonies for morphology consistent with *Streptococcus pneumoniae*.

Fastidious Gram-negative rods

Evaluate for fastidious gram-negative rods including *Haemophilus influenzae Francisella tularensis*, *Bordatella*, *Pasteurella*.
Do not identify most other fastidious Gram-negative rods, such *as Eikenella*, unless they are predominant and present in large amounts, since they are part of the normal upper respiratory microbiota and rarely cause respiratory disease.

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Gram-negative diplococci

Moraxella catarrhalis
Neisseria gonorrhoeae or N. meningitidis.

Gram-negative rods that grow well on MAC.

Identify and perform AST on enteric Gram-negative rods, particularly *Klebsiella pneumoniae*, if there is only one morphology *in significant amount with no other pathogens in greater amounts.*

For inpatients, regardless of the presence of other pathogens, examine for significant numbers of *Pseudomonas aeruginosa*, *Acinetobacter*, *Burkholderia*, and *Stenotrophomonas* organism because they are typically resistant to multiple antimicrobials and can be implicated in nosocomial epidemics.

If more than one type of other Gram-negative rods are present in equal numbers, perform minimal testing to be able to describe the organisms (enteric, nonfermenter)

Staphylococci

Identify Staphylococcus aureus in significant amounts.

Identify coagulase negative staphylococcus, without species identification or AST, only if they are in 90% pure culture. Otherwise include in respiratory microbiota.

Gram-positive rods

Rule out Nocardia in any amount and *Rhodococcus equi* (mucoid and urease positive)
Examine for large, spore-forming, Gram-positive rods. If present, identify Bacillus anthracis and Bacillus cereus.
Limit identification of Corynebacterium, to those present in numerous and predominant amount when either
Identified as *Corynebacterium pseudodiphtheriticum* (rapid urea positive)
the specimen is from an intubated patient from an ICU.
Generally, do not pursue other Gram-positive rods, as they are unlikely to cause pneumoniae.

Identify Molds (submitted to VCPH)

Rule out Cryptococcus and do not identify other yeasts further.

NOTE: *Candida* organisms are not a cause of pneumoniae, except possibly in oncology (e.g. leukemia) or lung transplant patients or in neonates. Even in those cases, growth of *Candida* in lower respiratory specimens, regardless of species, does not correlate with disease. Yeasts are normal inhabitants of the mouth.

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INTERPRETATION

Count the colonies from the dilution with the greatest number of colonies without confluence. Multiply by the dilution factor listed for each dilution (e.g., 40 colonies on the "x 1,000" plate is 40 x 1,000 or 40,000 or 4 x 10^4 CFU/ml.
Count each morphotype individually.
If growth is too numerous to count on the highest dilution, report the count as greater than that dilution.

Counts for BAL fluid of less than 10^4 (10,000CFU/ml) are considered to indicate contamination with oronasal contamination.

Counts for BAL fluid of greater than or equal to 10^4 (10,000CFU/ml) are consistent with bacterial pneumonia. **(BALCOM)**

Counts for PBS fluid of greater than or equal to 10^3 (1,000CFU/ml) are consistent with bacterial pneumonia. **(PBSCOM)**

Counts for PBS of less than 10^3 (1,000CFU/ml) are considered to indicate contamination.

REPORTING RESULTS

Gram stain: Report smear as indicated. Any organism seen in a cytocentrifuged smear of BAL fluid is considered indicative of bacterial pneumonia.
Report number of each pathogen found as CFU per milliliter of specimen. If culture count is lower than the threshold (counts less than 10^4 (10,000CFU/ml)), identification and susceptibility testing are not generally indicated unless there is a pure growth of a primary pathogen.
Candida species are most often contaminants of the procedure and generally should not be identified to the species level.

LIMITATIONS

Counts near thresholds may be difficult to interpret accurately.

Not all pathogens will grow on the media used and may result in a false negative culture.

Anaerobes are implicated in disease, especially in the elderly or those obtunded with aspiration pneumonia. Cultures are generally not cost-effective or helpful because they vary in sensitivity from 20 to 60%, possibly due to aeration during collection and dilution of the specimen.

Loop cultures are not as accurate as pipette cultures, but both are quite sensitive provided that a rod is used to spread the colonies on the plate. Spreading with a loop is not as sensitive a method and will underestimate the quantity of organisms present.

Even a single dose of antimicrobial therapy prior to specimen collection can negate the ability to isolate the causative agent of disease from the specimen.

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Approval Signatures

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Hospital Administration	Jason Arimura: Associate Hospital Administrator, VCMC & SPH	3/2/2026
Policy Owner	Linda Conboy: Supervisor-Microbiology, Laboratory Services	3/1/2026
Policy Owner	M. Anwar Molani: Medical Director, Laboratory Services	2/23/2026
Policy Owner	Erlinda Roxas: Director, Laboratory Services	2/23/2026

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Owner	Linda Conboy: Supervisor-Microbiology, Laboratory Services
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L.MIC 7.30 YEAST ID SCHEME

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PRINCIPLE

Identification to the species level of yeasts isolated from clinical specimens is often problematic for diagnostic laboratories, but it has become increasingly necessary. Greater number of immunosuppressed patients, a widening range of recognized pathogens, and the discovery of resistance to antifungal drugs mean that the common practice of identification or exclusion of *Candida albicans* alone is no longer adequate.

Colonial appearance on Chromagar Candida can be used to identify many of the commonly isolated yeasts.

MATERIALS

Sab-Dex Agar Plate

Chromagar Candida Plate

PROCEDURE

Subculture isolate, if necessary, onto Sab Dex agar plate streaking for isolation. Incubate at 35°C. Using isolated colony, inoculate a Chromagar Candida plate streaking for isolation. Incubate at 37°C in air for 48 hours. Isolation is very important. Colonial morphology is based on single isolated colonies.

INTERPRETATION

YEAST	COLONY CHARACTERISTICS ON CHROMAGAR	COMMENTS & PRECAUTIONS
Candida albicans	Apple green colonies; consistent distinctive appearance	Must be distinguished from C.dubliniensis which is forest green

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Candida glabrata	Large pale pink to purple glossy colonies	Presumptive identification, Identify with biochemicals and morphology essential.
Candida tropicalis	Dull blue, sometimes pink, colonies; all developed purple halo of pigment that diffused into surrounding agar; distinctive appearance	Accurate identification with Chromagar. Morphology is essential.
Candida krusei	Large, flat, spreading, pale pink colonies with matt surfaces; distinctive appearance	Accurate identification
Candida parapsilosis	Off-white to pale pink colonies; variable appearance	Not always able to identify without biochemicals
Candida guilliermondii	Small pink to purple colonies; variable appearance	Not always able to identify without biochemicals
Candida dubliniensis	Dark green colonies	
Trichosporon spp.	Tiny, rough, dry-looking, dirty blue-to grey colonies, distinctive appearance	Accurate identification.
Cryptococcus neoformans	Pink colonies, sometimes mucoid	Accurate identification, morphology essential. Urea positive.
Saccharomyces cerevisiae	Small purple colonies	Accurate identification, morphology essential.
Prototheca wickerhamii	Large, variably sized spherical cells, some containing sporangia; distinctive appearance	Accurate identification, morphology essential. Not in API database.

COPY

If unable identify using ChromAgar , on **all blood isolates**, or if more definitive ID is needed, set up the MALDI or Vitek Yeast ID card. If still unable to identify or if the isolate is unfamiliar to you, consult the microbiology supervisor for the possibility of referring the isolate to a reference lab for identification. If susceptibilities are requested, submit isolate to reference lab for testing.

LIMITATIONS

Chromagar Candida agar alone was found to be effective for the presumptive identification of *C. albicans*, *Candida tropicalis*, and *Trichosporon.* MALDI or Vitek Yeast ID card completes the identification.

Candida glabrata cannot be distinguished by its appearance on Chromagar Candida plates alone, having an appearance similar to those of *C. parapsilosis, Saccharomyces cerevisiae, P. wickerhamii, Cryptococcus neoformans*, and *C. guilliermondii.* May get presumptive identification of *C glabrata* if colonies on Chromagar Candida plate are pink glossy colonies.

The clinical importance of *C. neoformans* requires confirmation of its identity by serological or biochemical methods.

Definitive identification of *C. dubliniensis* requires MALDI or Yeast ID Card. Note that the formation

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of dark green colonies on Chromagar Candida may be lost on repeated subculture. It is important to differentiate between these species, because significant resistance to azoles has been reported in *C. dubliniensis*.

REFERENCE

Koehler, Ann P. et al, "Simple, Reliable, and Cost-Effective Yeast Identification Scheme for the Clinical Laboratory," **Journal of Clinical Microbiology**, Feb 1999, p. 422-426.

Larone, Davise H., **Medically Important Fungi: A Guide to Identification**, 3rd edition, ASM Press, Washington D.C., 1995, p. 241.

All Revision Dates

3/2/2026

Attachments

COPY

- REF 7.30 MYCOLOGY SET UP GUIDE.XLS
- REF 7.30 YEAST FLOW CHART.XLS

Approval Signatures

Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator, VCMC & SPH	3/2/2026
Policy Owner	Linda Conboy: Supervisor-Microbiology, Laboratory Services	3/1/2026
Policy Owner	M. Anwar Molani: Medical Director, Laboratory Services	2/23/2026
Policy Owner	Erlinda Roxas: Director, Laboratory Services	2/23/2026

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Status **Active** PolicyStat ID **20034350**

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Next Review	3/2/2028
Owner	Linda Conboy: Supervisor-Microbiology, Laboratory Services
Policy Area	Laboratory Services - Microbiology

L.MIC 8.10 Compressed Gas Regulators and Handling of Cylinders

COPY

EFFECTIVE DATE : 3/13/1997	REVIEW DATES: 4/1998,5/1999,3/2000,8/2001, 9/2002,4/2003,10/2003,4/2004, 4/2005,6/2006,11/2007, 9/2008,7/2009,11/2010,11/2011, 2/2014,12/201512/2016, 12/2017, 3/2019, 11/2021, 11/2023, 1/2025, 20/2026
	REVISION DATES:

PRINCIPLE:

Gas pressure regulators are used to control the flow of gas from a pressurized storage tank (usually in the form of a cylinder) to an end-stage instrument that requires gas flow at a pressure less than that in the storage cylinder. Diaphragms made up of interlocking leaves of metal (much like the condenser diaphragm on a microscope) are used to vary the size of the opening through which the gas flows. The smaller the opening, the less gas is allowed to flow through. Flow is controlled precisely, because relatively small movements in the interlocking leaves are achieved with relatively large turns of the threaded control knob or handle.

DESCRIPTION

Regulators control the flow of gas and incorporate pressure gauges (either float gauges or circular scales) for visual readout of gas pressure. The flow of gas is controlled by a manually operated handle that opens and closes the diaphragms. A threaded joint connects the

regulator to the-outlet valve of the gas cylinder, and flexible tubing leading to the instrument is connected to the other end of the gas flow channel.

Two-stage regulators are used with high-pressure cylinders of compressed, noncorrosive gases (e.g. nitrogen, oxygen, carbon dioxide, compressed air, etc.). The first stage controls the pressure of gas exiting the cylinder, usually reducing it by 90%; the second stage protects the end instrument from right-pressure surges and fine tunes the gas pressure. A gauge in line with the first stage measures the pounds per square inch in the gas cylinder, which usually ranges from 3,000 to 0 lb per square inch, depending on the gas. The gauge with the second stage measures the delivery pressure, which usually ranges from 1 to 1001b/in2. Most gauges are 2.5-in. (1 in. = 2.54 cm)-diameter circular scales; second-stage gauges may be metal float balls in a linear channel.

USE OF GAS PRESSURE REGULATORS IN MICROBIOLOGY

Anaerobic chambers
CO2 Incubators
Evacuation and replacement of gases for anaerobic jar

SPECIAL PRECAUTION & ENVIRONMENTAL CONCERNS

The Compressed Gas Association standard numbers for the gas cylinder and the regular must match.
Be certain that the screw-on valve cap that covers the outlet valve knob is securely tightened before moving a gas cylinder. Do not move a cylinder with a regulator attached. If the cylinder should fall with the valve open (or if it jars open or breaks), the cylinder behaves as a powerful torpedo, destroying everything in its path. In this event, HIT THE DECKS, and stay out of the way until all compressed gas is exhausted and the cylinder stops moving.

Try to keep a very substantial object (like a laboratory bench) between you and the cylinder.
Use only cylinders that are secured upright, If a valve should malfunction, the cylinder will be propelled into the floor instead of horizontally across it,

COMPRESSED-GAS REGULATOR & HANDLING OF GAS CYLINDERS

For certain cylinder types (identified in the catalog and the product insert and received with the washer in place), you must place a new washer or 0 ring between the gas cylinder and the inside of the regulator hexagonal nut before connecting the regulatory and cylinder. Never use oil or grease to lubricate joints; the equipment works without lubricant, which can be flammable.
Open and close the gas cylinder valve briefly to clear the valve of dust and particles before attaching the regulator.
Do not allow the pressure on a 35-liter or larger cylinder (diameter, >21cm) to go below 200 lb per square inch before changing the cylinder.
Scoring on the outer hexagonal nut of a regulator indicates that it has a left-handed thread and

COPY

opens with counterclockwise turning.
If the temperature of storage is substantially below room temperature (less than 15 degree C), you must allow the cylinders to equilibrate inside before use. Otherwise, pressure cannot be regulated with consistency. To be safe, when cylinders are stored outside in the cold, bring cylinders indoors 1 day before you plan to use them. If this cannot be anticipated, allow them to equilibrate at room temperature for 8 h before opening.

ENVIRONMENTAL CONCERNS

Secure all gas cylinders in an upright position to a wall by using heavy chains and/or metal clamps at top and bottom.

When cylinders are not in use, keep valve openings tightly closed and valve caps tightened securely.

Empty cylinders may be stored securely chained on a movable gas cylinder cart as a temporary measure.

Try to place the cylinders as close as possible to the instrument they are supplying to avoid tubing entanglements and leakage.

Cylinders containing >5% volume of volatile gas should be stored in separate, strongly secured facilities specifically designed for cylinder storage. Never store any gas cylinders at temperatures of >120 degrees F (55 degrees C).

To transport cylinders, remove regulators, tighten valve caps, and secure cylinders upright on a cart. Single cylinders may be carefully "walked" in an upright position across short distances by persons strong enough to handle the job. Never place a cylinder in a horizontal position.

Do not discard empty cylinders, as their handling is regulated by federal and state statutes. Return empty cylinders to an authorized distributor.

MATERIALS

REAGENT

- Soap solution for leak detection (thick suspension of dishwashing liquid in water in a squirt bottle.
  EQUIPMENT
- Gas cylinders, usually 21 by 310 cm (35-liter capacity) or 23 by 130 cm (43.8-liter capacity)
- Chain and/or clamp apparatus for wall mounting
- Regulator (usually two-stage, low pressure)

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- Washers (if appropriate for your gauge-cylinder combination)

INITIAL CALIBRATION

After installing a new gauge onto the first gas cylinder, adjust the second-stage regulator to the correct final pressure for the instrument being supplied by turning the diaphragm valve (or handle). Turning outward (toward looseness) closes the diaphragm and inhibits and flow of gas: turning inward (toward tightness) slowly opens the diaphragm and increases the pressure of gas allowed to flow through.

For gases that establish special atmospheric conditions, it would be ideal to check for adequate growth of appropriate control organisms after new gas mixture is installed in the system before using the system for patient specimens. Periodic sub culturing of QC stock organisms is a practical method for detecting problems.

Once the final flow pressure is established, draw a line on the gauge with a wax china marker at that level so that everyone will know the correct adjustment for that gauge in that capacity. Note: Most incubators and chambers require 10 to 15 lb per square inch of inlet pressure.

When first using a new gauge, it is also helpful to use a marking pen to draw an arrow on the hex nut in the direction that it should be turned to open it, with the "open" written next to it. When it is time to replace the cylinder, there will be no guesswork as to which direction to turn the nut.

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QUALITY CONTROL

DAILY

Check and record pressure of cylinder on a form near the cylinder. Change to a new cylinder if pressure goes below 200 lb per square inch. If the weekend or a holiday is approaching, higher cylinder pressure may be chosen as the minimum for changing to a new cylinder, depending on predicted usage.

Check and record pressure of second-stage regulator.

AS NEEDED

Record date and time each fresh cylinder is placed into use.

If regulator requires it, change the washer each time the cylinder is changed.
Check tubing and connections for leaks.

Clean gauge lens with soapy water, rinse, and wipe dry with soft cloth. Do not use solvents on plastic lenses.

ROUTINE OPERATION

CHANGING THE GAS CYLINDER *(Performed by the Maintenance Department)*

Change the cylinder before pressure drops below 200 lb per square inch.

Turn off cylinder outlet valve (on top of gas cylinder) by turning the valve downward (usually clockwise) until it no longer turns. This will result in the valve being at the bottom of its vertical range of motion.

Use end wrench to loosen the hexagonal nut at the end of the pressure regulator closest to the gas cylinder. A small amount of residual gas usually hisses out at this point. If the gas seems to be hissing more strongly as you loosen the nut, check to be certain that you have closed the valve to the cylinder and not inadvertently opened it.

Remove the regulator assembly from the cylinder, and lay it down gently, There is not need to disassemble the tubing or change the gauge settings except as noted above for changing gas to an anaerobic chamber.

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Replace the protective cover on the used gas cylinder, and write EMPTY in large letters on a piece of tape so that it is easily visible. Alternatively, use perforated labeled cardboard tags supplied with some cylinders. Move the empty cylinder to its temporary storage position.

Be certain that the protective cover is tightly fastened on the new cylinder to be moved into position. Move the full cylinder into position by maneuvering it carefully in an upright position or by rolling it on a cylinder cart. Attach the new cylinder to its support system (chains, clamps, etc.)

Unscrew the protective cover, and remove it to a readily accessible place. Rotate the cylinder so that the outlet valves face the direction in which the gauge is to be attached.

If appropriate, replace the washer in the regulator. Even if the washer is not replaced, examine the threads of the cylinder outlet (female coupling) and the gas gauge (male coupling) to be certain that they are clean and free of any particles and bits of old Teflon pipe thread tape.

Insert gauge coupling into cylinder outlet, and tighten hex nut manually until it can no longer be moved easily. Use the correct size end wrench to tighten the nut completely, turning the gauge dials with one hand to allow them to remain in the proper alignment for easy visual access when the cylinder is in its working position.

After tightening the nut, gently release the cylinder outlet valve by turning
it slowly until the pressure can be read on the gauge. If no leaks are apparent, continue to release the valve to its full open position.

Slowly open the second-stage control valve until the desired outlet delivery pressure is reached.

Check for leaks with soap solution. If leaks are apparent or if the cylinder loses pressure very quickly, perform troubleshooting activities.

Check that the second-stage gauge is reading properly, and then mark the date that the cylinder was placed in use in large letters on a piece of tape affixed to the gauge itself or to the cylinder.

REMOVING REGULATOR FROM CYLINDER

Close the main valve on the gas cylinder.

Open the regulator outflow valve to bleed off all pressure within the gauge.

Open the high-pressure valve to bleed off remaining pressure.

Remove the regulator.

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CHECKING FOR LEAKS

The threaded piece fitting into the cylinder outlet valve is the most likely source of leaks. Close the cylinder valve, remove the regulator, and check for particles in the threads. If none are found, check that the washer (if present) is new and properly seated.

Sealing the threads with Teflon pipe thread tape can correct many leaks.

Cut a piece of tape long enough to wrap twice around the tubing fitting. Warp the tape onto the threads of the male coupling so that the outer loose end is in the direction opposite to the direction that the coupling is turned, Wrap the tape slightly past the end of the threads so that it will not catch during insertion, and use your fingers to smooth the tape into the threads. Note: Pipe thread tape is superior to pipe sealing compound, which could leak into the regulator and cause damage.

Use a bubbly soap solution in a squirt bottle to check for other leaks. The most likely sources are the connections to the regulator and the instrument itself Shake up the soap solution to form fine bubbles, hold a wad of paper towels or a rag under the area to be tested, and squirt a small stream of solution onto the top surface of the connection so that the soap flows around the connection. Watch very carefully for formation of new bubbles. This may take a minute and be subtle, so look closely for at least 1 min before checking another area.

The tubing is less likely to be leaking, but it is appears worn or cracked or if a leak is found, change it.

MALFUNCTIONING INSTRUMENT

Read the product manual for instrument troubleshooting hints.

MALFUNCTIONING REGULATOR

Regulators can be reconditioned by the manufacturer.

REFERENCE

1.ChEit ASM, Supplemental Revision 1996, pages12.9.1 to12.9.8

All Revision Dates

3/3/2026

Approval Signatures

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Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator, VCMC & SPH	3/3/2026
Policy Owner	Erlinda Roxas: Director, Laboratory Services	3/3/2026
Policy Owner	M. Anwar Molani: Medical Director, Laboratory Services	3/2/2026
Policy Owner	Linda Conboy: Supervisor-Microbiology, Laboratory Services	3/2/2026

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Next Review	3/2/2028
Owner	Linda Conboy: Supervisor-Microbiology, Laboratory Services
Policy Area	Laboratory Services - Microbiology

L.MIC 8.11 Calibration of Microscope with an Ocular Micrometer

COPY

EFFECTIVE DATE: 09/20/2010	REVIEW DATES: 9/6/2011, 5/19/13, 12/12/13, 7/20/15, 12/2016, 12/2017, 3/2019, 11/2021, 11/2023, 1/2025, 2/2026
	REVISION DATES: 08/27/2015

PRINCIPLE:

The identification of protozoa and other parasites depends on several factors, one of which is size. Any laboratory doing diagnostic work in parasitology should have a calibrated microscope available for precise measurements. Measurements are made with a micrometer disk that is placed in the ocular of the microscope; the disk is usually calibrated as a line divided into 50 units (U). Depending on the objective magnification used, the divisions in the disk represent different measurements. The ocular disk division is compared with a known calibrated scale, usually a stage micrometer with a scale of 0.1 and 0.01 mm divisions.

MATERIALS:

Supplies

Ocular micrometer disk (line divided into 50 U)
Stage micrometer with a scale of 0.1 and 0.01 mm divisions
Immersion oil

Lens paper
Equipment
Binocular microscope with 10X, 40X and 100X objectives
Oculars should be 10X

PROCEDURE:

Unscrew the eye lens of a 10X ocular, and place the micrometer disk (engraved side down) within the ocular. Use lens paper to handle the disk; keep all surfaces free of dust or lint.

Place the calibrated micrometer on the stage and focus on the scale. You should be able to distinguish the difference between the 0.1 and 0.01 mm divisions. Make sure you understand the divisions on the scale before proceeding.

Adjust the stage micrometer so the "0" line on the ocular micrometer is exactly lined up on top of the0 line on the stage micrometer.
When these two lines are lined up, do not move the stage micrometer any farther. Look to the right of the 0 lines for another set of lines superimposed on each other. The second set of lines should be as far to the right of the 0 lines as possible; however, the distance varies with the objectives being used.

Count the number of ocular divisions between the 0 lines and the point where the second set of lines is superimposed. Then, on the stage micrometer, count the number of 0.1 mm divisions between the 0 lines and the second set of superimposed lines.
Calculate the portion of a millimeter that is measured by a single small ocular unit.

When the high dry and oil immersion objectives are used, the 0 line of the stage micrometer will increase in size, whereas the ocular 0 line will remain the same size. The thin ocular 0 line should be lined up in the center or at one edge of the broad stage micrometer 0 line. Thus, when the second set of superimposed lines is found, the thin ocular line should be lined up in the center or at the corresponding edge of the broad stage micrometer line.

CALCULATIONS:

Calculate the factors as follows:

Stage reading (mm) 1,000 um
---------- X ---------- = ocular units (um)
Ocular reading 1mm

Low power (10X): 0.8mm 1,000um
--------- X ---------- = 8.0 um (factor)
100 U 1mm

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High dry power (40X): 0.1 mm 1,000um
---------- X ---------- = 2.0 um (factor)
50 U 1 mm

Oil immersion (100X): 0.05 mm 1,000 um
---------- X ---------- = 0.8 um (factor)
62 U 1mm

RESULTS:

For each objective magnification, a factor will be generated (1 ocular unit=certain number of micrometers)
If a RBC is measured with various objectives, the size should be the same (or very close) regardless of the objective magnification.

REPORTING RESULTS:

Post the multiplication factor for each objective on the base of the microscope for easy reference.

Once the number of ocular lines per width and length of the organism is measured, then, depending on the objective magnification, the factor (1 ocular unit = certain number of micrometers) can be applied to the number of lines to obtain the width and length of the organism.

Comparison of these measurements with reference measurements in various books and manuals should confirm the organism identification.

PROCEDURAL NOTES:

The final multiplication factors will be only as good as your visual comparison of the ocular 0 and stage micrometer 0 lines.

As a rule of thumb, the high dry objective (40X) factor should be approximately 2.5 times more than the factor obtained from the oil immersion objective (100X). The low power objective (10X) factor should be approximately 10 times that of the oil immersion objective (100X).

LIMITATIONS:

After each objective has been calibrated, the oculars containing the disk and or these objectives cannot be interchanged with corresponding objectives or oculars on another microscope.

If there are no changes to a particular microscope's optical components, there is no need to recheck calibration. Calibrations can be checked against a micrometer or other objects of known dimensions.

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Each microscope used to measure organisms must be calibrated as a unit. The original oculars and objectives that were used to calibrate the microscope must also be used when an organism is measured.

REFERENCES:

Garcia, Lynne S., **Clinical Microbiology Procedures Handbook**, 2nd edition, 2007, ASM, Washington, D.C.

All Revision Dates

3/3/2026

Attachments

Micro 8.11 (a) Ocular Micrometer Calibration Log.xls

COPY

Approval Signatures

Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator, VCMC & SPH	3/3/2026
Policy Owner	Erlinda Roxas: Director, Laboratory Services	3/3/2026
Policy Owner	M. Anwar Molani: Medical Director, Laboratory Services	3/2/2026
Policy Owner	Linda Conboy: Supervisor-Microbiology, Laboratory Services	3/2/2026

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Last Approved	3/3/2026		
Effective	3/3/2026	Policy Area	Laboratory Services - Microbiology
Last Revised	3/3/2026		
Next Review	3/2/2028		

L.MIC 8.4 Use of Kwik Stik Microorganisms

COPY

EFFECTIVE DATE 3/2/1997	REVIEW DATES: 4/1998, 5/1999, 3/2000, 8/2001, 9/2002,4/2003,10/2003, 4/2004, 6/2006,11/2007,9/2008,7/2009, 11/2010,11/2011, 2/2014, 12/2015, 12/2016, 12/2017, 3/2019, 11/2021, 11/2023, 1/2025, 2/2026
	REVISION DATES:4/2005

PRINCIPLE:

KWIK-STIK™ and KWIK-STIK™ Plus microorganisms provide equivalent results to traditional methods used in preparing, storing and maintaining reference stock culture collections. The microorganism preparations are traceable to the American Type Culture Collection (ATCC®) or other authentic reference.

KWIK-STIK™ and KWIK-STIK™ Plus microorganism pellets consist of a microorganism population (>1000 CFUs per pellet), gelatin, skim milk, ascorbic acid, carbohydrate, and charcoal. The gelatin serves as a carrier for the microorganism. Skim milk, ascorbic acid, and carbohydrate protect the microorganism by preserving the integrity of the cell wall during freeze-drying and storage. The charcoal is included to neutralize any toxic substances formed during the lyophilization process .

PRODUCT DESCRIPTION:

A. **KWIK-STIK™:** each KWIK-STIK™ unit contains a lyophilized microorganism pellet, an ampoule of hydrating fluid, and an inoculating swab. Each device is sealed within a laminated pouch that contains a desiccant to prevent adverse moisture accumulation. KWIK-STIK™ microorganisms are 3 passages or less from the reference culture and are

available in packs of 2 and

B. **KWIK-STIK™ Plus:** each KWIK-STIK™ Plus unit contains a lyophilized microorganism pellet, an ampoule of hydrating fluid, and an inoculating swab. Each device is sealed within a laminated pouch that contains a desiccant to prevent adverse moisture accumulation. KWIK-STIK™ Plus microorganisms are 2 passages from the reference culture and are available in packs of

PRECAUTIONS AND LIMITATIONS:

The hydrating fluid in the KWIK-STIK™ and KWIK-STIK™ Plus may cause serious eye irritation. If in eyes, rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If irritation persists, get medical advice/attention.

Wear protective gloves/protective clothing/eye protection/face protection. Wash hands thoroughly after handling.
These devices contain viable microorganisms that may produce disease. Proper techniques must be employed to avoid exposure and contact with any microorganism growth.

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STORAGE:

Store KWIK-STIK™ and KWIK-STIK™ Plus microorganisms at 2°C to 8°C in the original, sealed vial or pouch containing the desiccant. KWIK-STIK™ and KWIK-STIK™ Plus microorganisms should not be used if:

- Stored improperly
- There is evidence of excessive exposure to heat or moisture
- The expiration date has passed

PROCEDURE:

A. **KWIK-STIK™ and KWIK-STIK Plus™ Microorganism Procedure**

Allow the unopened KWIK-STIK™ pouch to equilibrate to room temperature. Tear open pouch at notch and remove the KWIK-STIK™ unit.

Tear off Pull-Tab portion on the label and attach it to the primary culture plate or QC record. Do not disassemble the device during hydration.

Pinch (once only) the ampoule at the top of the KWIK-STIK™ (just below the fluid meniscus of the ampoule) found in the cap to release the hydrating fluid.

Hold vertically and tap on a hard surface to facilitate flow of fluid through shaft into bottom of unit containing pellet. Allow the hydrating fluid to flow through the swab shaft and into the bottom

portion of the unit containing the pellet.

Using a pinching action on the bottom portion of the unit, crush the pellet in the fluid until the pellet suspension is homogenous.

Immediately heavily saturate the swab with the hydrated material and transfer to agar medium or use according to the laboratory's SOP.

Inoculate the primary culture plate(s) by gently rolling the swab over one-third of the plate.

Using a sterile loop, streak to facilitate colony isolation.

Using proper biohazard disposal, discard the KWIK-STIK™.

Immediately incubate the inoculated primary culture plate(s) at temperature and conditions appropriate to the microorganism.

ILLUSTRATED INSTRUCTIONS

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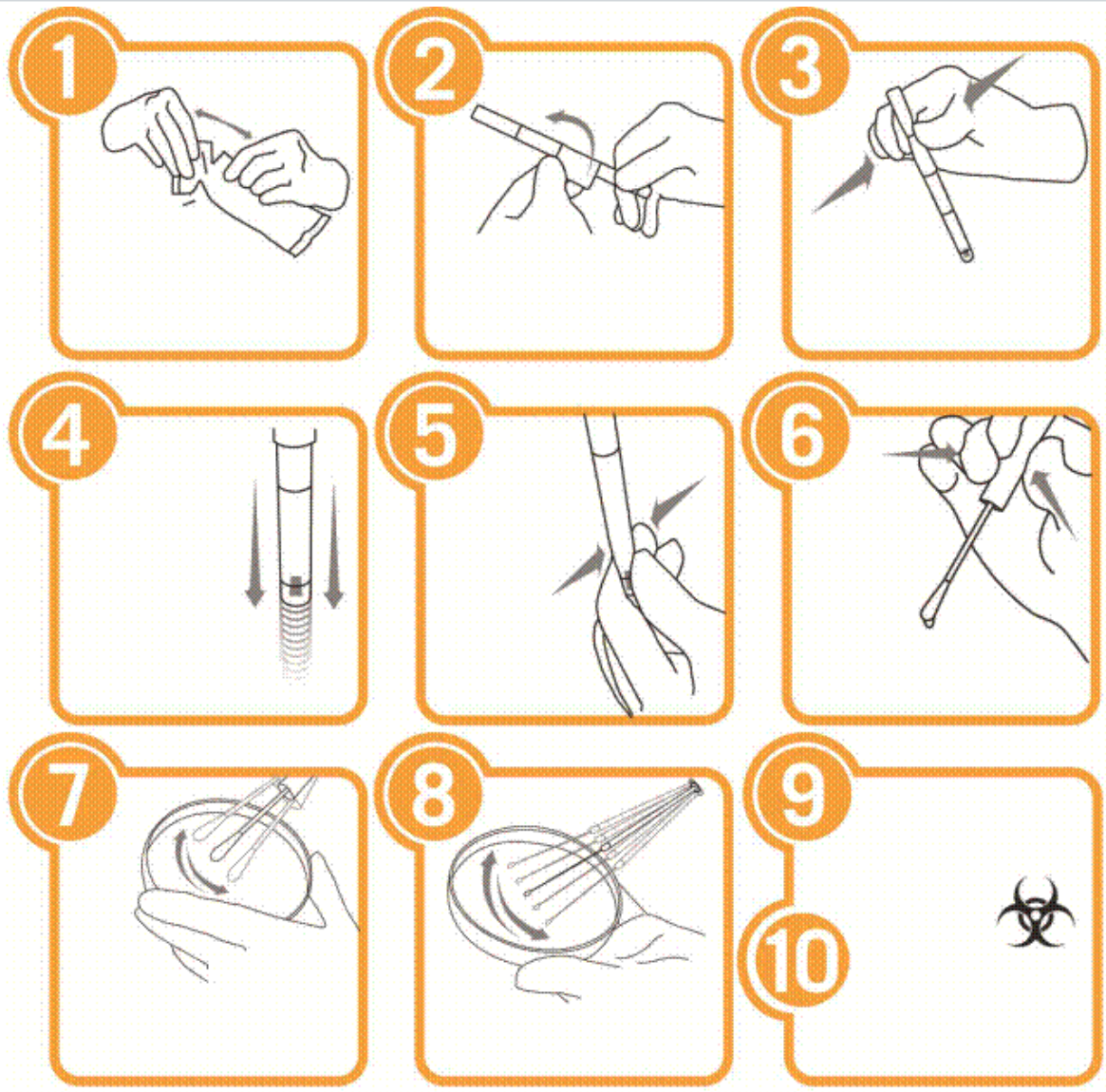

REFERENCES:

Microbiologics, Inc., Product Insert, PI. 194.ENG Rev B, 2016, February 22

All Revision Dates

3/3/2026

Attachments

Micro 8.4 REF Stock Organism List.xlsx

Approval Signatures

Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator, VCMC & SPH	3/3/2026
Policy Owner	Erlinda Roxas: Director, Laboratory Services	3/3/2026
Policy Owner	M. Anwar Molani: Medical Director, Laboratory Services	3/2/2026
Policy Owner	Linda Conboy: Supervisor-Microbiology, Laboratory Services	3/2/2026

COPY

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Last Revised	3/3/2026
Next Review	3/2/2028
Owner	Linda Conboy: Supervisor-Microbiology, Laboratory Services
Policy Area	Laboratory Services - Microbiology

L.MIC 8.5 Stock Culture Maintenance

COPY

EFFECTIVE DATE 12/27/2005	REVIEW DATES:6/2006, 11/2007, 11/2010, 11/2011, 2/2014, 12/2015
	REVISION DATES:7/2006, 5,2008,3/2009,11/2011, 6/2013, 12/31/2025, 2/2026

Quality Control Organisms

Source of Quality Control Organisms

Quality control organisms are available from the American Type Culture Collection (ATCC). Previously characterized organisms isolated from patients and shown to be phenotypically stable are also appropriate for media quality control.
Storage of Quality Control Organisms:

Quality Control Organisms	Storage Conditions	Type of Stock Culture	Length of Storage
All	Per manufacturer	Lyophilized	Until Expiration date
Rapidly growing bacteria and yeast	2-8 ?C	Stock QC cultures	<= 12 months
	2-8 ?C	Working QC cultures	4 weeks

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	<= -20 ?C	Suspension in Cryopreservative	<=12 months

Processing of Quality Control Organisms

Annual preparation of QC cultures

At least once a year, prepare a culture of each quality control organism routinely used by the laboratory. Use lyophilized or frozen organisms. Prepare a suspension in cryopreservative and store for <=12 months at -20 ?C.

See the specific procedures for ***Micro 8.4 Use of KwikStik Microorganisms*****.**

Monthly preparation of Stock Control (excluding AST QC)

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Inoculate one slant of an appropriate nonselective medium from lyophilized or frozen organisms. Incubate under conditions favorable for growth. Label as stock control, then the name of the organism and the date of inoculation. Tightly seal and store the slants for 1 month at 2 to 8 ?C.

(2) Streptococcus agalactiae, ATCC 27956
(3) Streptococcus pyogenes, ATCC 19615
(76) Streptococcus agalactiae 13813
(22) Escherichia coli, ATCC 25922
(24) Pseudomonas aeruginosa, ATCC 27853
(66) Klebsiella pneumoniae, ATCC 700603
(12) Escherichia coli, ATCC 35218.
(17) Staphylococcus aureus, ATCC 25913
(21) Enterococcus faecalis, ATCC 29212
(4) Enterococcus faecalis, ATCC 51299
(68) Staphylococcus aureus, ATCC BAA976
(69) Staphylococcus aureus, ATCC BAA977
(11) Staphylococcus aureus, ATCC BAA1026
(7) Staphylococcus epidermidis, ATCC 12228
(13) Proteus mirabilis, ATCC 12453
(57) Burkholderia cepacia, ATCC 25416
(5) Staphylococcus aureus ATCC 25923
(67) Staphylococcus aureus ATCC 43300
(105) Proteus mirabilis ATCC 43071
(17) Staphylococcus aureus 29213

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(111) Escherichia coli 8739
(29) Klebsiella aerogenes 13048

Certain fastidious bacteria require 25-35 ?C storage. More fastidious organisms such as *N. gonorrhoeae* may have limited survival on stored slants and may require more frequent subculture. The following CO_2 organisms will be reconstituted from lyophilized KwikStiks annually and saved on slants in 25-35 ?C storage as Stock QC Cultures.

(41) Neisseria gonorrhoeae, ATCC 43069
(42) Haemophilus influenzae, ATCC 10211
(38) Streptococcus pneumoniae, ATCC 49619

Subculture from Sab-Dex Slant in box labeled Fungal Holds to ½ Sab-Dex Plate each.
Incubate at room temperature in black box located on wound bench and labeled "Yeast Box".

(32) Candida glabrata MYA 2950
Candida glabrata MYA 2358
(39) Candida albicans ATCC 10231
(112) Candida auris B11903
(60) Candida tropicalis ATCC 750
(58) Candida krusei ATCC 14243

Store at Room Temperature for one month.

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Monthly Preparation of MALDI PRIME Quality Control

From Stock Control, inoculate four blood agar plates with Escherichia coli 8739 and label with #1, # 2, #3, and #4. These will be used as daily working stock for MALDI Prime Calibrator.

From Stock Control, inoculate Klebsiella aerogenes ATCC 13048 onto appropriate media and sub every third day for MALDI Prime Bacterial QC.

From Stock Control, inoculate Candida glabrata 2358 onto appropriate media and sub every third day for MALDI Prime Yeast QC.

Biweekly Preparation of Stock Control for Antimicrobial Susceptibilities

Inoculate one slant of an appropriate nonselective medium from lyophilized or frozen organisms. Incubate under conditions favorable for growth. Label as stock control, then the name of the organism and the date of inoculation. Tightly seal and store the slants for up to two weeks from 2

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to 8 ?C.

(4) Enterococcus faecalis, ATCC 51299
(12) Escherichia coli, ATCC 35218.
(17) Staphylococcus aureus, ATCC 25913
(21) Enterococcus faecalis, ATCC 29212
(22) Escherichia coli, ATCC 25922
(66) Klebsiella pneumoniae, ATCC 700603
(24) Pseudomonas aeruginosa ATCC27853
(68) Staphylococcus aureus, ATCC BAA976
(69) Staphylococcus aureus, ATCC BAA977
(11) Staphylococcus aureus, ATCC BAA1026
(38) Streptococcus pneumoniae, ATCC 49619

Daily or Weekly Preparation of Working Control

From stock control, prepare a subculture on to appropriate media. Label the working control with the name of the organisms and date of inoculation.

Incubate under conditions favorable for growth and proceed with testing as needed.

Store the working control at 2 to 8?C for one week in QC can.
Seal tightly if plates are used

(4) ***Enterococcus faecalis****, ATCC 51299 **
(12) ***Escherichia coli****, ATCC 35218 **
(17) ***Staphylococcus aureus****, ATCC 25913 **
(21) ***Enterococcus faecalis****, ATCC 29212 **
(22) ***Escherichia coli****, ATCC 25922 **
(66) ***Klebsiella pneumoniae, ATCC*** *700603 **
(24) ***Pseudomonas aeruginosa*** *ATCC27853 **
(68) Staphylococcus aureus*, ATCC BAA976 **
(69) Staphylococcus aureus, *ATCC BAA977 **
(11) Staphylococcus aureus*, ATCC BAA1026 **
(38) Streptococcus pneumoniae*, ATCC 49619 **
(115)Streptococcus pneumoniae, *ATCC 6305*
(3) ***Streptococcus pyogenes****, ATCC 19615*
(17) Staphylococcus aureus *29213*

NOTE: Just in cases will need to be inoculated on day of AST testing in the event an organism is needed for repeat testing the following day. (Marked w/ *)

NOTE: It is necessary to take inventory of media that needs to be QC'd on a weekly basis.

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Additional organisms will need to be inoculated from stock culture to be available for testing.

For the fastidious bacteria such as *N.gonorrhoeae,* and *Haemophilus influenzae,* the working control should be subbed to a quad plate, stored at 25-35 ?C in CO^2, and subbed every other day

Weekly Preparation of Anaerobic Quality Control

Subculture from Brucella Agar to a reduced Brucella Agar for Disk QC:
(WOUND BENCH ASSIGNMENT)

(51) Clostridium perfringens, ATCC 13124
(52) Fusobacterium nucleatum, ATCC 25586
(53) Peptostreptococcus anaerobius, ATCC 27337
(56) Bacteroides fragilis, ATCC 25285
(78) Clostridium difficile, ATCC 700059
(75) Clostridium difficile, ATCC 9689
(79) Cutibacterium acnes, ATCC 11827
(50) Clostridium sordelli, ATCC 9714

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LIMITATIONS

Subculture frozen or lyophilized cultures twice before use.

For Quality Control Testing, select isolated colonies from primary subcultures

If contaminated or questionable performance, prepare new primary subculture,working culture, or obtain new stock culture

REFERENCES

Quality Control for Commercially Prepared Microbiological Culture Media; Approved Standard-Third Edition. NCCLS. M22-A3 Vol.16 No. 16
Methods for Antimicrobial Dilution and Disk Susceptibility Testing of Infrequently Isolated or Fastidious Bacteria. 3rd Ed. Clinical and Laboratory Standards Institute. M45

All Revision Dates

3/3/2026

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Approval Signatures

Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator, VCMC & SPH	3/3/2026
Policy Owner	Erlinda Roxas: Director, Laboratory Services	3/3/2026
Policy Owner	M. Anwar Molani: Medical Director, Laboratory Services	3/2/2026
Policy Owner	Linda Conboy: Supervisor-Microbiology, Laboratory Services	3/2/2026

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Last Revised	3/3/2026
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Owner	Linda Conboy: Supervisor-Microbiology, Laboratory Services
Policy Area	Laboratory Services - Microbiology

L.MIC 8.6 Unavailability of QC Organisms

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DEPARTMENT: Laboratory AFFECTS: MICROBIOLOGY	EFFECTIVE DATE: 02/2014	REVIEW DATES: 12/2015, 12/2016, 12/2017, 3/2019, 11/2021, 11/2023, 1/2025, 2/2026
		REVISION DATES:

All media, biochemical, and susceptibility testing:

When a quality control organism normally used for media, biochemical and susceptibility testing is not available due to:

- Insufficient growth
- Insufficient stock
- Unavailability of the material from the vendor

Patient samples should not be processed until the QC Organism is available for testing against biochemical and susceptibility panels used for patient samples.

If the QC Organism is not available and there will be an extensive delay, patient care must not be hindered, and patient samples should be sent to reference laboratory, as indicated.

All Revision Dates

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Policy Owner	Erlinda Roxas: Director, Laboratory Services	3/3/2026
Policy Owner	M. Anwar Molani: Medical Director, Laboratory Services	3/2/2026
Policy Owner	Linda Conboy: Supervisor-Microbiology, Laboratory Services	3/2/2026

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Last Revised	3/3/2026		
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L.MIC 8.7 General Instrument Maintenance

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EFFECTIVE DATE 12/27/2005	REVIEW DATES: 6/2006,11/2007,9/2008,7/2009, 12/2009, 11/2010, 11/2011,2/2014,12/2015, 12/2017, 3/2019, 11/2021, 11/2023, 4/2025, 2/2026
	REVISION DATES: 7/2015, 1/2016, 12/2023

GENERAL INSTRUMENT MAINTENANCE

PRINCIPLE

Every instrument or piece of equipment used in the performance of diagnostic tests or for reagent preparation and handling in the microbiology lab must function properly and perform according to established standards to ensure the reliability of diagnostic test results.

GENERAL MAINTENANCE

Cleaning external surfaces

Use paper towels soaked in 0.5% sodium hypochlorite (bleach) or 70% alcohol (mild disinfectant solution or Discide disinfectant towelettes.

Rinse with tap water to prevent disinfectant residue from attracting dirt. NOTE: Alcohol does not require rinsing.

If using 0.5% sodium hypochlorite (bleach) on metal parts, be sure to rinse thoroughly to prevent

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corrosion of the metal.

Cleaning up spills of biohazardous material

Major spill or possible aerosol formation.

Ask everyone in the room to hold their breath and leave the room (you do the same).

After 30 minutes, when most aerosol particles have settled, the designated cleaning person must enter the room wearing mask, gloves, and other protective garments as needed.

Flood the spilled surfaces or areas with disinfectant (freshly prepared 0.5 % sodium hypochlorite (bleach). Cover the spill with paper towels soaked in disinfectant.

Allow disinfectant to remain wet for 15 minutes, and then wipe up the spill. Discard contaminated materials in biohazard containers.
Rinse with tap water if necessary.

Minor Spill.

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Use paper towels soaked in disinfectant (0.5% sodium hypochlorite (bleach) to wipe up contaminated material.
Discard towels in trash.

Rinse area with tap water.

Temperature-dependent activities.

Place thermometers, calibrated to the NBS thermometer, wherever temperature is critical for proper performance or functioning of a parameter involved in diagnostic testing or reagent handling. Label each thermometer with its correction factor relative to the NBS thermometer.

Place a mark (use colored marker) above and below the critical range on the thermometer face or shaft to facilitate easy reading of the temperature.

If temperatures are not consistent within a temperature-controlled space, place several thermometers in different areas to document fluctuations and determine acceptable criteria for performance prior to initiating patient testing.

If certain temperature-controlled equipment is not used daily, record the temperature each time the associated test is performed.
Do not allow thermometers to touch the walls or sides of the instrument during temperature measurement.

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Instrument Performance Limits

INSTRUMENT	MINIMUM	MAXIMUM
CO2 Incubator, CO2 Level	5%	10%
CO2 Incubator,Temperature	34 degrees C	36 degrees C
Incubator, aerobic, Temperature	34 degrees C	36 degrees C
Campy Incubator	41 degrees C	43 degrees C
Heat Block, Temperature	34 degrees C	37 degrees C
Refrigerators	2 degrees C	8 degrees C
Virtuo, Temperature	35.0 degrees C	37.0 degrees C
Vitek 2XL	35.0 degrees C	37.0 degrees C
Freezer, Temperature	<=-15 degrees C	minus 25 degrees C
Room Temperature	15°C	30°C
Heat plate	35°C	55°C

Electrical precautions

All electrical equipment should be checked for proper grounding and electrical safety by the biomedical engineering department before installation and at least annually.

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QC recording forms

See Masters and Logs book.

Corrective action recording forms

See Masters and Logs book.

A lead CLS or supervisor must be notified of each out of limit occurrence.
This outlier must be documented on the corrective action log sheet including personnel notified and corrective actions taken.
In the event that the issue is not resolved, communications must be made to the person or department that can assist with the resolution of the issue.
All follow up communications must be documented on the corrective action log.

QC ACTIVITY SCHEDULE FOR INSTRUMENTS

See instructions for specific instruments.

DISTRIBUTION OF PREVENTIVE MAINTENANCE DUTIES

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Clinical laboratory scientists by monthly rotation.

REFERENCE

Clinical Microbiology Procedures Handbook, ASM, 2017, Volume 3, pages 14.2.1-14.2.3.

Clinical Microbiology Procedures Handbook, ASM, 2004, Volume 3, pages 14.2.1- 14.2.4.

All Revision Dates

3/3/2026

Attachments

- Micro 8.7 REF ACTIVITY SCHEDULE FOR INSTRUMENTS.xls
- Micro 8.7 REF Instrument Performance Limits.xls
- Micro 8.7 REF SCHEDULE OF INSTRUMENT PERFORMANCE.xls

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Approval Signatures

Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator, VCMC & SPH	3/3/2026
Policy Owner	Erlinda Roxas: Director, Laboratory Services	3/3/2026
Policy Owner	M. Anwar Molani: Medical Director, Laboratory Services	3/2/2026
Policy Owner	Linda Conboy: Supervisor-Microbiology, Laboratory Services	3/2/2026

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Owner	Linda Conboy: Supervisor-Microbiology, Laboratory Services
Policy Area	Laboratory Services - Microbiology

L.MIC 8.8 Verification of Procedures and Instrumentation

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DEPARTMENT: Laboratory AFFECTS: MICROBIOLOGY	EFFECTIVE DATE: 2/11/2014	REVIEW DATES: 12/2015, 12/2016, 12/2017, 12/2018, 3/2019, 11/2021, 11/2023, 1/2025, 2/2026
		REVISION DATES:

PRINCIPLE

Laboratories are required to establish policies and procedures to maintain or improve the reliability, efficiency and clinical utility of laboratory tests. Two of the most important analyses performed in the laboratory are verification and validation. While the definitions of these processes are often used interchangeably they are in fact two separate processes. Verification is the one-time process performed to determine or to confirm a test's expected performance prior to implementation in the clinical laboratory; simply put, it asks "does the test work?" Validation is an ongoing process of monitoring a test, procedure or method to ensure that it continuously performs as expected; simply put, it asks "does the test still work?" Validation is achieved through normal quality control, proficiency testing, staff competency testing, and instrument calibration.

VERIFICATION

When verification processes are applied to microbiology, where qualitative results are more common, where subjective interpretations are required, or where the results include the identification of microorganism with biological variation, more flexibility is required than in the chemistry laboratory.

The verification study of an assay should demonstrate that it can be detect or accurately characterize the analyte of interest and the verification plan and acceptance criteria should be established prior to the

beginning of the verification study.

Per CLIA Quality System Regulations, for unmodified, FDA-cleared or –approved (either moderate or high complexity), the laboratory is required to verify the manufacturer's performance specifications provided in the package insert before reporting patient test results. These specifications are:

- Accuracy
- Precision
- Reportable range
- Reference range

This requirement applies when the laboratory replaces a test system or instrument (with the same model or a different model), adds a new test, or changes the manufacturer of a test system.

ACCURACY

The accuracy portion of test verification is usually accomplished by performing the new or revised test method in parallel with a reference method that has an established and satisfactory level or accuracy. However, in the absence of a suitable reference method, analytic performance characteristics can be established using previously characterized clinical samples, characterized clinical isolates, or simulated samples prepared by spiking the appropriate test matrix with various concentrations of characterized clinical isolates or the analyte of interest. That is, the accuracy of a new test can be established by either method comparison or recovery studies and is a measure of the agreement between observed and expected results.

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PRECISION

Precision (or reproducibility should be verified within runs, between runs, and between operators, if the test system is considered to be highly operator dependent. Fully automated systems are generally not considered to be operator dependent. Precision can be verified by testing several negative and positive specimens (or for quantitative tests, various levels of analyte) at least in duplicate in the same run and in different runs. For operator-dependent tests, this process is performed by at least two different operators. The comparability of repeated results (either qualitative or quantitative, as appropriate) is assessed relative to the manufacturer's specifications.

REPORTABLE RANGE

The reportable range is verified by testing characterized samples with known values near the lower and upper ends of the manufacturer's reportable range as well as samples in the normal range (usually negative for analyte).

REFERENCE RANGE

The reference range (normal values) provided by the test manufacturer or as published in textbooks or scientific articles can be used by the laboratory, provided the laboratory's patient population is similar.

PROCEDURE

- Submit a written proposal to Laboratory Director and/or Laboratory Manager stating the test/

instrumentation to be added or replaced with the rationale for this proposed change.

- Obtain a source of standardized testing material and procedures.
- Write procedure for the new test/instrumentation according to Clinical and Laboratory Standards Institute guidelines.
- Verify instrument and procedure by testing specimens as outlined below.
- If needed, develop or implement interface from instrument to laboratory information system.
- If needed, develop test ordering, reporting, and charge structures in the laboratory information system.
- If needed, develop test charge structures in the hospital/clinic information system.
- Train staff and document competency.
- Develop ongoing validation procedure to ensure the test/instrument is performing as expected on a daily basis.
- Submit in a written report the verification raw data, data analysis and conclusion to the Laboratory Director and/or Laboratory Manager for their approval and signature. See attached Summary Statement.
- If needed, inform providers about the new test, including interpretation of test results.

SPECIMEN TESTING

The new test should be performed in parallel with the existing test or a reference method on at least 20 specimens generally divided equally among those positive for the analyte and those negative for the analyte. Both weakly and strongly positive specimens should be included to verify the reportable range of the assay. If weakly positive specimens are unavailable, dilution of strongly positive specimens with the appropriate specimen matrix can achieve the same results.

Samples used for method verification should be well characterized clinical specimens or culture isolates from either retrospective or prospective clinical specimens or studies whenever possible. Proficiency and/or commercially prepared reference panels characterized by one or more methods are suitable for method verification studies.

With careful planning, all of the test characteristics may be verified using the same set of samples. For example, the laboratory can test samples with known values at the lower and upper ends of the manufacturer's reportable range along with samples in the normal range for the institution's patient population, in different runs, on different days, and by different personnel.

After the results of the new test are compared with those of the reference method (gold standard), the number of true-positive, true-negative, false-positive, and false-negative results obtained with the test to be verified should be documented. Total accuracy should be at least 90% relative to the reference method.

CONCLUSION

The results of test verification should indicate one of three possibilities:

- The test is acceptable for routine use

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- Further verification studies are required.
- An immediate corrective action is required by the manufacturer, the user, or both. The test is unsuitable for routine use until its performance parameters can be verified.

Records of the actual test verification results must be maintained for at least 2 years after retirement of the test system.

COMPARABILITY OF INSTRUMENTS AND METHODS

If the laboratory uses more than one non waived instrument/method to test for a given analyte, the instruments and methods must be checked against each other at least twice a year for comparability of results. The purpose of this requirement is to evaluate the relationship between test results using different methodologies, instruments, or testing sites. Logs of performance will be maintained in Comparability of Instruments manual.

Test on a minimum of 10 specimens unless otherwise approved by medical director or designee.

Acceptance criteria:

Number out of Range with initial testing (Based on 10 Reps)	Conclusion From Initial Testing (Based on 10 Reps)	Number Out of Range After Repeat Testing (Based on all 20 reps)	Conclusion After Repeat Testing
0-1	Plan is successful	N/A	N/A
2-3	Test another 10 reps	2	Plan is successful
>=4	Plan fails. Investigate and take corrective action as appropriate.	>=3	Plan fails. Investigate and take corrective action as appropriate.

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Calculations:

N=number specimens tested

Acceptable >=90%

Not Acceptable <90%

Notify supervisor of any failures

REFERENCES

Clark, R.B., M.A. Lewinski, M.J. Loeffelholz, and R.J. Tibbetts, 2009. Cumitech 31A, Verification and Validation of Procedures in the Clinical Microbiology Laboratory. Coordinating ed., S.E.Sharp. ASM Press, Washington DC

Wilson, Michael L. Assuring the Quality of Clinical Microbiology Test Results. CID 2008:47. Web. 8Feb2014

Centers for Medicare and Medicaid Services. Clinical Laboratory Improvements Amendments (CLIA) Verification of Performance Specifications Brochure #2. February 2004. Web. 8Feb2014

All Revision Dates

3/3/2026

Attachments

Micro 8.8 REF COMPARABILITY OF INSTRUMENTS AND METHODS.xlsx

Micro 8.8 REF SUMMARY STATEMENT OF VERIFICATION.doc

Approval Signatures

Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator, VCMC & SPH	3/3/2026
Policy Owner	Erlinda Roxas: Director, Laboratory Services	3/3/2026
Policy Owner	M. Anwar Molani: Medical Director, Laboratory Services	3/2/2026
Policy Owner	Linda Conboy: Supervisor-Microbiology, Laboratory Services	3/2/2026

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Effective	9/19/2024		
Last Revised	3/2/2026	Policy Area	Laboratory Services - Microbiology
Next Review	3/1/2028		

L.MIC 9.2 E test Daptomycin

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INTENDED USE:

ETEST® Daptomycin is a manual, quantitative technique for the determination of antimicrobial susceptibility Gram-positive aerobic bacteria and fastidious bacteria. The system comprises a predefined antibiotic gradient which is used to determine the Minimum Inhibitory Concentration (MIC, in µg/mL) of daptomycin against microorganisms tested on agar media after overnight incubation.

INDICATIONS FOR USE:

ETEST® DPC can be used to determine the MIC of Daptomycin against the following microorganisms: • Aerobes: ◦ Gram-positive aerobes: Staphylococcus, Enterococcus • Streptococcus: S. pyogenes A, S. agalactiae B, S. dysgalactiae.

PRINCIPLE:

ETEST® is a thin, inert, non-porous plastic strip carrying the MIC reading scale in µg/mL on one side (A) and a predefined antibiotic gradient on the other side (B). When the strip is applied to an inoculated agar surface, the preformed antibiotic gradient immediately transfers into the agar matrix to form a stable, continuous, exponential gradient of antibiotic concentrations directly

underneath the strip. Bacterial growth becomes visible during incubation and a symmetrical inhibition ellipse centered along the strip appears. The MIC value is read from the scale in terms of µg/mL at complete inhibition of bacterial growth, where the pointed end of the ellipse intersects the strip.

Although processed like the disk diffusion test (similar inoculum preparation, choice of agar media and incubation conditions), ETEST® is not a diffusion method and differs totally in concept from conventional disk methods. The ETEST® antimicrobial concentration gradient is preformed, predefined and stable, and is not dependent on diffusion.

MATERIALS:

Test Strips:
Each strip contains: • Daptomycin MIC range: 0.016-256 µg/mL

Swabs (sterile) and test tubes, forceps, and McFarland Standard (Ref. 70900) or equivalent, Incubator (+35°C ± 2°C) and Quality control organisms.

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STORAGE AND STABILITY:

Store -20C-8C as specified on the packaging.

Do not use reagents after the expiration date indicated on the packaging.

Protect ETEST® strips from moisture, heat and direct exposure to strong light always.

Do not store ETEST® strips from Single Packs that have been opened

HANDLING:

Before using the ETEST® strips from an unopened package, visually inspect to ensure the package is intact. Do not use it if the package has been damaged.

When removed from the refrigerator/freezer, allow the cartridge to reach room temperature before opening (approx. 15 minutes if stored at +4°C or approx. 30 minutes if stored at -20°C) and remove the strip from the package just before use.

Ensure that moisture condensing on the outer surface has evaporated completely before opening the package.

Do not touch the surface of the strip that contains the gradient (the side opposite the MIC scale). It is recommended to use forceps or a similar device] to pick up ETEST® strips. When handling ETEST® strips manually with forceps, only grip the handle of the strip (the area containing the 2- or 3-letter code).

INSTRUCTIONS FOR USE

Inoculum preparation and Inoculation

Bring the Mueller Hinton agar and ETEST® strips to room temperature.

Prepare the inoculum: emulsify well-isolated colonies from an overnight agar plate. Ensure that the inoculum suspension has the correct number of CFU/mL (Colony Forming Units) to match the appropriate McFarland standard, especially important for fastidious and mucoid organisms. If the inoculum is correct, a confluent or almost confluent lawn of growth will be obtained after incubation.
Inoculate: dip a sterile, non-toxic and not too tightly spun swab into the inoculum suspension. Remove excess fluid by pressing the swab against the inside wall of the test tube. Remove more fluid when streaking a 90 mm plate and less for a 150 mm plate. Swab the entire agar surface three times, rotating the plate approximately 60 degrees each time to ensure an even distribution of inoculum.
Allow excess moisture to be absorbed for about 15 to 20 minutes so that the surface is completely dry before applying the ETEST® gradient strip.

Check that the inoculated agar surface is completely dry.

Open the ETEST packaging as indicated in the handling and opening instructions.

ETEST® strips can be applied to the inoculated agar surface using forceps.

Position the ETEST® gradient strip with the MIC scale facing upwards (towards the opening of the plate) and the highest concentration nearest the rim of the plate.

Up to six ETEST® strips can be placed on a 150 mm agar plate (Figure 6a) and up to two strips on a 90 mm agar plate.

Ensure that the whole strip is in complete contact with the agar surface. Do not place the strip upside down as no inhibition ellipse will form since the antibiotic will not diffuse across the non-

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porous plastic strip. If air pockets are seen under the strip, remove them by pressing gently on the strip (without moving it) with the applicator tip or forceps, working from the lowest concentration upwards.
Small bubbles will not affect results. Once applied, the strip cannot be moved because of instantaneous release of antibiotic into the agar.

Incubate the agar plates in an inverted position (lid down) in stacks no higher than 5, according to conditions outlined in the following guide:

Organism group	Agar media	Suspension	Turbidity (McFarland)	Temperature	Atmosphere	Time(hrs)
Aerobes	Mueller Hinton	0.85% NaCl	0.5	+35°C	Ambient	16-20

Notes: The inherent calcium content in Mueller Hinton agar may vary between brands and from batch to batch. Perform quality control of agar plates on a batch-to-batch basis to qualify them for use.

Ensure the inoculum does not exceed 0.5 (1 if mucoid) McFarland Standard. When using small agar plates, press out extra fluid from the swab before streaking to avoid excess inoculum. Excessive growth on the agar can "hug" the strip and give falsely elevated MIC results.

Ensure the agar plate is incubated for the recommended period before reading, especially for delayed expression of resistance and slow-growing and fastidious organisms.

LIMITATION: Daptomycin should not be reported for isolates from the respiratory tract.

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RESULTS AND INTERPRETATION

Reading

When bacterial growth is clearly visible, read the MIC value where the respective inhibition ellipses intersect the strip. ETEST® MIC endpoints are usually clear-cut although different growth/ inhibition patterns may be seen
Do not read the plate if the culture appears mixed or if the lawn of growth is too light or too heavy; repeat the test.
For Daptomycin, read the MIC endpoint at complete inhibition of growth. Haze and macro-colonies or microcolonies within 3 mm from the strip should be read as growth.

Growth along the entire gradient (no inhibition ellipse) indicates that the MIC is higher than or equal to the highest value on the reading scale.

An inhibition ellipse below the gradient indicates an MIC less than the lowest value on the scale. Read the MIC at the end of the dip for Daptomycin. Excessively wet plates prior to inoculation, insufficient drying before applying strips and/or unevenly streaked surfaces may give non-confluent growth or jagged ellipse edges.
Repeat the test if MIC endpoints are difficult to read. In the case of uneven MIC intersections, read the higher value. If > 1 dilution, repeat the test.

For streptococci and enterococci, tilt the plate and/or use a magnifying glass to carefully examine endpoints.
In case of tunnel growth, ignore the thin line of growth alongside the strip.

Interpretation

Organism	Susceptible	Intermediate	Resistant	Nonsusceptible*
Staphylococci	<=1	--	--	
Enterococci	<=4	4	>=8	
E.faecium	<=4	--	--	>=8

*The nonsusceptible category is used when the MIC is above the susceptible breakpoint but only a susceptible interpretation has been designated by CLSI because of the absentee or rare occurrence of resistant strains (for E.faecium, specifically)

Being a fully quantitative MIC method, ETEST® enables the laboratory to report the exact MIC value together with the interpretive category. ETEST® generates MIC values from a continuous scale and can give results between conventional two-fold dilutions (half dilutions). An ETEST® MIC value which falls between standard two-fold dilutions must be rounded up to the next upper two-fold value before categorization.

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QUALITY CONTROL

Check the performance of ETEST reagents, quality of media, inoculum and procedure used with the QC strains listed in the table each day of use. The reagents and test procedure are considered satisfactory if MIC values obtained fall within the quality control specifications provided below.

Staph. Aureus	ATCC 29213	0.25-1
E. faecalis	ATCC 29212	1-4

Perform QC using both S. aureus 29213 and E. faecalis 29212. Use of the two QC strains allows verification of results within the susceptible range and around the breakpoint. When results are out of QC specifications or consistently skewed at the limits, repeat the test using a different brand of MHA.

REPORTING

ETEST for daptomycin can be ordered directly in the LIS. The documentation released to the clinician will be in mcg/ml. Interpretation will be indicated based on numerical entry.

If daptomycin is >=8 mcg/ml and the organism is E. faecium, the interpretation will be documented as nonsusceptible and the following comment must be added to the final report using the coded comment DAPNS.

The comment reads, "The nonsusceptible category is used when the MIC is above the susceptible breakpoint but only a susceptible interpretation has been designated by CLSI because of the absence or rare occurrence of resistant strains."

REFERENCES

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ETEST® Daptomycin (DPC) (0.016-256 µg/mL) Package insert, BioMerieux SA, 056110, Aug 2020.

Peter C. Fuchs et al., Evaluation of daptomycin susceptibility testing by Etest and the effect of different batches of Media, Academic.oup.com/jac/article/48/4/557/700336.

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4/2025, 2/2026
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3/2/2026

Approval Signatures

Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator, VCMC & SPH	3/2/2026

Policy Owner	Linda Conboy: Supervisor-Microbiology, Laboratory Services	3/1/2026
Policy Owner	M. Anwar Molani: Medical Director, Laboratory Services	3/1/2026
Policy Owner	Erlinda Roxas: Director, Laboratory Services	2/28/2026

COPY

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Owner	Linda Conboy: Supervisor-Microbiology, Laboratory Services
Policy Area	Laboratory Services - Microbiology

L.MIC.2.2 Meningitis Encephalitis Panel

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PURPOSE:

This procedure provides instructions for testing cerebrospinal fluid (CSF) using the FilmArray Meningitis/ Encephalitis Panel (ME) Kit.

POLICY:

Intended Use

The FilmArray Meningitis/Encephalitis (ME) Panel is a qualitative multiplexed nucleic acid-based in vitro diagnostic test intended for use with FilmArray systems. The FilmArray ME Panel is capable of simultaneous detection and identification of multiple bacterial, viral, and yeast nucleic acids directly from CSF specimens obtained via lumbar puncture from individuals with signs and/or symptoms of meningitis and/or encephalitis. The following organisms are identified using the FilmArray ME Panel:

Bacteria:

- *Escherichia coli* K1
- *Haemophilus influenzae*
- *Listeria monocytogenes*
- *Neisseria meningitidis* (encapsulated)
- *Streptococcus agalactiae*
- *Streptococcus pneumoniae*

Viruses:

- Cytomegalovirus

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- Enterovirus
- Herpes simplex virus 1
- Herpes simplex virus 2
- Human herpesvirus 6
- Human parechovirus
- Varicella zoster virus

Yeast:

- *Cryptococcus neoformans/gattii*

PRINCIPLE:

The FilmArray ME pouch is a closed system disposable that houses all the chemistry required to isolate, amplify, and detect nucleic acid from multiple meningitis and encephalitis pathogens within a single CSF specimen obtained from a lumbar puncture. The rigid plastic component (fitment) of the FilmArray ME pouch contains reagents in freeze-dried form.

The flexible plastic portion of the pouch is divided into discrete segments (blisters) where the required chemical processes are carried out. The user of the FilmArray ME Panel loads the sample into the FilmArray ME pouch, places the pouch into the FilmArray instrument, and starts the run. All other operations are automated.

Back up culture must be performed on both positive and negative cultures

The following is an overview of the operations and processes that occur during a FilmArray run:

1. **Nucleic Acid Purification** - Nucleic acid purification occurs in the first three blisters of the pouch. The sample is lysed by agitation (bead beating) and the liberated nucleic acid is captured, washed and eluted using magnetic bead technology. These steps require about ten minutes and the bead-beater apparatus can be heard as a high pitched whine during the first minute of operation.
2. **Reverse Transcription and 1st Stage Multiplex PCR** - Some pathogens identified by the FilmArray ME pouch are RNA viruses, and a reverse transcription (RT) step is performed to convert the viral RNA into cDNA prior to amplification. The purified nucleic acid solution is combined with a preheated master mix to initiate the RT step and subsequent thermocycling for multiplex PCR. The effect of 1st stage PCR is to enrich for the target nucleic acids present in the sample.
3. **2nd Stage PCR** - The products of 1st stage PCR are diluted and mixed with fresh PCR reagents containing an intercalating fluorescent DNA dye (LCGreen® Plus, BioFire Defense, LLC). This solution is distributed over the 2^{nd} stage PCR array. The individual wells of the array contain primers for different assays (each present in triplicate) that target specific nucleic acid sequences from each of the pathogens detected, as well as control template material. These primers are 'nested' or internal to the specific products of the 1st stage multiplex reaction, which enhances both the sensitivity and specificity of the reactions.
4. **DNA Melting Analysis** – After 2nd stage PCR, the temperature is slowly increased and fluorescence in each well of the array is monitored and analyzed to generate a melt curve. The temperature at which a

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specific PCR product melts (melting temperature or Tm) is consistent and predictable and the FilmArray software automatically evaluates the data from replicate wells for each assay to report results. For a description of data interpretation and reporting see the Interpretation of Results section of this book

Specimen:

CSF specimens should be collected via lumbar puncture and should not be centrifuged.

Minimum Sample Volume - 200µL of CSF specimen is required for testing.

Transport and Storage - Specimens should be processed and tested with the FilmArray ME Panel as soon as possible, though they may be stored for up to one day at room temperature, or under refrigeration for up to seven days.

Materials Provided	Materials Required But Not Provided
Each kit contains sufficient reagents to test 30 or 6 specimens: • Individually packaged FilmArray ME pouches • Single-use (1.0 mL) Sample Buffer ampoules • Single-use pre-filled (1.5 mL) Hydration Injection Vials (blue) • Single-use Sample Injection Vials (red) • Individually packaged Transfer Pipettes	FilmArray System including: FilmArray Instrument and software FilmArray Pouch Loading Station compatible with the use of the FilmArray Injection Vials

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Quality Control:

Controls for each analyte should be either included in each run or rotated so that all analytes are tested periodically

Process Controls

Two process controls are included in each pouch:

1. **RNA Process Control -** The RNA Process Control assay targets an RNA transcript from the yeast *Schizosaccharomyces pombe*. The yeast is present in the pouch in a freeze-dried form and becomes rehydrated when sample is loaded. The control material is carried through all stages of the test process, including lysis, nucleic acid purification, reverse transcription, 1st stage PCR, dilution, 2nd stage PCR and DNA melting. A positive control result indicates that all steps carried out in the FilmArray ME pouch were successful.
2. **PCR2 Control -** The PCR2 Control assay detects a DNA target that is dried into wells of the array along with the corresponding primers. A positive result indicates that 2nd stage PCR was successful.

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Both control assays must be positive for the test run to pass. When either control fails, the Controls field of the test report (upper right hand corner) will display Failed and all results will be listed as Invalid. If the controls fail, the sample should be retested using a new pouch.

Monitoring Test System Performance

The FilmArray software will automatically fail the run if the melting temperature (Tm) for either the RNA Process Control or the PCR2 Control is outside an acceptable range (80.2-84.2 for the RNA Process Control and 74.1-78.1 for the PCR2 Control). The PCR2 Control is used in all FilmArray pouch types (e.g., RP, GI, ME, and BCID) and can therefore be used to monitor the system when multiple pouch types are used on the same FilmArray system or instrument.

Good laboratory practice recommends running external positive and negative controls regularly. Molecular grade water, or artificial CSF, can be used as an external negative control. Previously characterized positive CSF samples or negative samples spiked with well characterized organisms can be used as external positive controls. External controls should be used with each new lot or shipment or after maintenance.

Refer to the FilmArray Meningitis/Encephalitis Panel Quick Guide, the FilmArray Training Video, or the FilmArray Operator's Manual for more detail and pictorial representations of these instructions.

Gloves and other Personal Protective Equipment (PPE) should be used when handling pouches and samples. Only one FilmArray ME pouch should be prepared at a time. Once sample is added to the pouch, it should be promptly transferred to the instrument to start the run. After the run is complete, the pouch should be discarded in a biohazard container.

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Prepare Pouch

1. **Thoroughly clean the work area with 70% ethanol and the FilmArray Pouch Loading Station with freshly prepared 10% bleach (or suitable disinfectant) followed 70% ethanol.**

2. Remove the pouch from its vacuum-sealed package by tearing or cutting the notched outer packaging and opening the protective aluminum canister.

   Text Box: NOTE: If the vacuum seal of the pouch is not intact, the pouch may still be used. Attempt to hydrate the pouch using the steps in the Hydrate Pouch section. If hydration is successful, continue with the run. If hydration fails, discard the pouch, and use a new pouch to test the sample.

3. Slide the pouch into the FilmArray Pouch Loading Station so that the red and blue labels on the pouch align with the red and blue arrows on the FilmArray Pouch Loading Station.
4. Place a blue-capped Hydration Injection Vial in the blue well of the FilmArray Pouch Loading Station.
5. Place a red-capped Sample Injection Vial in the red well of the FilmArray Pouch Loading Station.

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Hydrate Pouch

1. Twist and lift the Hydration Injection Vial, leaving blue cap in the well of the FilmArray Pouch Loading Station.
2. Insert the cannula tip into the port in the pouch located directly below the blue arrow of the FilmArray Pouch Loading Station. Push down forcefully in a firm and quick motion until you hear a faint “pop” and feel an ease in resistance. The correct volume of liquid will be pulled into the pouch by vacuum.
3. Verify that the pouch has been hydrated. Flip the barcode label down and check to see that fluid has entered the reagent wells (located at the base of the rigid plastic part of the pouch). Small air bubbles may be seen. If the pouch fails to hydrate (dry reagents appear as white pellets), repeat Step 2 to verify that the seal of the port was broken or retrieve a new pouch and repeat from Step 2 of the Prepare Pouch section.

Prepare Sample Mix

1. Hold the Sample Buffer ampoule so that the tip is facing up.
2. Gently pinch the textured plastic tab on the side of the ampoule until the seal snaps.
3. Invert the ampoule over the red-capped Sample Injection Vial and re-position thumb and forefinger to grip the bottom of the ampoule. Dispense Sample Buffer using a slow, forceful squeeze, followed by a second squeeze. Squeezing the ampoule additional times will generate excessive bubbles, which should be avoided.
4. Thoroughly mix the patient sample.
5. Using the Transfer Pipette provided in the test kit, draw cerebrospinal fluid (CSF) sample to the second line (approximately 0.2 mL) of the Transfer Pipette. Add the sample to the Sample Buffer in the Sample Injection Vial. Discard the Transfer Pipette in a biohazard waste container and tightly close the lid of the Sample Injection Vial.
6. Remove the Sample Injection Vial from the FilmArray Pouch Loading station and gently invert the vial at least 3 times to mix.
7. Return the Sample Injection Vial to the FilmArray Pouch Loading Station.

Load Sample Mix

1. Slowly twist the Sample Injection Vial so it loosens from its red cap and pause for 3-5 seconds. Lift the Sample Injection Vial, leaving the red cap in the well of the FilmArray Pouch Loading Station.
2. Insert the cannula tip into the port in the pouch fitment located directly below the red arrow of the FilmArray Pouch Loading Station. Push down forcefully in a firm and quick motion until you hear a faint “pop” and feel an ease in resistance. The correct volume of liquid will be pulled into the pouch by vacuum.
3. Verify that the sample has been loaded. Flip the barcode label down and check to see that fluid has entered the reagent well next to the sample loading port. If the pouch fails to pull sample from the Sample Injection Vial, the pouch should be discarded. Retrieve a new pouch and repeat from the

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Prepare Pouch section. Discard the Sample Injection Vial and the Hydration Injection Vial in an appropriate biohazard sharps container.

4. Discard the Sample Injection Vial and the Hydration Injection Vial in an appropriate biohazard sharps container.
5. Record the Sample ID in the provided area on the pouch label (or affix a barcoded Sample ID) and remove the pouch from the FilmArray Pouch Loading Station.

Run Pouch

1. Ensure that the FilmArray device is powered on and ready for use.
2. Follow on-screen instructions and procedures described in the Operator's Manual to place the pouch in an instrument, enter pouch, sample, and operator information, and start the run.
3. Pouch identification (Lot Number and Serial Number), Pouch Type and Protocol are preprogrammed in the rectangular barcode located on the FilmArray pouch. The information will be automatically entered when the barcode is scanned. If it is not possible to scan the barcode, the pouch Lot Number, Serial Number, Pouch Type and Protocol can be manually entered from the information provided on the pouch label into the appropriate fields. To reduce data entry errors, it is strongly recommended that the pouch information be entered by scanning the barcode.
4. Enter the Sample ID. The Sample ID can be entered manually or scanned in by using the barcode scanner when a barcoded Sample ID is used.
5. If necessary, select the appropriate protocol for your sample type from the Protocol drop down list.
6. Enter a username and password in the Name and Password fields.
7. Start run.
8. When the run is finished, follow the on-screen instructions to remove the pouch and immediately discard the pouch in a biohazard container.
9. The run file is automatically saved in the FilmArray database, and the results report can be viewed, printed, and/or saved as a PDF file.
10. The FilmArray software automatically analyzes and interprets assay results and displays the final results in a test report (see the FilmArray Meningitis/Encephalitis Panel Quick Guide to view an example of a test report). The analyses performed by the FilmArray software and details of the test report are described below.

Assay Interpretation

When 2nd stage PCR is complete, the FilmArray instrument performs a high-resolution DNA melting analysis on the PCR products and measures the fluorescence signal generated in each well (for more information see FilmArray Operator's Manual). The FilmArray software then performs several analyses and assigns a final assay result. The steps in the analyses are described below.

Analysis of melt curves. The FilmArray software evaluates the DNA melt curve for each well of the 2nd stage PCR array to determine if a PCR product was present in that well. If the melt profile indicates the presence of a PCR product, then the analysis software calculates the melting temperature (Tm) of the curve. The Tm value is

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then compared against the expected Tm range for the assay. If the software determines that the melt curve is positive and the Tm falls inside the assay-specific Tm range, the melt curve is called positive. If the software determines that the melt curve is negative or is not in the appropriate Tm range, the melt curve is called negative.

Analysis of replicates. Once melt curves have been identified, the software evaluates the three replicates for each assay to determine the assay result. For an assay to be called positive, at least two of the three associated melt curves must be called positive, and the Tm for at least two of the three positive melt curves must be similar (within 1°C). Assays that do not meet these criteria are called negative.

Organism Interpretation. The reported FilmArray ME Panel organism results (Detected or Not Detected) are based on analysis and interpretation of a single assay (most organisms) or a combination of two assays (*Haemophilus influenzae*, Herpes simplex virus 2 and Varicella zoster virus). For results that rely on two assays, a Detected result is reported when either one or both assays are positive and a Not Detected result is reported only when both assays are negative.

NOTE: Non-K1 *E. coli* serotypes may be present in a specimen and will not be detected by the FilmArray ME Panel.

NOTE: Non-encapsulated strains of *Neisseria meningitidis* are not detected by the FilmArray ME Panel.

NOTE: The FilmArray ME Panel does not distinguish between latent and active CMV and HHV-6 infections. Detection of these viruses may indicate primary infection, secondary reactivation, or the presence of latent virus. Results should always be interpreted in conjunction with other clinical, laboratory, and epidemiological information.

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FilmArray ME Panel Test Report

The FilmArray ME Panel test report is automatically displayed upon completion of a run and contains three sections, the Run Summary, the Result Summary, and the Run Details (see the FilmArray Meningitis/ Encephalitis Panel Quick Guide to view an example of a test report). The test report can be saved as a PDF or printed.

The Run Summary section of the test report provides the Sample ID, time and date of the run, control results and an overall summary of the test results. Any organism with a Detected result will be listed in the corresponding field of the summary. If all of the organism assays were negative than None will be displayed in the Detected field. Controls are listed as Passed, Failed or Invalid. See the Controls Field section below for detailed information about the interpretation of controls and appropriate follow-up in the case of control failures.

The Result Summary section of the test report lists the result for each target tested by the panel. Possible results for each organism are Detected, Not Detected, or Invalid. See Results Summary section below for detailed information about interpretation of test results and appropriate follow-up for Invalid results.

The Run Details section provides additional information about the run including pouch information (type, lot number, and serial number), Run Status (Completed, Incomplete, Aborted, Instrument Error, Instrument Communication Error, or Software Error), the protocol that was used to perform the test, the identity of the operator that performed the test, and the instrument used to perform the test.

Once a run has completed, it is possible to edit the Sample ID. If this information has been changed, an additional section called Change History will be added to the test report. This Change History section lists the field that was changed, the original entry, the revised entry, the operator that made the change, and the date

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that the change was made. Sample ID is the only field of the report that can be changed.

Controls Field

The Controls field on the test report will display Passed, Failed, or Invalid. The Controls field will display Passed only if the run completed successfully (no instrument or software errors) and both of the pouch control assays (RNA Process Control and PCR2 Control) were successful. The Controls field will display Failed if the run was completed successfully (no instrument or software errors) but one or both of the pouch control assays failed. If the control result is Failed, then the result for all of the tests on the panel are displayed as Invalid and the sample will need to be retested with a new pouch. Table 1 provides a summary and explanation of the possible control results and follow-up actions.

Table 1. Interpretation of Controls Field on the FilmArray ME Panel Test Report

Control Result	Explanation	Action Required	Outcome
Passed	The run was successfully completed AND Both pouch controls were successful.	None	Report the results provided on the test report.
Failed	The run was successfully completed BUT At least one of the pouch controls (RNA Process Control and/or PCR2 Control) failed.	Repeat the test using a new pouch.	Accept the results of the repeat testing. If the error persists, contact Technical Support for further instruction.
Invalid	The controls are invalid because the run did not complete. (Typically this indicates a software or hardware error).	Note any error codes displayed during the run and the Run Status field in the Run Details section of the report. Refer to the FilmArray Operator's Manual or contact Technical Support for further instruction. Once the error is resolved, repeat the test or repeat the test using another instrument.	Accept the valid results of the repeat testing. If the error persists, contact Technical Support for further instruction.

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Result Reporting

The Result Summary section provides a complete list of the test results. Possible results for each organism include Detected, Not Detected, and Invalid. Table 2 provides an explanation for each interpretation and any follow-up necessary to obtain a final result.

Table 2. Reporting of Results and Required Actions

Result	Explanation	Action

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Detected	The run was successfully completed AND The pouch controls were successful (Passed) AND The assay(s) associated with the interpretation were positive based on the following requirements for at least 2 of the 3 assay replicates: -a positive melt curve, and -the Tm for the melt data were within the assay specific limits, and -the Tm for the melt data were within 1°C of each other.	Report results. NOTE: If Detected results are reported for 2 or more organisms in a specimen, a retest of the specimen is recommended to confirm the polymicrobial result.
Not Detected	The run was successfully completed AND The pouch controls were successful (Passed) AND The assay(s) associated with the interpretation were negative (did not meet the requirements for a positive assay described in Detected).	Report results.
Invalid	The run did not complete successfully (Aborted, Incomplete, Instrument Communication Error, Instrument Error, or Software Error) OR The pouch controls were not successful (Failed)	See Table 1, *Interpretation of Controls Field on FilmArray Report,* for instruction

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References:

- FilmArray Meningitis/Encephalitis Panel (ME) CE-IVD Instruction Booklet (RFIT-PRT-0005), BioFire Diagnostics, LLC.

All Revision Dates

3/2/2026

Approval Signatures

Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator, VCMC & SPH	3/2/2026
Policy Owner	Linda Conboy: Supervisor-Microbiology, Laboratory Services	3/1/2026
Policy Owner	Erlinda Roxas: Director, Laboratory Services	2/28/2026

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Policy Owner	M. Anwar Molani: Medical Director, Laboratory Services	2/23/2026

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Next Review	3/1/2028		

L.MIC.2.3 Film Array GI Panel

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PURPOSE:

The FilmArray Gastrointestinal (GI) Panel is a qualitative multiplexed nucleic acid-based *in vitro* diagnostic test intended for use with FilmArray systems. The FilmArray GI Panel is capable of the simultaneous detection and identification of nucleic acids from multiple bacteria, viruses, and parasites directly from stool samples in Cary Blair transport media obtained from individuals with signs and/or symptoms of gastrointestinal infection. The following bacteria (including several diarrheagenic *E. coli/ Shigella* pathotypes), parasites, and viruses are identified using the FilmArray GI Panel:

1. *Campylobacter* (*C. jejuni/C. coli/C. upsaliensis*)
2. *Clostridium difficile* (*C. difficile*) toxin A/B
3. *Plesiomonas shigelloides*
4. *Salmonella*
5. *Vibrio* (*V. parahaemolyticus/V. vulnificus/ V. cholerae*), including specific identification of *Vibrio cholerae*
6. *Yersinia enterocolitica*
7. Enteroaggregative *Escherichia coli* (EAEC)
8. Enteropathogenic *Escherichia coli* (EPEC)
9. Enterotoxigenic *Escherichia coli* (ETEC) *lt/st*
10. Shiga-like toxin-producing *Escherichia coli* (STEC) *stx1/stx2* (including specific identification of the *E. coli* O157 serogroup thin STEC)

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11. *Shigella*/ Enteroinvasive *Escherichia coli* (EIEC)
12. *Cryptosporidium*
13. *Cyclospora cayetanensis*
14. *Entamoeba histolytica*
15. *Giardia lamblia* (also known as *G. intestinalis* and *G. duodenalis*)
16. Adenovirus F 40/41
17. Astrovirus
18. Norovirus GI/GII
19. Rotavirus A
20. Sapovirus (Genogroups I, II, IV, and V)

The FilmArray GI Panel is indicated as an aid in the diagnosis of specific agents of gastrointestinal illness and results are meant to be used in conjunction with other clinical, laboratory, and epidemiological data. Positive results do not rule out co-infection with organisms not included in the FilmArray GI Panel. The agent detected may not be the definite cause of the disease.

Concomitant culture is necessary for organism recovery and further typing of bacterial agents.

This device is not intended to monitor or guide treatment for *C. difficile* infection.

Performance characteristics for *Entamoeba histolytica,* and *Vibrio* (*V. parahaemolyticus, V. vulnificus,* and *Vibrio cholerae*) were established primarily using contrived clinical specimens.

Negative FilmArray GI Panel results in the setting of clinical illness compatible with gastroenteritis may be due to infection by pathogens that are not detected by this test or non-infectious causes such as ulcerative colitis, irritable bowel syndrome, or Crohn's disease.

SUMMARY AND EXPLANATION OF THE TEST

Despite advances in food safety, sanitation, and medical treatment, infectious gastroenteritis remains a significant problem in industrialized countries among all age groups. In the United States, around 76 million cases of foodborne disease, resulting in 325,000 hospitalizations and 5,000 deaths, are estimated to occur each year. Additionally, there are over 300,000 *C. difficile* diagnoses per year in the US4 resulting in estimated costs of at least $1 billion. Globally, infectious diarrheal illness is a significant cause of mortality in young children resulting in an estimated 800,000 deaths per year in children under the age of 5. In addition to this significant morbidity and mortality, diarrhea in children contributes to malnutrition, increased susceptibility to other infections, and may lead to delays in growth and intellectual development. The FilmArray GI Panel simultaneously tests for 22 pathogens from stool specimens collected in Cary Blair transport medium. Results from the FilmArray GI Panel test are available within about one hour.

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Summary of Detected Organisms

Bacteria

***Campylobacter* (*C. jejuni/C. coli/C. upsaliensis*).** *Campylobacter* are gram-negative, non-spore forming, s-shaped or spiral bacteria that are usually motile. Most sporadic infections are acquired through ingestion of undercooked poultry or from cross-contamination of other foods. Outbreaks have been associated with unpasteurized dairy, contaminated water, poultry, and produce. Transmission from the stool of household pets has also been documented. *C. jejuni* and *C. coli* are the species most commonly associated with diarrheal illness. Infection with *Campylobacter* species is common throughout the world, representing a large and perhaps under-recognized health burden. *Campylobacter* are a leading cause of bacterial enteritis in the US (est. 845,000 infections annually with almost 8,500 hospitalizations). Enteric *Campylobacter* infections range from asymptomatic to severe infections characterized by bloody or non-bloody diarrhea, fever, and abdominal cramping. Infections may also lead to long-term health issues such as Guillain-Barré syndrome (GBS) and reactive arthritis.

Clostridium difficile are obligately anaerobic, gram-positive rods capable of forming hardy spores and are widespread in nature. These bacteria are acquired from the environment or transmitted via the fecal-oral route. Some *C. difficile* strains produce two enterotoxins, toxin A and toxin B, that damage the large intestine of the infected individual. *C. difficile* infection (CDI) is the major cause of hospital-acquired diarrhea and is responsible for more than 300,000 cases of diarrheal disease and 14,000 deaths annually in the US, resulting in over a billion dollars in health care costs

Plesiomonas shigelloides. *Plesiomonas shigelloides*, gram-negative rod-shaped bacteria and members of the *Enterobacteriaceae* family, are isolated from a wide range of environmental sources including freshwater and many animals, both wild and domestic. *P. shigelloides* gastroenteritis often follows consumption of seafood, as well as contaminated water used for drinking or used in preparing uncooked foods.10 Symptoms generally include watery diarrhea, though dysenteric diarrhea can occur, and infections may be prolonged (>2 weeks duration) but are generally self-limiting. Most cases reported in the US are from individuals with pre-existing health problems leading to a more severe disease outcome.

Salmonella. *Salmonella enterica* and *S. bongori* are the sole members of the *Salmonella* genus. Greater than 2,500 different serotypes of *Salmonella* have been recognized, with the majority of pathogenic serotypes being within the *S. enterica* species.22 These motile, rod-shaped, gram-negative, facultative bacteria are commonly recognized as a food contaminant associated with meat, poultry, produce, and manufactured products. *Salmonella* may be classified as typhoidal and non-typhoidal based on the disease that they cause. The non-typhoidal *Salmonella* are associated with intestinal illness resulting in acute, watery diarrhea, often with fever, and are a common cause of foodborne illness in the US. *Salmonella* is one of the most common causes of foodborne illness in the US with greater than one million cases per year. While large outbreaks do occur, the majority of cases are sporadic with peak in incidence in late summer/early fall. The highest incidence is seen in children aged <5 years. In general *Salmonella*-related gastroenteritis is self-limiting.

***Vibrio* (*V. parahaemolyticus/V. vulnificus/V. cholerae*).** *Vibrio* are motile, gram-negative, comma-shaped bacteria typically found in marine environments. Several species are capable of causing illness in

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humans, both extraintestinal (soft tissue infection, septicemia, eye and ear infections) and intestinal. Gastrointestinal illness is most commonly associated with *V. cholerae, V. parahaemolyticus, V. vulnificus, V. fluvialis*, *V.mimicus* or *V. alginolyticus* and infections are associated with consumption of contaminated food, particularly in coastal regions.24

Yersinia enterocolitica are small, gram-negative bacilli, which generally appear as single cells or short chains. *Y. enterocolitica* is transmitted through ingestion of contaminated food or water, often raw undercooked meats (especially pork), and is estimated to cause almost 100,000 foodborne illnesses in the US annually (though only about 1,000 cases are laboratory-confirmed; possibly because *Y. enterocolitica* are not identified by routine enteric pathogen testing). The severity of the illness is based on the serotype of the infecting strain and ranges from self-limiting gastroenteritis to terminal ileitis and mesenteric lymphadenitis. Symptoms of illness mimic appendicitis and may lead to unnecessary surgery, highlighting the importance of properly identifying this organism when it is present in stool specimens.

Diarrheagenic *Escherichia coli/Shigella*

Pathogenic *E. coli*/*Shigella* are a significant cause of diarrheal illness worldwide. There are several pathotypes of Diarrheagenic *E. coli*/*Shigella* that differ in the mechanisms and location of colonization as well as the clinical manifestations, progression, and severity of the diseases they cause. Some of these differences are attributable to the production of specific virulence factors including adhesins, invasins, and toxins. Genes encoding these virulence factors or their regulators are targeted as genetic markers by molecular assays to detect and differentiate these pathogens. The five major Diarrheagenic *E. coli*/*Shigella* pathotypes are Enteroaggregative *E. coli* (EAEC), Enteropathogenic *E. coli* (EPEC), Enterotoxigenic *E. coli* (ETEC), Shiga-like toxin-producing *E. coli* (STEC), and *Shigella*/Enteroinvasive *E. coli* (EIEC).

Enteroaggregative *E. coli* (EAEC) Transmission of EAEC is generally by the fecal-oral route via contaminated food and water. EAEC cause an inflammatory diarrheal illness characterized by watery and sometimes bloody stool, accompanied by low grade fever, vomiting, and abdominal pain. EAEC infections may also be asymptomatic. Data regarding the incidence of EAEC are limited due to the lack of widespread testing; however, based upon various studies, EAEC are suggested to be one of the most common causes of diarrheal illness in the US across all age groups, a cause of persistent diarrhea in children and HIV-infected individuals, the second most common cause of travelers' diarrhea, and has been identified as the cause of large outbreaks worldwide.

Enteropathogenic *E. coli* (EPEC) do not produce enterotoxins or Shiga-like toxins. Rather, EPEC contain additional virulence factors. Outbreaks appear to peak in the warmer months of summer and early fall. Illness caused by typical EPEC is associated with acute diarrhea whereas atypical EPEC cause a prolonged, non-bloody diarrhea, and vomiting with fever. When untreated in children, EPEC illness can lead to malnutrition and associated growth defects.

Enterotoxigenic *E. coli* (ETEC). The presence of heat-labile (*lt*) and/or heat-stable (*st*) enterotoxins defines Enterotoxigenic *E. coli* (ETEC). These toxins (which may be found together or separately in ETEC strains) bind to intestinal epithelial cells triggering loss of electrolytes resulting in watery diarrhea. ETEC are an important cause of diarrhea in developing countries especially among children, and are the most

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common bacterial cause of watery diarrhea in US and EU travelers returning from abroad (commonly referred to as travelers' diarrhea). ETEC are transmitted via the fecal-oral route and are becoming more common as a foodborne pathogen. However, ETEC infection remains significantly under-diagnosed and underreported due to the difficulty of identification and because infected adults may not seek treatment, as infections resolve in a few days with supportive care (rehydration).

Shiga-like toxin-producing *E. coli* (STEC), including *E. coli* O157. There are two main types of Shiga-like toxins, Shiga-like toxin 1 (Stx1) and Shiga-like toxin 2 (Stx2) (also known as verotoxins). Shiga-like toxin-producing *E. coli* (STEC) may contain either one or both *stx* genes. STEC are a primary cause of bloody diarrhea and can progress to a potentially fatal condition known as hemolytic uremic syndrome (HUS; caused by Shiga-like toxin destruction of red blood cells that leads to renal failure), especially in the very young and very old. STEC are important foodborne pathogens. Antimicrobial therapy for STEC may lead to an increased risk for HUS, especially in antibiotic-resistant strains, potentially by up-regulating production and thus increasing the amount of Shiga-like toxin available for absorption. Therefore, identification of Shiga-like toxin genes in a patient with gastrointestinal illness can aid in the decision of whether or not to prescribe antibiotics for patient care.

***E. coli* O157:H7** is currently the most frequently identified diarrheagenic *E. coli* in North America. There are over 170,000 STEC infections in the US each year, of which an estimated 73,000 illnesses and 60 deaths per year are attributable specifically to *E. coli* O157. Disease presentation ranges from mild, non-bloody diarrhea to hemorrhagic colitis and HUS. An estimated 4% of O157:H7 infections lead to HUS and this serotype of *E. coli* is responsible for up to 80% of all HUS illness. The infectious dose is low, facilitating person-to-person transmission but most illness is caused by ingestion of contaminated ground beef, as dairy and beef cattle are often colonized with this bacterium.

***Shigella*/Enteroinvasive *E. coli* (EIEC).** There are four subgroups of *Shigella* species: subgroup A (*S. dysenteriae*), subgroup B (*S. flexneri)*, subgroup C (*S. boydii)*, and subgroup D (*S. sonnei*). All *Shigella* are non-motile, gram-negative rods which are typically transferred through person-to-person contact or ingestion of contaminated food or water (humans and other primates are the only known animal reservoirs). Infections are most common where hygiene is compromised, for example institutional settings (day care, nursing homes) and may become endemic in developing societies without running water and indoor plumbing. *Shigella* are responsible for multiple illnesses including shigellosis and bacillary dysentery which can result in bloody or non-bloody diarrhea.

Enteroinvasive *E. coli* (EIEC), unlike most *E. coli* do not decarboxylate lysine, and do not ferment lactose. EIEC strains contain a plasmid encoding virulence factors (such as invasion plasmid antigen *ipaH*) that allow the bacteria to invade the colon and produce a watery diarrhea syndrome that is identical to that caused by *Shigella* . EIEC is rare in the US

Parasites

Cryptosporidium is a genus of protozoa capable of causing infections of the human stomach, intestine, and biliary ducts following ingestion of chlorine-tolerant oocysts which are shed in fecal material and can contaminate drinking water, recreational water, or food. *Cryptosporidium* are among the most common parasitic causes of diarrhea in developed nations. There are an estimated 60,000 illnesses

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every year in the US due to *Cryptosporidium* infection with rates being highest in summer months. Illness is generally characterized by short-term gastroenteritis that resolves without treatment. However, severe illness is possible in immunocompromised individuals, particularly those with AIDS, where illness resolves slowly or not at all and can be fatal.

Cyclospora cayetanensis are parasitic protozoa that cause gastroenteritis in humans, which are the only known hosts. Unsporulated oocysts are disseminated in feces. After a period of maturation (days to weeks), the oocysts become infectious and can cause illness if ingested through contaminated food or water. Infections are most common in tropical, subtropical, or warm temperate regions. In the US, infections are associated with travelers' diarrhea in persons returning from endemic areas. Additionally, outbreaks have been associated with consumption of contaminated food from other countries. Illness presents as non-bloody diarrhea that may be up to several months in duration.

Entamoeba histolytica are pathogenic protozoa which are found worldwide with a particularly high prevalence in tropical and subtropical regions. *E. histolytica* cysts are generally ingested from materials contaminated with feces, such as food and water, but infection may also be transmitted sexually. Humans are the primary reservoir. Most infections from *E. histolytica* appear to be asymptomatic but some infections cause invasive amebiasis which results in colitis or dysentery-like illness that can be severe and include amebic liver abscess.

Giardia lamblia (also referred to as *G. duodenalis* and *G. intestinalis*) are intestinal flagellate parasites found world-wide. *Giardia* are the most common intestinal parasites isolated in the US and are a leading cause of parasitosis worldwide. Populations with the highest risk of *G. lamblia* infection include children in day care centers, hikers, and the immunocompromised. Transmission occurs through ingestion of contaminated food or water, with approximately 77,000 foodborne illnesses in the US annually. Infection rates are highest during summer months. The majority of *G. lamblia* infections are asymptomatic, but those who develop illness experience nausea, fever, and watery diarrhea.45 Infections are generally self-limiting; though symptoms are long-lasting, and some patients go on to develop chronic illness, which can lead to complications.

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Viruses

Adenovirus F 40/41. Adenoviruses are double-stranded DNA viruses of the *Adenoviridae* family that cause a variety of diseases including respiratory illness and gastrointestinal illness. They are resistant to chemical and physical damage and are thus persistent in the environment, facilitating transmission. GI illness is primarily associated with species F (which is comprised of serotypes 40 and 41). Adenovirus F 40/41 is responsible for 5 to 15% of all acute diarrheal illness in children (especially in those under two years of age). Transmission is mostly through fecal-oral spread and outbreaks have been reported in hospitals and child care centers. Illness is generally mild but of a relatively long duration (5-12 days). Immunocompromised patients may suffer chronic, prolonged diarrheal illness and other complications. Virus may be shed in stool for weeks to months following acute illness; therefore identification of infected individuals may be important for patient isolation and control of disease spread.

Astrovirus. Astroviruses (RNA viruses of the family *Astroviridae*) are named for their characteristic star-like structure and are found in a variety of animals, including birds and mammals. The infection route is

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fecal-oral and at-risk populations include children, immunocompromised adults, caregivers of sick children, military troops, and those in nursing homes. Symptoms are reported to be milder than other enteric viruses and include diarrhea, vomiting, abdominal pain, and fever lasting 72 hours.

Norovirus GI/GII. Noroviruses are highly contagious members of the *Caliciviridae* family of RNA viruses and can be divided into five genogroups (GI – GV). GI, GII, and GIV have been found most commonly in humans (though GIV is very rare) where they cause moderate to severe gastroenteritis consisting primarily of nausea, vomiting, and diarrhea accompanied by fever. Transmission occurs via the fecal-oral route or through aerosolized vomitus and the infectious dose may be as low as 18 particles. Symptoms of infection generally last 24-48 hours and the illness is self-limiting; though immunocompromised persons may suffer chronic diarrhea and some children have been reported to develop necrotizing colitis.

Rotavirus A. Rotaviruses are double stranded RNA viruses of the *Reoviridae* family and are the single most important etiologic agents of severe diarrheal illnesses in infants and young children worldwide. Symptoms of infection may be mild and last for a few days, but prolonged illness can lead to severe dehydration in children <2 years of age and Rotavirus A infections are a considerable cause of infant mortality in the developing world. Rotaviruses are shed before and after acute illness and are hardy to environmental factors, allowing them to survive on surfaces and resist inactivation. Disease rates peak during winter/spring in temperate climates.

Sapovirus Sapovirus is a *Calciviridae* family member that is similar to Norovirus both genetically and in disease presentation. Sapovirus causes disease mostly in children, though adults are susceptible as well, with outbreaks reported in long-term care facilities, prisons, cruise ships, and hospitals in the US

Like Norovirus, Sapovirus is spread via the fecal-oral route and infections are highest during winter months. Symptoms primarily include vomiting and diarrhea with nausea and fever lasting 5 to 10 days.

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PRINCIPLE:

The FilmArray GI pouch is a closed system disposable that houses all the chemistry required to isolate, amplify and detect nucleic acid from multiple gastrointestinal pathogens within a single stool specimen. The rigid plastic component (fitment) of the FilmArray GI pouch contains reagents in freeze-dried form. The flexible plastic portion of the pouch is divided into discrete segments (blisters) where the required chemical processes are carried out. The user of the FilmArray GI Panel loads the sample into the FilmArray GI pouch, places the pouch into the FilmArray instrument/Module, and starts the run. All other operations are automated.

The following is an overview of the testing procedure:

PROCEDURE OVERVIEW:

1. Remove the FilmArray pouch from its vacuum-sealed package. Since solutions are drawn into the FilmArray GI pouch by vacuum, it is important to keep pouches in their protective packaging until the time of use.
2. Place the FilmArray GI pouch into the FilmArray Pouch Loading Station. The FilmArray Pouch

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Loading Station has been designed to prevent error by providing visual cues in the form of color-coded arrows to ensure that the pouch is properly loaded.

3. Load Hydration Solution into the FilmArray GI pouch using the Hydration Injection Vial. The vial is fitted with a blunt stainless steel cannula, which is used to deliver the solution into the pouch. Loading the pouch with Hydration Solution rehydrates the freeze-dried reagents contained in the pouch fitment.
4. Prepare the Sample Injection Vial by squeezing the contents of the Sample Buffer ampoule into the Sample Injection Vial. Thoroughly mix the stool specimen (stool in Cary Blair transport media) and transfer it to the Sample Injection Vial using the Transfer Pipette. Tightly close the lid of the Sample Injection Vial and invert at least three times to mix. The Sample Buffer contains reagents that promote binding of nucleic acids to magnetic beads for isolation.
5. Load the sample/buffer mixture into the FilmArray GI pouch using the Sample Injection Vial. When the sample mixture is loaded, a process control contained in the fitment of the pouch is introduced into the sample. The process control monitors all of the critical processes that occur in the pouch.
6. Transfer the pouch to the instrument/Module and initiate a run. The FilmArray software provides on-screen animations illustrating the steps needed to start the run.
7. View results on the test report at the completion of the run.

The following is an overview of the operations and processes that occur during a FilmArray run:

1. **Nucleic Acid Purification** - Nucleic acid purification occurs in the first three blisters of the pouch. The sample is lysed by a combination of chemical and mechanical (bead beating) mechanisms and the liberated nucleic acid is captured, washed and eluted using magnetic bead technology. These steps require about ten minutes, and the bead-beater apparatus can be heard as a high-pitched whine during the first few minutes of operation.
2. **Reverse Transcription and 1st Stage Multiplex PCR** - Since the GI Panel includes RNA viruses, a reverse transcription (RT) step is performed to convert the viral RNA into cDNA prior to amplification. The purified nucleic acid solution is combined with a preheated master mix to initiate the RT step and subsequent thermocycling for multiplex PCR. The effect of 1st stage PCR is to enrich for the target nucleic acids present in the sample.
3. **2nd Stage PCR** - The products of 1st stage PCR are diluted and mixed with fresh PCR reagents containing an intercalating fluorescent DNA dye (LCGreen® Plus, BioFire Diagnostics, LLC). This solution is distributed over the 2nd stage PCR array. The individual wells of the array contain primers for different assays (each present in triplicate) that target specific nucleic acid sequences from each of the pathogens detected, as well as control template material. These primers are 'nested' or internal to the specific products of the 1st stage multiplex reaction, which enhances both the sensitivity and specificity of the reactions.
4. **DNA Melting Analysis** – After 2nd stage PCR, the temperature is slowly increased and fluorescence in each well of the array is monitored and analyzed to generate a melt curve. The

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temperature at which a specific PCR product melts (melting temperature or Tm) is consistent and predictable and the FilmArray software automatically evaluates the data from replicate wells for each assay to report results.

5. The FilmArray software controls the operation of the instrument/Module, collects and analyzes data, and automatically generates a test report at the end of the run. The entire process takes about an hour.

MATERIALS PROVIDED

Each kit contains sufficient reagents to test 30 or 6 samples (30 pouch kit or 6 pouch kit):

Individually packaged FilmArray GI Panel pouches

Single-use (1.0 mL) Sample Buffer ampoules

Single-use pre-filled (1.5 mL) Hydration Injection Vials (blue)

Single-use Sample Injection Vials (red)

Individually packaged Transfer Pipettes

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MATERIALS REQUIRED BUT NOT PROVIDED

FilmArray system including:

FilmArray, FilmArray 2.0, or FilmArray Torch and software

FilmArray Pouch Loading Station

WARNINGS AND PRECAUTIONS

General Precautions

Always check the expiration date on the pouch and do not use a pouch after its expiration date

FilmArray pouches are stored under vacuum in individually wrapped canisters. To preserve the integrity of the pouch vacuum for proper operation, be sure that a FilmArray instrument/Module will be available and operational before unwrapping any pouches for loading.

Safety Precautions

Wear appropriate Personal Protective Equipment (PPE), including (but not limited to) disposable powder-free gloves and lab coats. Protect skin, eyes and mucus membranes. Change gloves often when handling reagents or samples.

Handle all samples and waste materials as if they could transmit infectious agents.

Follow your institution's safety procedures for handling biological samples.

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Dispose of materials used in this assay, including reagents, samples, and used buffer vials, according to federal, state, and local regulations.

Sample Buffer will form hazardous compounds and fumes when mixed with bleach or other disinfectants.

WARNING: Bleach should never be added to Sample Buffer or sample waste.

Laboratory Precautions

Preventing organism contamination

Due to the sensitive nature of the FilmArray GI Panel, it is important to guard against contamination of the work area by carefully following the testing process outlined in this booklet, including these guidelines:

Stool samples may contain a high concentration of organisms. To avoid possible contamination, samples should be processed in a biosafety cabinet.

Prior to processing a sample, thoroughly clean both the work area and the FilmArray Pouch Loading Station using a suitable cleaner such as freshly prepared 10% bleach or a similar disinfectant. To avoid residue build-up and potential PCR inhibition, wipe disinfected surfaces with water.

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Samples and pouches should be handled one at a time.

Use clean gloves to remove materials from bulk packaging bags, and reseal bulk packaging bags when not in use.

Change gloves and clean the work area between each sample.

Preventing amplicon contamination

A common concern with PCR-based assays is false positive results caused by contamination of the work area with PCR amplicon. Because the FilmArray GI pouch is a closed system, the risk of amplicon contamination is low provided that pouches remain intact after the test is completed. Adhere to the following guidelines to prevent amplicon contamination:

Discard used pouches in an appropriate biohazard container immediately after the run has completed.

Avoid excessive handling of pouches after test runs.

Avoid exposing pouches to sharp edges or anything that might cause a puncture.

WARNING: If liquid is observed on the exterior of a pouch, the liquid and pouch should be immediately contained and discarded in a biohazard container. The instrument/Module and workspace must be decontaminated as described in the appropriate FilmArray Operator's Manual.

DO NOT PERFORM ADDITIONAL TESTING UNTIL THE AREA HAS BEEN DECONTAMINATED.

REAGENT STORAGE, HANDLING AND

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STABILITY

All kit components should be stored and used together at room temperature (15–25 ºC), including reagent pouches and buffers. Do not use components from one kit with those of another kit. **DO NOT REFRIGERATE.**

Avoid storage of any materials near heating or cooling vents or in direct sunlight.

Always check the expiration date and do not use reagents beyond the expiration date printed on the pouch or kit.

Do not remove pouches from their packaging until a sample is ready to be tested. Once the pouch packaging has been opened, the pouch should be loaded as soon as possible (within approximately 30 minutes).

Once a pouch has been loaded, the test run should be started as soon as possible (within 60 minutes).

SAMPLE REQUIREMENTS

This section describes the requirements for specimen collection, preparation, and handling that will help ensure accurate test results.

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Stool Specimen Collection – Stool specimens should be collected in Cary Blair transport media according to manufacturer's instructions.

Minimum Sample Volume – 0.2 mL (200 µL) of sample is required for testing.

Transport and Storage - Specimens should be processed and tested as soon as possible, though they may be stored at room temperature or under refrigeration for up to four days.

Stool Specimen Number/Timing Limitations- No more than two specimens/patient as there is limited yield provided by additional specimens.

Do not accept specimens from inpatients after the third hospital stay.

PROCEDURE:

Gloves and other Personal Protective Equipment (PPE) should be used when handling pouches and samples. Only one FilmArray GI pouch should be prepared at a time. Once sample is added to the pouch, it should be promptly transferred to the instrument/Module to start the run. After the run is complete, the pouch should be discarded in a biohazard container.

Prepare Pouch

Thoroughly clean the work area and the FilmArray Pouch Loading Station with freshly prepared 10% bleach (or suitable disinfectant) followed by a water rinse. Obtain the following required materials and place in the clean hood:

- FilmArray GI Panel pouch

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- Sample Buffer ampoule
- Hydration Injection Vial (blue cap)
- Sample Injection Vial (red cap)
- Transfer Pipette

1. Place a blue-capped Hydration Injection Vial in the blue well of the Pouch Loading Station.
2. Place a red-capped Sample Injection Vial in the red well of the Pouch Loading Station.
3. Obtain patient sample and place into hood.
4. Remove the FilmArray GI pouch from its vacuum-sealed package by tearing or cutting the notched outer packaging and opening the protective aluminum canister.

   NOTE: If the vacuum seal of the pouch is not intact, the pouch may still be used. Attempt to hydrate the pouch using the steps in the Hydrate Pouch section. If hydration is successful, continue with the run. If hydration fails, discard the pouch and use a new pouch to test the sample.
5. Slide the pouch into the Pouch Loading Station so that the red and blue labels on the pouch align with the red and blue arrows on the Pouch Loading Station.

Hydrate Pouch

1. Twist the Hydration Injection Vial (blue cap), leaving cap in Pouch Loading Station, and insert the tip of the cannula into the hydration port of the pouch located directly below the blue arrow of the Pouch Loading Station. Push down forcefully in a firm and quick motion until you hear a faint “pop” and feel an ease in resistance. The correct volume of liquid will be pulled into the pouch by vacuum.
2. Verify that the pouch has been hydrated. Flip the barcode label down and check to see that fluid has entered the reagent wells (located at the base of the rigid plastic part of the pouch). Small air bubbles may be seen. If the pouch fails to hydrate (dry reagents appear as white pellets), verify that the seal of the port was broken by ensuring the vial cannula was fully inserted into the hydration port. If the pouch fails to hydrate, retrieve a new pouch and repeat from Step 2 of the Prepare Pouch section.

Prepare Sample Mix

1. Hold the Sample Buffer ampoule so that the tip is facing up.
2. Gently pinch the textured plastic tab on side of ampoule until the seal snaps.
3. Re-position thumb and forefinger to grip between the textured plastic tab and the bottom of the ampoule, then invert over the red Sample Injection Vial and dispense Sample Buffer using a slow, forceful squeeze, followed by a second squeeze. Avoid generating excessive bubbles.

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4. Thoroughly mix the patient specimen.
5. Using the Transfer Pipette provided in the test kit, draw sample to the second line (approximately 0.2 mL). Add sample to the red Sample Injection Vial.
6. Tightly close the lid of the Sample Injection Vial and mix by gently inverting at least 3 times.
7. Return the Sample Injection Vial to the Pouch Loading Station.

Load Sample Mix

1. Slowly unscrew the Sample Injection Vial from the cap and pause for 3-5 seconds.
2. Remove Sample Injection Vial leaving cap in Pouch Loading Station and insert the cannula tip into the port in the pouch fitment located directly below the red arrow of the Pouch Loading Station. Push down forcefully in a firm and quick motion until you hear a faint “pop” and feel an ease in resistance. The correct volume of liquid will be pulled into the pouch by vacuum.
3. Verify that the sample has been loaded. Flip the barcode label down and check to see that fluid has entered the reagent well next to the sample loading port. If the pouch fails to pull sample from the Sample Injection Vial, the pouch should be discarded. Retrieve a new pouch and repeat from Step 2 of the Prepare Pouch section.
4. Discard the Hydration Injection Vial and Sample Injection Vial in an appropriate biohazard sharps container.
5. Record the Sample ID in the provided area on the pouch label (or affix a barcoded Sample ID) and remove the pouch from the Pouch Loading Station.

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Run Pouch

The FilmArray Software includes step-by-step on-screen instructions that guide the operator through performing a run. Brief instructions for FilmArray, FilmArray 2.0, and FilmArray Torch systems are given below. Refer to the appropriate FilmArray Operator’s Manual for more detailed instructions.

FilmArray and FilmArray 2.0

1. Ensure that the computer and FilmArray instrument(s) are on and the FilmArray software is launched
2. Open the lid of an available instrument (if not already open).

   NOTE: An available instrument is indicated by a constant green light on the front of the instrument.
3. Insert the FilmArray pouch into the instrument.
4. Position the pouch so that the array is on the right with the film directed downward into FilmArray instrument. The red and blue labels on the FilmArray pouch should align with the red and blue arrows on the FilmArray instrument. The pouch will click into place. If inserted

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correctly, the barcode is visible and the label is readable on the top of the pouch. The instrument and software must detect that the pouch has been inserted correctly before continuing to the next step.

NOTE: If the pouch does not slide into the instrument easily, gently push the lid of the instrument back to be sure that it is completely open.

5. Scan the barcode on the FilmArray pouch using the barcode scanner.
6. Pouch identification (Lot Number and Serial Number), Pouch Type and Protocol are preprogrammed in the barcode located on the FilmArray pouch and will be automatically entered when the barcode is scanned. If it is not possible to scan the barcode, the pouch Lot Number, Serial Number, Pouch Type and Protocol can be manually entered from the information provided on the pouch label. To reduce data entry errors, it is strongly recommended that the pouch information be entered by scanning the barcode.

   NOTE: The barcode cannot be scanned prior to inserting the pouch in the instrument.
7. Enter the Sample ID. The Sample ID can be entered manually or scanned in by using the barcode scanner when a barcoded Sample ID is used.
8. If necessary, select and/or confirm a protocol from the Protocol drop down list.
9. Enter a user name and password in the Name and Password fields.
10. Close the FilmArray instrument lid.
11. Click the Start Run button on the screen.

    NOTE: The bead-beater apparatus can be heard as a high-pitched noise (whine) during the first few minutes of operation.
12. Once the run has started, the screen displays a list of the steps being performed by the instrument and the number of minutes remaining in the run.
13. When the run is finished, results are automatically displayed in the report section of the screen. The report is automatically saved into the database.
14. Select **Print** to print the report, or **Save** to save the report as a PDF file.
15. Follow the on-screen instructions to open the instrument and remove the pouch.
16. Immediately discard the pouch in a biohazard container.
17. Ensure that the FilmArray Torch system is on.
18. Select an available Module on the touch screen.
19. Scan the barcode on the FilmArray pouch using the barcode scanner.
20. Pouch identification (Lot Number and Serial Number), Pouch Type and Protocol are preprogrammed in the rectangular barcode located on the FilmArray pouch. The information

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will be automatically entered when the barcode is scanned. If it is not possible to scan the barcode, the pouch Lot Number, Serial Number, Pouch Type and Protocol can be manually entered from the information provided on the pouch label into the appropriate fields. To reduce data entry errors, it is strongly recommended that the pouch information be entered by scanning the barcode.

21. Enter the Sample ID. The Sample ID can be entered manually or scanned in by using the barcode scanner when a barcoded Sample ID is used.
22. Insert the pouch into the Module.
23. Ensure that the pouch fitment label is lying flat on top of pouch and not folded over. As the pouch is inserted, the Module will grab onto the pouch and pull it into the chamber.
24. If necessary, select and/or confirm a protocol from the protocol drop down list.
25. Enter operator username and password, then select Next.

    NOTE: The font color of the username is red until the username is recognized by the software.
26. Review the entered run information on the screen. If correct, select Start Run.
27. Once the run has started, the screen displays a list of the steps being performed by the instrument and the number of minutes remaining in the run.

    NOTE: The bead-beater apparatus can be heard as a high-pitched noise (whine) during the first minute of operation.
28. At the end of the run, the status of the Module changes to Finished and the pouch is partially ejected.
29. Select the Finished Module on the Dashboard to view the report.
30. Select Print to print the report, or Save to save the report as a file
31. Removed the pouch from the Module and immediately discard the pouch in a biohazard container.

NOTE: Once the pouch has been removed, the report can only be viewed through the Browse Run Feature.

QUALITY CONTROL

Controls for each analyte should be either included in each run or rotated so that all analytes are tested periodically

Process Controls

Two process controls are included in each pouch:

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RNA Process Control

The RNA Process Control assay targets an RNA transcript from the yeast *Schizosaccharomyces pombe*. The yeast is present in the pouch in a freeze-dried form and becomes rehydrated when sample is loaded. The control material is carried through all stages of the test process, including lysis, nucleic acid purification, reverse transcription, 1st stage PCR, dilution, 2nd stage PCR and DNA melting. A positive control result indicates that all steps carried out in the FilmArray GI pouch were successful.

PCR2 Control

The PCR2 Control assay detects a DNA target that is dried into wells of the array along with the corresponding primers. A positive result indicates that 2nd stage PCR was successful.

Both control assays must be positive for the test run to pass. If either control fails, the Controls field of the test report (upper right hand corner) will display Failed and all results will be listed as Invalid. If the controls fail, the sample should be retested using a new pouch.

Monitoring Test System Performance

The FilmArray software will automatically fail the run if the melting temperature (Tm) for either the RNA Process Control or the PCR2 Control is outside an acceptable range (80.2-84.2 for the RNA Process Control and 74.1-78.1 for the PCR2 Control). If required by local, state, or accrediting organization quality control requirements, users can monitor the system by trending Tm values for the control assays and maintaining records according to standard laboratory quality control practices.66,67 The PCR2 Control is used in all pouch types and can therefore be used to monitor the system when multiple pouch types (e.g., RP, GI, ME and BCID) are used on the same FilmArray instrument/Module.

Good laboratory practice recommends running external positive and negative controls regularly. Enteric transport media can be used as an external negative control. Previously characterized positive stool samples or negative samples spiked with well characterized organisms can be used as external positive control.

INTERPRETATION OF RESULTS:

The FilmArray software automatically analyzes and interprets assay results and displays the final results in a test report (see the FilmArray Gastrointestinal Panel Quick Guide to view an example of a test report). The analyses performed by the FilmArray software and details of the test report are described below.

Assay Interpretation:

When 2nd stage PCR is complete, the FilmArray instrument/Module performs a high resolution DNA melting analysis on the PCR products and measures the fluorescence signal generated in each well (for more information see appropriate FilmArray Operator's Manual). The FilmArray software then performs several analyses and assigns a final assay result.

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Organism Interpretation:

For many organisms detected by the FilmArray GI Panel, the organism is Detected if a single corresponding assay is positive. For example, *Plesiomonas shigelloides* will have a result of "*Plesiomonas shigelloides* Detected" if at least two of the three replicates of the one *Plesiomonas shigelloides* assay have similar positive melt peaks with Tm values that are within the assay-specific Tm range.

The following organisms are detected using a single assay: toxigenic *C. difficile*, *P. shigelloides, Salmonella, Y. enterocolitica*, EAEC, *Shigella/*EIEC, Adenovirus F 40/41, Astrovirus, Sapovirus (Genogroups I, II, IV, and V), *C. cayetanensis, E. histolytica* and *G. lamblia*.

In contrast, the test results for several organisms rely on the combination of multiple assays. These include *Campylobacter (C. jejuni/C. coli/C. upsaliensis), Vibrio* (*V. parahaemolyticus/ V. vulnificus/V. cholerae)* and *Vibrio cholerae*, *Cryptosporidium,* Norovirus GI/GII, and Rotavirus A.

The test results for several Diarrheagenic *E. coli*(s) include multiple assays for genetic markers to identify various classic pathotypes of *E. coli* including EPEC, ETEC, and STEC (including O157), (as well EAEC and *Shigella*/EIEC included above). rules for these assays are described below. Also included are summary descriptions of the assays' expected reactivity; for a full description of assay reactivity see Inclusivity.

NOTE: If four or more distinct organisms are detected in a specimen, retesting is recommended to confirm polymicrobial result.

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FilmArray GI Test Report:

The FilmArray GI test report is automatically displayed upon completion of a run and contains three sections, the Run Summary, the Result Summary, and the Run Details (see the FilmArray Gastrointestinal Panel Quick Guide to view an example of a test report). The test report can be saved as a PDF or printed.

The **Run Summary** section of the test report provides the Sample ID, time and date of the run, control results and an overall summary of the test results. Any organism with a Detected result will be listed in the corresponding field of the summary. If all of the tests were negative, then None will be displayed in the Detected field. Controls are listed as Passed, Failed or Invalid. See the Controls Field section below for detailed information about the interpretation of controls and appropriate follow-up in the case of control failures

The **Result Summary** section of the test report lists the result for each target tested by the panel. Possible results for each organism are Detected, Not Detected, Not Applicable (N/A), or Invalid. See Results Summary section below for detailed information about interpretation of test results and appropriate follow-up for Invalid results.

The **Run Details** section provides additional information about the run including pouch information (type, lot number, and serial number), Run Status (Completed, Incomplete, Aborted, Instrument Error, Instrument Communication Error, or Software Error), the protocol that was used to perform the test, the

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identity of the operator that performed the test, and the instrument/Module used to perform the test.

Once a run has completed, it is possible to edit the Sample ID. If this information has been changed, an additional section called **Change History** will be added to the test report. This Change History section lists the field that was changed, the original entry, the revised entry, the operator that made the change, and the date that the change was made. Sample ID is the only field of the report that can be changed.

NOTE: The following isolates/specimens shall be submitted as soon as available to the Ventura County Public Health Laboratory for confirmation and typing when detected in the Gastrointestinal Panel.

- Salmonella sp. *(VCPH Orderable: Salmonella Screen)*
- Shigella sp. *(VCPH Orderable: Shigella Screen)*
- Shiga toxin-producing Escherichia coli (STEC), including O157 and non-O157 strains (*VCPH Orderable: E. coli Culture-PH Lab*)

The Eswab can be submitted for testing and must include the name, address, and the date of birth from whom the specimen was obtained.

For full requirements, refer to California Code of Regulations Title 17 Section 2505

Controls Field:

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The Controls field on the test report will display Passed, Failed, or Invalid. The Controls field will display Passed only if the run completed successfully (no instrument or software errors) and both of the pouch control assays (RNA Process Control and PCR2 Control) were successful. The Controls field will display Failed if the run was completed successfully (no instrument or software errors) but one or both of the pouch control assays failed. If the control result is Failed, then the result for all of the tests on the panel are displayed as Invalid and the sample will need to be retested with a new pouch.

Table 4 provides a summary and explanation of the possible control results and follow-up actions.

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Table 4. Interpretation of Controls Field on the FilmArray GI Test Report

Control Result	Explanation	Action Required	Outcome
Passed	The run was successfully completed AND Both pouch controls were successful.	None	Report the results provided on the test report.
Failed	The run was successfully completed BUT At least one of the pouch controls (RNA Process Control and/or PCR2 Control) failed.	Repeat the test using a new pouch.	Accept the results of the repeat testing. If the error persists, contact Technical Support for further instruction.
Invalid	The controls are invalid because the run did not complete. (Typically this indicates a software or hardware error).	Note any error codes displayed during the run and the Run Status field in the Run Details section of the report. Refer to the appropriate FilmArray Operator's Manual or contact Technical Support for further instruction. Once the error is resolved, repeat the test or repeat the test using another instrument/Module.	Accept the valid results of the repeat testing. If the error persists, contact Technical Support for further instruction.

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Results Summary – Interpretations:

The Results Summary – Interpretations section provides a complete list of the test results. Possible results for each organism include Detected, Not Detected, N/A and Invalid. Table 5 provides an explanation for each interpretation and any follow-up necessary to obtain a final result

Table 5. Reporting of Results and Required Actions

Result	Explanation	Action
Detected	The run was successfully completed AND The pouch controls were successful (Passed) AND The assay(s) associated with the interpretation were positive based on the following requirements for at least 2 of the 3 assay replicates: -a positive melt curve, and -the Tm for the melt data were within the assay specific limits, and -the Tm for the melt data were within 1°C of each other.	None. Report results.
Not Detected	The run was successfully completed AND The pouch controls were successful (Passed) AND The assay(s) associated with the interpretation were negative (did not meet the requirements for a positive assay described in Detected).	None. Report results.
N/A (applies to *E. coli* O157 and EPEC only)	The run was successfully completed AND The pouch controls were successful (Passed) AND For *E.* coli O157: Shiga-like toxin-producing *E. coli* was Not Detected. For EPEC: Shiga-like toxin-producing *E. coli* was Detected.	None. Report results.
Invalid	The run did not complete successfully (Aborted, Incomplete, Instrument Communication Error, Instrument Error, or Software Error) OR The pouch controls were not successful (Failed)	See Table 4, *Interpretation of Controls Field on FilmArray Report*, for instruction.

LIMITATIONS OF THE PROCEDURE:

FilmArray Gastrointestinal (GI) Panel performance has only been established on the FilmArray, FilmArray 2.0, and FilmArray Torch systems.

This test is a qualitative test and does not provide a quantitative value for the organism(s) in the

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sample.

The performance of this test has only been validated with human stool collected in Cary Blair transport medium, according to the media manufacturers' instructions. It has not been validated for use with other stool transport media, raw stool, rectal swabs, endoscopy stool aspirates, or vomitus.

This product should not be used to test stool samples in fixative (e.g., formalin or polyvinyl alcohol; PVA).

The performance of this test has not been established for patients without signs and symptoms of gastrointestinal illness.

Virus, bacteria, and parasite nucleic acid may persist *in vivo* independently of organism viability. Additionally, some organisms may be carried asymptomatically. Detection of organism targets does not imply that the corresponding organisms are infectious or are the causative agents for clinical symptoms.

Results from this test must be correlated with the clinical history, epidemiological data, and other data available to the clinician evaluating the patient. Due to high rates of asymptomatic carriage of *Clostridium difficile*, especially in very young children and hospitalized patients, the detection of toxigenic *C. difficile* should be interpreted within the context of guidelines developed by the testing facility or other experts (e.g., guidelines/policy statements published by The American Academy of Pediatrics or the Society for Healthcare Epidemiology of America and the Infectious Disease Society of America).18,19

The performance of this test has not been established for monitoring treatment of infection with any of the panel organisms.

Discrepancies between the FilmArray GI Panel and other microbial identification methods may be caused by the inability to reliably differentiate species based on standard phenotypic microbial identification methods. Examples include differentiation of *Yersinia enterocolitica* from other *Y. enterocolitica* group members such as *Y. kristensenii* or *Y. fredricksonii,* differentiation of *Entamoeba histolytica* from *E. dispar*, and differentiation of *Helicobacter pullorum* from *Campylobacter*. See Organism Interpretation section of this document for other specific examples.

There is a risk of false negative values due to the presence of sequence variants in the gene targets of the assay, procedural errors, amplification inhibitors in specimens, or inadequate numbers of organisms for amplification.

The identification of several diarrheagenic *E. coli* pathotypes has historically relied upon phenotypic characteristics, such as adherence patterns or toxigenicity in certain tissue culture cell lines. The FilmArray GI Panel targets genetic determinants characteristic of most pathogenic strains of these organisms but may not detect all strains having phenotypic characteristics of a pathotype. In particular, the FilmArray GI Panel will only detect Enteroaggregative *E. coli* (EAEC) strains carrying the *aggR* and/or *aatA* genes on the pAA (aggregative adherence) plasmid; it will not detect all strains exhibiting an aggregative adherence pattern.

Target genes associated with the diarrheagenic *E. coli*/*Shigella* pathotypes are capable of horizontal transfer between strains, thus Detected results for multiple diarrheagenic *E. coli/Shigella* may be due to

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co-infection with multiple pathotypes or, less frequently, may be due to the presence of a single organism containing genes characteristic of multiple pathotypes. An example of the latter is the 2011 *E. coli* O104:H4 outbreak strain that contains determinants of both STEC and EAEC.

The FilmArray GI Panel detects the heat-labile toxin (LT) and heat-stable toxin variants (ST1a and ST1b) of Enterotoxigenic *E. coli* (ETEC), which are associated with human disease. The variant LT-II toxin (structurally similar to LT) and the STB/ST2 toxin (structurally dissimilar to ST1) are not targeted by the ETEC assays and have not been established as important in human disease.

The FilmArray GI Panel detects Enteropathogenic *E. coli* (EPEC) through targeting of the *eae* gene, which encodes the adhesin intimin. As some Shiga-like toxin-producing *E. coli* (STEC) also carry *eae* (in particular, strains identified as enterohemorrhagic *E. coli*; EHEC), the FilmArray GI Panel cannot distinguish between STEC containing *eae* and a co-infection of EPEC and STEC. Therefore, the EPEC result is not applicable (N/A) and not reported for specimens in which STEC has also been detected. In rare cases, STEC may be reported as EPEC when an STEC carrying *eae* (EHEC) is present in a specimen below the LoD of the STEC assay(s), or the strain carries an *stx* variant that is not detected well by the STEC assay(s) (e.g. *stx2* variant f).. Rare instances of other organisms carrying *eae* have been documented; e.g., *Aeromonas* spp., *Citrobacter* spp., *Escherichia albertii*, and *Shigella boydii*.

Shigella dysenteriae possess a shiga toxin gene (*stx*) that is identical to the *stx1* gene of STEC. The detection of both *Shigella*/Enteroinvasive *E. coli* (EIEC) and STEC *stx1/stx2* analytes in the same specimen may indicate the presence of *S. dysenteriae*. Rare instances of the detection of shiga-like toxin genes in other genera/species have been reported; e.g., *Aeromonas caviae*, *Acinetobacter haemolyticus*, *Shigella sonnei*, *Enterobacter cloacae*, *Citrobacter freundii*, and *Klebsiella pneumoniae*.

The *E. coli* O157 result is only reported in association with STEC *stx1/stx2*. While non-STEC O157 strains have been detected in human stool, their role in disease has not been established. Serotype O157 EPEC have been identified and will be detected by the FilmArray GI Panel (by the EPEC assay) due to their carriage of the *eae* gene.

The FilmArray GI Panel cannot distinguish between infections with a single toxigenic STEC O157 or rare co-infections of STEC (non-O157) with an *stx1/stx2*-negative *E. coli* O157.

This test only detects *Campylobacter jejuni*, *C. coli* and *C. upsaliensis* and does not differentiate between these three species of Campylobacter. Additional testing is required to differentiate between these species and to detect other Campylobacter species that may be present in stool specimens.

The detection of organism nucleic acid is dependent upon proper sample collection, handling, transportation, storage, and preparation. Failure to observe proper procedures in any one of these steps can lead to incorrect results. There is a risk of false positive and false negative results caused by improperly collected, transported, or handled specimens. The RNA process control and the PCR 2 control will not indicate whether or not nucleic acid has been lost due to inadequate collection, transport or storage of specimens.

Due to the complex and highly variable nature of stool specimens, **freezing may affect analyte integrity** and subsequent test results for some specimens.

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A negative FilmArray GI Panel result does not exclude the possibility of gastrointestinal infection. Negative test results may occur from sequence variants in the region targeted by the assay, the presence of inhibitors, technical error, sample mix-up, or an infection caused by an organism not detected by the panel. Test results may also be affected by concurrent antimicrobial therapy or levels of organism in the sample that are below the limit of detection for the test. **Negative results should not be used as the sole basis for diagnosis, treatment, or other management decisions.**

Organism and amplicon contamination may produce erroneous results for this test. Particular attention should be given to the Laboratory Precautions noted under the Warnings and Precautions section.

If four or more distinct organisms are detected in a specimen, retesting is recommended to confirm the polymicrobial result.

The performance of the FilmArray GI Panel has not been established in individuals who received Rotavirus A vaccine. Recent oral administration of a Rotavirus A vaccine may cause positive results for Rotavirus A if the virus is passed in the stool.

The effect of interfering substances has only been evaluated for those listed in the labeling. Interference by substances other than those described in the Interference section below could lead to erroneous results.

Several organisms were shown to have the potential to cross-react with FilmArray GI Panel assays. These include *Entamoeba dispar* when present at high levels (*E. histolytica* assay); *Bifidobacterium* spp. and *Ruminococcus* spp. (*G. lamblia* assay); certain strains of *Citrobacter koseri*, *Citrobacter sedlakii*, *Hafnia alvei*, and *Cedeceae davisiae* containing variants of a flagellar assembly protein (ETEC 2 assay), *E. coli* containing a variant type III secretion protein (*Salmonella* assay), *Grimontia hollisae* which was formerly classified as a *Vibrio* sp. (*Vibrio* assay), *Yersinia frederiksenii* and *Yersinia kristensenii*, which are members of the *Y. enterocolitica* group (*Y. enterocolitica* assay). Please refer to the Organism Interpretation and Analytical Specificity sections of this document for additional information.

Cross-reactivity with organisms other than those listed above or in the Organism Interpretation or Analytical Specificity sections may lead to erroneous results.

Cross-re*activity w*ith the *Salmonella* assay may occur with certain *E. coli* strains containing variants of the cryptic ETT2 type-III secretion system

REFERENCE:

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Approval Signatures

Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator, VCMC & SPH	3/2/2026
Policy Owner	Linda Conboy: Supervisor-Microbiology, Laboratory Services	3/1/2026
Policy Owner	Erlinda Roxas: Director, Laboratory Services	2/28/2026
Policy Owner	M. Anwar Molani: Medical Director, Laboratory Services	2/23/2026

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VENTURA COUNTY HEALTH CARE AGENCY

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Owner	Linda Conboy: Supervisor-Microbiology, Laboratory Services
Policy Area	Laboratory Services - Microbiology

L.MIC.2.4 Biofire Blood Culture Identification

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PURPOSE:

The BioFire BCID Panel is a multiplexed nucleic acid test intended for use with the BioFire® FilmArray® 1.5, BioFire® FilmArray® 2.0, or BioFire® FilmArray® Torch Systems for the simultaneous qualitative detection and identification of multiple bacterial and fungal nucleic acids in positive blood culture samples.

The following gram-positive bacteria, gram-negative bacteria, and yeast are identified using the BioFire BCID Panel:

Gram-positive bacteria

- *Enterococcus*
- *Listeria monocytogenes*
- *Staphylococcus*
- *Staphylococcus aureus*
- *Streptococcus*
- *Streptococcus agalactiae*
- *Streptococcus pneumoniae*
- *Streptococcus pyogenes*

Gram-negative bacteria

- *Acinetobacter baumannii*
- *Enterobacteriaceae*
- *Enterobacter cloacae* complex

- *Escherichia coli*
- *Klebsiella oxytoca*
- *Klebsiella pneumoniae*
- *Serratia marcescens*
- *Proteus*
- *Haemophilus influenza*
- *Neisseria meningitidis* (encapsulated)
- *Pseudomonas aeruginosa*

Yeast

- *Candida albicans*
- *Candida glabrata*
- *Candida krusei*
- *Candida parapsilosis*
- *Candida tropicalis*

Antimicrobial resistance genes

- *mecA* – methicillin resistance
- *vanA/B* – vancomycin resistance
- KPC – carbapenem resistance

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The BioFire® FilmArray® Blood Culture Identification (BCID) Panel also contains assays for the detection of genetic determinants of resistance to methicillin (*mecA*), vancomycin (*vanA* and *vanB*), and carbapenems (KPC) to aid in the identification of potentially antimicrobial resistant organisms in positive blood culture samples.

PRINCIPLE:

The BioFire BCID Panel pouch is a closed system disposable that houses all the chemistry required to isolate, amplify, and detect nucleic acid from multiple bloodstream pathogens within a single blood culture sample. The rigid plastic component (fitment) of the BioFire BCID Panel pouch contains reagents in freeze-dried form. The flexible plastic portion of the pouch is divided into discrete segments (blisters) where the required chemical processes are carried out. The user of the BioFire BCID Panel pouch loads the sample into the BioFire BCID Panel pouch, places the pouch into the BioFire® FilmArray® Instrument, and starts the run. All other operations are automated.

The following is an overview of the operations and processes that occur during a pouch run:

1. Nucleic Acid Purification—Nucleic acid purification occurs in the first three blisters of the pouch. The sample is lysed by agitation (bead beating) and the liberated nucleic acid is captured, washed, and

eluted using magnetic bead technology. These steps require about 10 minutes, and the bead-beater apparatus can be heard as a high-pitched whine during the first minute of operation.

2. 1st Stage Multiplex PCR—The purified nucleic acid solution is combined with a preheated master mix to initiate thermocycling for multiplex PCR. The effect of 1st stage PCR is to enrich for the target nucleic acids present in the sample.
3. 2nd Stage PCR—The products of first-stage PCR are diluted and mixed with fresh PCR reagents containing a double-stranded DNA binding dye (LCGreen® Plus, BioFire Diagnostics, LLC). This solution is distributed over the 2nd stage PCR array. The individual wells of the array contain primers for different assays (each present in triplicate) that target specific nucleic acid sequences from each of the pathogens detected, as well as control template material. These primers are "nested," or internal to the specific products of the 1st stage multiplex reaction, which enhances both the sensitivity and specificity of the reactions.
4. DNA Melting Analysis—After 2nd stage PCR, the temperature is slowly increased, and fluorescence in each well of the array is monitored and analyzed to generate a melt curve. The temperature at which a specific PCR product melts (melting temperature or Tm) is consistent and predictable, and the BioFire® FilmArray® Software automatically evaluates the data from replicate wells for each assay to report results. For a description of data interpretation and reporting, see the Interpretation of Results section of this booklet.

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Sample Requirements

The following table describes the requirements for specimen collection, preparation, and handling that will help ensure accurate test results.

Sample Type	Blood culture samples (aerobic, anaerobic, peds) identified as positive by a continuous monitoring blood culture system. Results are intended to be interpreted in conjunction with Gram stain results.
Sample Collection	Sample should be collected from the blood culture bottle using a syringe that is capable of measuring 0.2 mL.
Sample Volume	0.2 mL (200 µL)
Sample Age and Storage	Blood culture samples should be processed and tested as soon as possible after being flagged as positive by the culture instrument. If storage is required, specimens can be held: • At room temperature for up to 8 hours (15-25 °C) • In the culture instrument prior to testing

Materials

Materials Provided	Materials Required But Not Provided
Each kit contains sufficient reagents to test 30 specimens:	BioFire® FilmArray® System including:

• Individually packaged BioFire® FilmArray® Blood Culture Identification (BCID) Panel pouches • Single-use (1.0 mL) Sample Buffer ampoules • Single-use, pre-filled (1.5 mL) Hydration Injection Vials (blue) • Single-use Sample Injection Vials (red) • Individually packaged Transfer Pipettes	• FilmArray® Torch Systems • BioFire FilmArray Software • Pouch Loading Station compatible with the use of the Injection Vials

Quality Control

Controls for each analyte should be either included in each run or rotated so that all analytes are tested periodically

PROCESS CONTROLS

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Two process controls are included in each pouch:

1. **DNA Process Control -** The DNA Process Control assay targets DNA from the yeast *Schizosaccharomyces pombe*. The yeast is present in the pouch in a freeze-dried form and is hydrated and introduced into the test when the sample is loaded. The control material is carried through all stages of the test process, including lysis, nucleic acid purification, 1st stage PCR, dilution, 2nd stage PCR, and DNA melting. A positive control result indicates that all steps carried out in the pouch were successful.
2. **PCR2 Control -** The PCR2 Control assay detects a DNA target that is dried into the wells of the array along with the corresponding primers. A positive result indicates that 2nd stage PCR was successful.

Both control assays must be positive for the test run to pass. When either control fails, the Controls field of the test report (upper right-hand corner) will display Failed and all results will be listed as Invalid. If the controls fail, the sample should be retested using a new pouch.

Monitoring Test System Performance

The BioFire® FilmArray® Software will automatically fail the run if the melting temperature (Tm) for either the DNA Process Control or the PCR2 Control is outside an acceptable range (77.6–81.6 for the DNA Process Control and 74.2–78.2 for the PCR2 Control). If required by local, state, or accrediting organization quality control requirements, users can monitor the system by trending Tm values for the control assays and maintaining records according to standard laboratory quality control practices. The PCR2 Control is used in all pouch types and can therefore be used to monitor the system when multiple pouch types (e.g., RP, RP2, GI, ME, and BCID) are used on the same BioFire® FilmArray® Instrument.

Good laboratory practice recommends running external positive and negative controls regularly. Uninnoculated blood culture media can be used as an external negative control. Previously characterized

positive blood culture samples or samples spiked with well-characterized organisms can be used as external positive controls. External controls should be used in accordance with the appropriate accrediting organization requirements, as applicable.

Procedure

Refer to the BioFire® FilmArray® Blood Culture Identification (BCID) Panel Quick Guide for more details and pictorial representations of these instructions.

Gloves and other Personal Protective Equipment (PPE) should be used when handling pouches and samples. Only one BioFire BCID Panel pouch should be prepared at a time. Once the sample is added to the pouch, it should be promptly transferred to the BioFire® FilmArray® Instrument to start the run. After the run is complete, the pouch should be discarded in a biohazard container.

STEP 1:Prepare Pouch

1. Thoroughly clean the work area with 70% ethanol and the Pouch Loading Station with freshly prepared 10% bleach (or suitable disinfectant) followed by a water rinse.
2. Do not use bleach in the biological safety cabinet as it will degrade the stainless-steel surface.
3. Remove the pouch from its vacuum-sealed package by tearing or cutting the notched outer packaging and opening the protective aluminum canister.

   Text Box: NOTE: If the vacuum seal of the pouch is not intact, the pouch may still be used. Attempt to hydrate the pouch using the steps in the Hydrate Pouch section. If hydration is successful, continue with the run. If hydration fails, discard the pouch and use a new pouch to test the sample.

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4. Slide the pouch into the Pouch Loading Station so that the red and blue labels on the pouch align with the red and blue arrows on the Pouch Loading Station.
5. Place a blue-capped Hydration Injection Vial in the blue well of the Pouch Loading Station.
6. Place a red-capped Sample Injection Vial in the red well of the Pouch Loading Station.

STEP 2: Hydrate Pouch

1. Twist and lift the Hydration Injection Vial, leaving blue cap in the well of the Pouch Loading Station.
2. Insert the cannula tip into the port in the pouch located directly below the blue arrow of the Pouch Loading Station. Push down forcefully in a firm and quick motion until you hear a faint “pop” and feel an ease in resistance. The correct volume of liquid will be pulled into the pouch by vacuum.
3. Verify that the pouch has been hydrated.
4. Flip the barcode label down and check to see that fluid has entered the reagent wells (located at the base of the rigid plastic part of the pouch). Small air bubbles may be seen. If the pouch fails to hydrate (dry reagents appear as white pellets), repeat Step 2 to verify that the seal of the port was broken or retrieve a new pouch and repeat from Step 2 of the Prepare Pouch Section.

STEP 3: Prepare Sample Mix

1. Hold the Sample Buffer ampoule so that the tip is facing up.

   Text Box: NOTE: Use care to avoid touching the tip during handling, as this may introduce contamination.

2. Gently pinch the textured plastic tab on the side of the ampoule until the seal snaps.
3. Invert the ampoule over the red-capped Sample Injection Vial and re-position thumb and forefinger to grip the bottom of the ampoule. Dispense Sample Buffer using a slow, forceful squeeze, followed by a second squeeze. Squeezing the ampoule additional times will generate excessive bubbles, which should be avoided.
4. Invert the positive blood culture bottle several times to mix.
5. Wipe the bottle septum with alcohol and air dry.
6. Tilt the bottle and hold in the tilted position to allow the bottle resin to settle (approximately 10 seconds).
7. Using a syringe, withdraw 200 uL of blood culture sample through the bottle septum, taking care to avoid drawing resin beads into the sample, or the formation of bubbles.
8. Add sample directly to Sample Buffer in the Sample Injection Vial. Discard syringe in an appropriate biohazard sharps container and return the Sample Injection Vial to the Pouch Loading Station.
9. Alternately: Draw the desired amount of blood culture sample (>200 uL) from the bottle into the syringe and transfer to a sterile secondary container. Draw the blood culture sample from the secondary container to the second line of the Transfer Pipette (200 uL) and add the sample to Sample Buffer in the Sample Injection Vial. Tightly close the lid of the Sample Injection Vial.

   Text Box: NOTE: DO NOT use the Transfer Pipette to mix the sample once it is added to the Sample Injection Vial.

10. Remove the Sample Injection Vial from the Pouch Loading Station and gently invert the vial at least three times to mix.
11. Return the Sample Injection Vial to the Pouch Loading Station.

STEP 4: Load Sample Mix

1. Slowly twist the Sample Injection Vial so it loosens from its red cap and pause for 3–5 seconds. Lift the Sample Injection Vial, leaving the red cap in the well of the Pouch Loading Station.
2. Insert the cannula tip into the port in the pouch fitment located directly below the red arrow of the Pouch Loading Station. Push down forcefully in a firm and quick motion until you hear a faint “pop” and feel an ease in resistance. The correct volume of liquid will be pulled into the pouch by vacuum.
3. Verify that the sample has been loaded. Flip the barcode label down and check to see that fluid has entered the reagent well next to the sample loading port. If the pouch fails to pull sample from the Sample Injection Vial, the pouch should be discarded. Retrieve a new pouch and repeat from the

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Prepare Pouch section.

4. Discard the Sample Injection Vial and the Hydration Injection Vial in an appropriate biohazard sharps container.
5. Record the Sample ID in the provided area on the pouch label (or affix a barcoded Sample ID) and remove the pouch from the Pouch Loading Station.

STEP 5: Run Pouch

The BioFire® FilmArray® Software includes step-by-step instructions that guide the operator through performing a run. Brief instructions are given below. Refer to the BioFire® FilmArray® Operator's Manual for more detailed instructions.

BioFire® FilmArray® Torch

1. Ensure that the BioFire Torch system is on.
2. Select an available Module on the touch screen.
3. Scan the barcode on the pouch using the barcode scanner.
4. Pouch identification (Lot Number and Serial Number), Pouch Type, and Protocol are preprogrammed in the rectangular barcode located on the pouch. The information will be automatically entered when the barcode is scanned. If it is not possible to scan the barcode, the pouch Lot Number, Serial Number, Pouch Type, and Protocol can be manually entered from the information provided on the pouch label into the appropriate fields. To reduce data entry errors, it is strongly recommended that the pouch information be entered by scanning the barcode.
5. Enter the Sample ID. The Sample ID can be entered manually or scanned in by using the barcode scanner when a barcoded Sample ID is used.
6. Insert the pouch into the Module.
7. Ensure that the pouch fitment label is lying flat on top of pouch and not folded over. As the pouch is inserted, the Module will grab onto the pouch and pull it into the chamber.
8. If necessary, select and/or confirm a protocol from the protocol drop-down list.
9. Enter operator user name and password, then select Next.

   Text Box: NOTE: The font color of the username is red until the user name is recognized by the software.

10. Review the entered run information on the screen. If correct, select Start Run.
11. Once the run has started, the screen displays a list of the steps being performed by the instrument and the number of minutes remaining in the run.

    Text Box: NOTE: The bead-beater apparatus can be heard as a high-pitched noise (whine) during the first minute of operation.

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12. At the end of the run, the status of the Module changes to Finished and the pouch is partially ejected.
13. Select the Finished Module on the Dashboard to view the report.
14. Select Print to print the report, or Save to save the report as a file.\
15. Remove the pouch from the Module and immediately discard the pouch in a biohazard container.

    Text Box: NOTE: Once the pouch has been removed, the report can only be viewed through the Browse Runs feature.

Interpretation

The BioFire® FilmArray® Software automatically analyzes and interprets the assay results and displays the final results in a test report (see the BioFire Blood Culture Identification Panel Quick Guide to view an example of a test report). The analyses performed by the BioFire Software and details of the test report are described below.

Assay Interpretation

When 2nd stage PCR is complete, the BioFire® FilmArray® Instrument performs a high-resolution DNA melting analysis on the PCR products and measures the fluorescence signal generated in each well (for more information see the BioFire® FilmArray® Operator's Manual). The BioFire® FilmArray® Software then performs several analyses and assigns a final assay result.

Analysis of melt curves. The BioFire Software evaluates the DNA melt curve for each well of the 2nd stage PCR array to determine if a PCR product was present in that well. If the melt profile indicates the presence of a PCR product, then the analysis software calculates the melting temperature (Tm) of the curve. The Tm value is then compared against the expected Tm range for the assay. If the software determines that the melt curve is positive and the Tm falls inside the assay-specific Tm range, the melt curve is called positive. If the software determines that the melt curve is negative or is not in the appropriate Tm range, the melt curve is called negative.

Analysis of replicates. Once melt curves have been identified, the software evaluates the three replicates for each assay to determine the assay result. For an assay to be called positive, at least two of the three associated melt curves must be called positive, and the Tm for at least two of the three positive melt curves must be similar (within 1°C). Assays that do not meet these criteria are called negative.

Organism Interpretation

Interpretations for many of the organisms are based on the results of a single assay. Interpretations for *Haemophilus influenzae* and the *Staphylococcus, Streptococcus*, and *Enterobacteriaceae* groups rely on the results of several assays. The antimicrobial resistance genes are also based on the result of a single assay; however, the test results are only reported when specific organisms are also detected in the same sample. Interpretation guidelines for actions to be taken based on the test result are described in the FilmArray Blood Culture Identification Panel Instruction Booklet. The FilmArray Blood Culture Identification Booklet contains information about known assay limitations (e.g., cross-reactivity, strains that are not detected) that may be important in the interpretation of the test result and in correlating the results with the result of standard

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culture and biochemical identification.

Polymicrobial blood cultures with 3 or more distinct organisms are possible but rare. If Detected results are reported for 3 or more organisms in a sample, a retest of the sample is recommended to confirm the polymicrobial result.

In some cases, the Gram stain result and results from the FilmArray BCID Panel may be discrepant (for example, detection of gram-positive cocci by the FilmArray BCID Panel when gram-positive cocci are not observed in the Gram stain). In these cases, the FilmArray BCID Panel results should be confirmed (e.g. by culture) before reporting, unless the result is concordant with other laboratory, epidemiological, or clinical findings.

Blood culture media may contain non-viable organisms and/or nucleic acid, at levels that can be detected by the BioFire BCID2 Panel, leading to false positive test results. Typically, these false positives will be present with one or more additional true positive results because the BioFire BCID2 Panel will also detect the organism that is growing in the culture bottle.

BioFire BCID Panel Test Report

The BioFire BCID Panel test report is automatically displayed upon completion of a run and contains three sections: the Run Summary, the Results Summary, and the Run Details (see the BioFire Blood Culture Identification Panel Quick Guide to view an example of a test report). The test report can be saved as a PDF or printed.

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The **Run Summary** section of the test report provides the Sample ID, time and date of the run, control results, and an overall summary of the test results. Any organism with a Detected result will be listed in the corresponding field of the summary. If all of the tests were negative, then None will be displayed in the Detected field. Antimicrobial resistance genes with a result of Detected or Not Detected will be listed in the corresponding field of the summary. Controls are listed as Passed, Failed, or Invalid. See the Controls Field section below for detailed information about the interpretation of controls and appropriate follow-up in the case of control failures.

The **Results Summary—Interpretations** section of the test report lists the result for each target tested by the panel. Possible results for each organism are Detected, Not Detected, or Invalid. Possible results for antimicrobial resistance genes are Detected, Not Detected, N/A, or Invalid. See Results Summary section below for detailed information about interpretation of test results and appropriate follow-up for Invalid results.

The **Run Details** section provides additional information about the run, including pouch information (type, lot number, and serial number), Run Status (Completed, Incomplete, Aborted, Instrument Error, Instrument Communication Error, or Software Error), the protocol that was used to perform the test, the identity of the operator that performed the test, and the instrument used to perform the test.

Once a run has completed, it is possible to edit the Sample ID. If this information has been changed, an additional section called Change History will be added to the test report. This Change History section lists the field that was changed, the original entry, the revised entry, the operator that made the change, and the date that the change was made. Sample ID is the only field of the report that can be changed.

Control Field

The Controls field on the test report will display Passed, Failed, or Invalid. The Controls field will display

Passed only if the run completed successfully (no instrument or software errors) and both of the pouch control assays (DNA Process Control and PCR2 Control) were successful. The Controls field will display Failed if the run was completed successfully (no instrument or software errors) but one or both pouch control assays failed (0 or 1 positive replicates for either of the controls, each of which is tested in triplicate). If the control result is Failed, then the result for all of the tests on the panel are displayed as Invalid and the sample will need to be retested with a new pouch.

The table below provides a summary and explanation of the possible control results and follow-up actions.

Control Result	Explanation	Action Required	Outcome
Passed	The run was successfully completed AND Both pouch controls were successful.	None	Report the results provided on the test report.
Failed	The run was successfully completed BUT At least one of the pouch controls (RNA Process Control and/or PCR2 Control) failed.	Repeat the test using a new pouch.	Accept the results of the repeat testing. If the error persists, contact technical support for further instruction.
Invalid	The controls are invalid because the run did not complete. (Typically this indicates a software or hardware error.)	Note any error codes displayed during the run and the Run Status field in the Run Details section of the report. Refer to the Operator's Manual or contact Technical Support for further instruction. Once the error is resolved, repeat the test or repeat the test using another instrument. If the error occurred in the first 30 seconds of the run, the same pouch may be used for the repeat test (within 60 minutes of pouch loading) using the same instrument or another instrument, as available. If the error occurred later in the run or you are unsure when the error occurred, return to the original sample to load a new pouch. Repeat the test with the new pouch on the same instrument or another instrument, as available.	Accept the valid results of the repeat testing. If the error persists, contact Technical Support for further instruction.

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Result Reporting

The Results Summary—Interpretations section provides a complete list of the test results. Possible results for each organism include Detected, Not Detected, N/A, and Invalid. The table below provides an explanation for each interpretation and any follow-up necessary to obtain a final result.

Result	Explanation	Action
Detected	The run was successfully completed AND The pouch controls were successful (Passed) AND The assay(s) for the organism (or antimicrobial resistance gene) were POSITIVE.	Report results. NOTE: If Detected results are reported for 3 or more organisms in a sample, a retest of the sample is recommended to confirm the polymicrobial result.
Not Detected	The run was successfully completed AND The pouch controls were successful (Passed) AND The assay(s) for the organism (or antimicrobial resistance gene) were NEGATIVE.	Report results.
Invalid	The pouch controls were not successful (Failed) OR The run did not complete successfully (Run Status displayed as: Aborted, Incomplete, Instrument Error, Software Error, or Instrument Communication Error).	See Table 11 Interpretation of Controls Field on the Test Report for instruction.
N/A (Antimicrobial Resistance Genes only)	The run was successfully completed AND The pouch controls were successful (Passed) AND The assay(s) for the organism(s) associated with the antimicrobial resistance gene were NEGATIVE so the results of the antimicrobial resistance gene are not applicable to the test results.	Report results.

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REFERENCE:

- FilmArray Blood Culture Identification Panel (BCID) Instruction Booklet (RFIT-PRT-0369), BioFire Diagnostics, LLC

All Revision Dates

3/2/2026

Approval Signatures

Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator, VCMC & SPH	3/2/2026
Policy Owner	Linda Conboy: Supervisor-Microbiology, Laboratory Services	3/1/2026
Policy Owner	Erlinda Roxas: Director, Laboratory Services	2/28/2026
Policy Owner	M. Anwar Molani: Medical Director, Laboratory Services	2/23/2026

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Status **Active** PolicyStat ID **19760868**

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Next Review	2/24/2028
Owner	Linda Conboy: Supervisor-Microbiology, Laboratory Services
Policy Area	Laboratory Services - Microbiology

L.MIC.7.01 Blood Culture Collection

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PRINCIPLE

When bacteria or fungi overcome the host's normal defense mechanisms and enter the bloodstream through the lymphatics or from extra-vascular sites, they can quickly disseminate throughout the body, causing severe illness. In addition, the by-products of their metabolism can lead to septic shock, among the most serious complications of infectious diseases. Rapid recognition and immediate institution of appropriate treatment are essential.

CLINICAL INDICATIONS

Blood cultures are collected whenever there is reason to suspect clinically significant bacteremia or fungemia. Bacteremia or fungemia may present in several ways.As a classical septicemia with invasion of the blood stream from a focus of infection accompanied by malaise, raised pulse and temperature, and chills followed by fever and prostration.

1. As "sepsis" in the newborn and immunologically compromised adult or child, sometimes with minimal clinical signs, such as failure to suck or thrive in the newborn, but with a rapid downhill course.
2. As part of a more chronic infection such as disseminated gonococcal disease of chronic meningococcal bacteremia.
3. As part of "spill-over" in certain severe infections such as meningitis, pneumonia, deep-seated abscess or biliary infections.

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4. As a result of a localized intravascular infection, such as a heart valve or in an infected and sometimes thrombosed blood vessel.
5. As part of the natural history of certain multi-system infections such as enteric fever, leptospirosis, or brucellosis (usually fever of unknown origin).
6. With sudden introduction of many bacteria into the bloodstream by trauma to heavily infected areas, (e.g., urinary tract catheterization) or from contaminated external sources, (e.g., IV infusions).
7. As an asymptomatic, brief, and rapidly cleared introduction of bacteria into the bloodstream from minor traumatic events, e.g., members of the normal microbial flora at the time of tooth extraction or endoscopy.

One blood culture usually consists of blood from a single venipuncture inoculated into two separate bottles to accommodate the volume of blood removed (usually 10-20 ml for adults). The use of more than one formulation of medium (usually one aerobic and one anaerobic bottle) for each blood culture generally maximized recovery of all possible pathogens.

Adequate volume is the single most important factor in the laboratory detection of microorganisms in the bloodstream; the more blood cultured, the more likely a culture will be positive. In one study of adults, increasing the total volume cultured from 20 to 40 ml increased the yield by 19%; increasing the volume from 40 to 60 ml increased the yield by an addition 10%.
The total volume of blood drawn should be divided equally between at least two separate venipunctures, to allow evaluation of the recovery of a skin organism in a single positive set that could have resulted from contamination of the culture during collection.

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Media

1. BacT/Alert FA Plus
    a. (Color-coded green) Pancreatic digest of casein, papaic digest of soybean meal, SPS (0.035% w/v), pyridoxine HCl, and other complex amino acid and carbohydrate substrates in purified water with adsorbent polymeric beads. Bottles are prepared with an atmosphere of N^2, O^2, and CO^2 under vacuum. 40 ml of media in each bottle.
2. BacT/Alert FN Plus
    a. (Color-coded Orange) Pancreatic digest of casein, papaic digest of soybean meal, SPS (0.035% w/v) menadion, hemin, reducing agents, and other complex amino acid and carbohydrate substrates in purified water with absorbent polymeric beads. Bottles are prepared with an atmosphere of CO^2 and N^2 under vacuum. 40 ml of media in each bottle
3. BacT/Alert PF Plus

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a. (Color-coded yellow) Pancreatic digest of casein, papaic digest of soybean meal, SPS (0.035% w/v) menadion, hemin, reducing agents, and other complex amino acid and carbohydrate substrates in purified water with absorbent polymeric beads. Bottles are prepared with an atmosphere of O^2, CO^2 and N^2 under vacuum. 40 ml of media in each bottle.

4. Sensor- Colorimetric carbon dioxide sensor attached internally to the bottom of each bottle.

Storage

Store bottles protected from direct sunlight at room temperature (15-30 degrees C)

SPECIMEN COLLECTION, TRANSPORT, AND HANDLING

Information Required

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Suspected diagnosis and severity of infection

1. Nature, timing, and dose of any antimicrobial agent that is being given.
2. If laboratory personnel collect the blood cultures, the urgency and requested time of collection should be stated.
3. Bone marrow cultures should be reserved for culture for specific pathogens such as Brucella sp., Salmonella sp., Listeria sp., fungi and mycobacteria; it adds little to detection of most other bacteria in the blood. Because of the complex nature of the collection procedure, it is more likely to result in a contaminated bacterial culture than a diagnostic one. Thus, routine cultures of bone marrow without a specific indication should be discouraged.

Recommended total volume and numbers of blood cultures

Adults: At least 10ml per bottle (20ml per set) and two draws is the minimal requirement for adults.
(set = aerobic and anaerobic bottles)
Neonates & Children aged 6 and under
Children 1 to 6 years old: 1ml per year of age.
Children weighing 30 to 80 lbs.: 5 to 10 ml per culture
Adults and children weighing more than 80 lbs.: 15 to 20 ml per culture

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Weight (lbs.)	Minimum Volume	Aerobic Bottle	Aerobic & Anaerobic Bottles
2.2	1.0 ml	Yes	
2.3 to	1.5 ml	Yes	

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8.6			
8.7 to 30.0	3.0 ml	Yes	
30.0 to 80.0	10.0 ml		Yes
>80	20.0 ml		Yes

1. Neonates: Two separate venipunctures are generally not possible.
2. Children have more bacteria circulating per ml than adults.
   In one study, levels of bacteremia in some infants equaled more than 1000 CFU/ml of
   blood
3. For specialized patients (e.g., pediatric patients that do not have abdominal abnormality), anaerobic cultures may not be indicated.
4. In adults, several studies have found levels of bacteremia of fewer than 30 CFU/ml of
   blood
5. Always include anaerobic culture for febrile neutropenic patients and patients with diabetes or wound infections.

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Low Blood Volumes

1. Blood culture Load list is reviewed daily for specimens with low blood volumes (<10mL).
2. Low blood volumes will be documented in LIS and a comment added to report that reads, **Results may be questionable due to suboptimal volume. Optimal volume is 10 mL per bottle**.
3. It is suggested that pediatric patients or those patients who are difficult to draw be collected in the yellow Pediatric blood culture bottles. The optimum volume is 4ml.
4. Phlebotomists with frequent incidence of low volume collections, will be brought to the attention of QC/QA supervisor or team lead for education.

Findings of one study suggested that the yield of bacteria increases by 3.2% per ml of blood cultured**.**

Timing of blood cultures

NOTE: Although drawing blood cultures before or during the fever spike is optimal for recovery, volume is more important than timing in the detection of agents of septicemia.

1. As a practical matter, blood cultures should be obtained simultaneously (or over a short time frame). A study found no significant difference in the yield between multiple blood cultures obtained simultaneously or those obtained at intervals. Drawing blood at intervals is only indicated when it is necessary to document continuous bacteremia in patients with suspected infective endocarditis or other endovascular (e.g. catheter-related) infections.

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2. When acute sepsis or another condition (osteomyelitis, meningitis, pneumonia, or pyelonephritis) requires immediate institution of antimicrobial agent therapy, draw two blood cultures of maximum volume consecutively from different anatomic sites before starting therapy.
3. For fever of unknown origin, subacute bacterial endocarditis, or other continuous bacteremia or fungemia, initially obtain three blood cultures with maximum volume. If those sets are negative at 24 hours, obtain two more sets of cultures, for a total of five sets overall.
4. When it is appropriate to draw blood cultures from patients on antimicrobial therapy, they should be drawn when antimicrobial agents are at their lowest concentration.

Skin antisepsis and collection of blood from venipuncture

NOTE: Universal precautions require that phlebotomists wear gloves for this procedure.

- Select a different venipuncture site for each blood culture.
- If poor access requires that blood for culture be drawn through a port in an indwelling catheter, the second culture must be from a peripheral site, because cultures drawn through catheters can indicate catheter colonization but may not be indicative of sepsis.
- Do not draw blood from a vein into which an intravenous solution is running.
- Except from neonates, draw the two blood cultures in succession. If the phlebotomy must be performed at the same site (usually because of bad veins), perform the second venipuncture at that site.

1. Prepare the site.
2. Choose the vein to be drawn by touching the skin before it has been disinfected. Careful attention to skin disinfection is essential to reduce the blood culture contamination rate.
3. For patients less than 2 months old:
   Cleanse the skin over the venipuncture site in a circular pattern 5cm in diameter with 70% alcohol, rubbing vigorously. Allow to air dry. Cleanse the skin over the venipuncture site in a circular pattern approximately 5 cm in diameter with providone-iodine. Allow the iodine to dry on the skin for one minute. Since the timing is critical, a watch or a timer should be used. If using tincture of iodine, allow the iodine to dry on the skin (usually in less than a minute).
4. For patients at least 2 months old:
   Use ChloraPrep One Step (chlorohexidine gluconate 2% w/v and isopropyl alcohol70%v/v). Pinch the wings on the applicator to break the ampule and release the antiseptic. Do not touch the sponge. Wet the sponge by repeatedly pressing and releasing the sponge against the area until liquid is visible on the skin. Using a back and forth motion, completely wet the treatment area (about 30 seconds). Do not blot or wipe the solution away. Allow the area to dry for 30 seconds.
5. If the site must be touched by the phlebotomist after preparation, the phlebotomist must disinfect the gloved fingers used for palpation in the same manner as the patient's arm. Insert the needle into the vein and withdraw blood.

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6. Prepare the septum of the blood culture bottle and the rubber stoppers on the bottles or tubes. Label the bottles with the patient's name, chart number, and the date and time of draw. Site of draw may also be listed.
7. Vigorously wipe septa with 70% alcohol and allow to dry completely, usually for 30 to 60 seconds.
   NOTE: Wiping the septum with iodine is usually unnecessary but may be considered if there is a history of problems with **Bacillus** spores or mold contamination.
8. While wearing gloves, insert the needle into the vein and withdraw the blood, use a new needle if the first attempt is not successful. *Do not re-palpate the skin after it is disinfected.*
9. *Apply a safety device to protect the phlebotomist from needle exposure.*
   NOTE: Safety devices consist of domes with internal needles that attach either to a syringe or directly to the tubing used in collecting the blood. The external port of these devices will accommodate a syringe or the end of a butterfly needle depending on the product.
10. Inoculate first the aerobic culture bottle and then the anaerobic culture bottle so that any oxygen trapped in the tubing will not be transferred to the anaerobic bottle. Inoculate with no more than 10 ml each.
    a. For direct inoculation into the bottles from the needle apparatus, mark the side of the bottle with the manufacturer's recommended draw.
    b. If using a needle and syringe, use the volume markings on the syringe to note the volume. *Hold the syringe plunger during transfer to avoid transfer of excess blood into bottles having a significant vacuum.*
       NOTE: There is no need to change the safety device **between** bottle inoculations.
    c. Alternatively, a pediatric bottle can be collected in a case where the minimal blood volume is unable to be collected. For optimal results, 4 mL of blood is needed for a pediatric bottle but those with lesser amounts will be tested with a disclaimer. An anaerobic bottle will not be collected as the collection of a pediatric bottle is indicative of the inability to collect adequate blood volumes for a single aerobic/anaerobic set.
11. Thoroughly mix bottles to avoid clotting.
12. After phlebotomy, dispose of needles in sharps container and remove residual tincture of iodine from the patient's skin by cleansing with alcohol to void development of irritation.

Collection of blood from intravascular catheters

NOTE: Using either quantitative cultures or time to positive signal of cultures processed on an automated instrument, the comparison of cultures that are drawn through an indwelling intravenous catheter and through a peripheral site may be useful for diagnosis of catheter-relation sepsis.

1. Label bottles with patient name, chart number, site of draw, and date and time of draw,

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and the phlebotomist's Cerner user ID.

2. Disinfect the septum of the blood culture bottle and the rubber stoppers on bottles or tubes with 70% alcohol as for peripheral draw. Allow to dry completely, usually 30 to 60 seconds.
3. Using two separate alcohol wipes, scrub catheter hub connection for 15 seconds with 70% alcohol. Air dry.
4. While wearing gloves, disconnect tubing or cap of catheter and attach syringe to collect discard blood (suggested amounts are 3 ml for adults and 0.2 ml for pediatric patients), which is not used for culture.
   NOTE: Avoid drawing from lines within an hour of completion of antimicrobial agent administration.
5. Using a new syringe, collect blood for culture through the hub. Quickly reconnect tubing.
6. Connect filled syringe to safety system adapter.
7. Holding the syringe plunger for control, inoculate the bottles with *no more* than the 10 ml each.
8. Thoroughly mix bottles to avoid clotting.

- In addition to labeling the blood culture bottles or tubes with patient demographic information and collection, indicate whether the collection was from a peripheral draw, or a catheter draw on the label and the initials of the phlebotomist or nurse.

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Specimen Transport and Loading

1. Transport inoculated culture bottles promptly to the laboratory in a biohazard specimen bag.
2. Do not refrigerate blood cultures. Inoculated culture bottles delayed in loading should be maintained at room temperature until they can be loaded into the instrument.
3. Delay in the transport and loading of inoculated bottles is not advised as it will delay the time to result of the culture and can impact the accuracy of patient results. Bottles should be loaded into the instrument as soon as possible but not to exceed 24 hours per manufacturer's recommendations.
4. If inoculated culture bottles have been delayed in their receipt into the lab or have been incubated prior to entry into the Virtuo instrument, visually inspect for indications of microbial growth. Macroscopic signs of growth include: a yellow bottle sensor, hemolysis, gas production, or turbidity. If microbial growth is evident, treat the bottles as positive and do not load into instrument.
5. Improvement in culture media and implementation of automated blood culture systems that increase recovery of these fastidious pathogens has made extended incubation of blood cultures to be **unnecessary** for the isolation of HACEK organisms. (Haemophilus, Actinobacillus, Cardiobacterium, Eikenella, and Kingella).

Check all information on the bottle and specimen label for completeness for the following information:

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1. **Patient's name (Last, First)**
2. **Medical Record Number**
3. **Date and Time of Collection**
4. **Site from which specimen was obtained**
5. **Nurse (CBN) or Phlebotomist's Cerner identification**

Under special circumstances, when a blood culture cannot be recollected due to initiation of therapy, correctly labeled blood cultures are not rejected even if volume or number of bottles is insufficient, or bottles were received up to 24 hours after collection. In these cases, notify the nurse and document the deficiency in the report, as well as the effect on the reliability of the culture results.
Blood culture specimens that meet the following criteria should be processed but the provider notified that the specimen is not optimal:

1. Inadequately filled bottles (<10mL)
2. Insufficient number of cultures
3. Single blood cultures
4. Blood inoculated into only aerobic or anaerobic bottles.

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Rejection criteria

1. Incorrectly labeled or unlabeled vials
2. Broken, damaged, or expired bottles
3. Clotted bottles
4. Tubes containing anticoagulants other than SPS.

Limitations

1. Prior to use, the BacT/Alert culture bottles should be examined for evidence of damage or deterioration (discoloration). The media should be clear, but there may be a trace of precipitate due to the anticoagulant SPS. Do not use a bottle, which contains media exhibiting turbidity or excess gas pressure; these are signs of possible contamination.
2. Inoculate one standard aerobic and one standard anaerobic medium for each culture.

NOTE: For specialized patients (e.g., pediatric whom do not have an abdominal abnormality), anaerobic cultures may not be indicated. However, always inoculate at least two bottles for adults. Always include anaerobic cultures for febrile neutropenic patients and patients with diabetes or would infections.

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All Revision Dates

2/24/2026

Approval Signatures

Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator, VCMC & SPH	2/24/2026
Policy Owner	Erlinda Roxas: Director, Laboratory Services	2/24/2026
Policy Owner	M. Anwar Molani: Medical Director, Laboratory Services	2/13/2026
Policy Owner	Linda Conboy: Supervisor-Microbiology, Laboratory Services	2/12/2026

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Status **Active** PolicyStat ID **19911145**

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Last Approved	3/2/2026		
Effective	9/11/2007		
Last Revised	3/2/2026	Policy Area	Laboratory Services - Microbiology
Next Review	3/1/2028		

L.MIC.7.11 CSF Cultures

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PRINCIPLE

Basic anatomy and physiology of the central nervous system (CNS)
The brain and spinal cord have two protective coverings: the skull on the outside and the meninges on the inside.
The meninges consists of three layers: dura matter (outer), arachnoid, pia mater (inner)
The CSF envelops the brain, cushions and provides buoyancy for the bulk of the brain, carries metabolites into the neural tissue and cleanses the tissues of wastes. Specialized secretory cells, called the choroid plexus, produce CSF. The choroid plexus is centrally located within the brain in the third and fourth ventricles. About 23ml of CSF are contained within the ventricles.
Bacterial meningitis is the result of infection of the meninges. Identification of the infecting agents is one of the most important functions of the diagnostic microbiology lab because acute meningitis is life threatening.
CSF from a patient suspected of meningitis is an emergency specimen that requires immediate processing to determine the etiologic agent.

CSF Routes of Infection

Hematogenous spread: followed by entry into the subarachnoid space through the choroid plexus or through the blood vessels of the brain. This is the most common route.
Direct spread from an infected site: the extension of an infection close to or contiguous with the CNS can occasionally occur; examples of such infections include otitis media, sinusitis, and mastoiditis.
Anatomic defects in CNS structures: anatomic defects because of surgery, trauma, or congenital abnormalities can allow organisms easy and ready access to the CNS.
Direct intraneural: Travel along nerves leading to the brain. This is the least common route usually

caused by organisms such as rabies virus and herpes simplex virus.
Aerobic bacteria commonly cause bacterial meningitis, but anaerobes may be present in CSF when a meningeal abscess or a similar infectious process is going on adjacent to the meninges. These include traumatic head injury or prosthesis such as shunt drains.
Inoculation of anaerobic media is not routinely recommended for the diagnosis of community acquired meningitis.
CSF may contain very few organisms per milliliter per fluid, so concentration of the gram stain is important for rapid diagnosis.
Concentration is not necessary for culture since the plate inoculum is sufficient to detect low numbers of organisms.
CSF is obtained by transcutaneous aspiration, and therefore all organisms recovered from the culture are potential pathogens.
Correlation with Gram stain findings is important. Any positive finding on Gram stain or culture must be reported to the physician immediately.

SPECIMEN COLLECTION

Cerebrospinal fluid (CSF): Tube #2 or #3, **minimum volume is 0.5ml**
Lumbar puncture
Ommaya reservoir fluid or ventricular shunt fluid.

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SPECIMEN TRANSPORT

STAT specimen handling**. Process immediately within 30 minutes of collection**.
Document accession number, collection time, received time, set up time and initials on the CSF culture log maintained in the department. Note in the comments any time discrepancies.
If a delay is unavoidable, hold specimen at room temperature or in 35° Celsius incubator. **Do not refrigerate specimen** (except for viral studies).
Perform all the initial processing of a CSF specimen in a biological safety cabinet to avoid contamination of the specimen and/or the primary inoculation medium.
Each bacteriologic procedure requires at least 0.5ml of CSF, although larger volumes are preferred.
Viral studies that are not performed at VCMC are referred to the Send Out Department for processing to Quest Laboratories.
AFB and/or Fungus cultures are submitted to and processed by Ventura County Public Health Department

Rejection Criteria

Call a physician to prioritize requests if there is insufficient volume.
Specimens received in a leaky container must be processed but alert the physician of the possibility of contamination.

MATERIALS

- Media
  BAP
  CHOC
  MAC If Gram negative enteric type bacilli are seen
  Anaerobic BHI broth (only on ventricular shunt fluid or Ommaya reservoir fluid)
  *Since THIO is mainly a broth for anaerobes and does not support the growth of the most common pathogens in CSF, it cannot be recommended for CSF culture.
  MTM -If Gram negative diplococci are present (selective for **Neisseria gonorrhea** and **Neisseria meningitidis)**
  Gram Stain reagents
  Because the number of organisms in the CSF can be as low as 10^3 CF/ml, concentration of the Gram stain by cytocentrifugation is important for rapid diagnosis. Cytospin concentration can increase the sensitivity up to 100-fold compared with both uncentrifuged and conventionally centrifuged fluid.

QUALITY CONTROL

Verify that the media meet expiration date and QC parameters per current CLSI document M22-A3
Refer to the individual biochemical test procedures for further QC requirements.

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PROCEDURE

Gram stain

Make smear using Cytospin method. Do not cytospin bloody or very turbid specimens. Smears get too thick to read. Instead of cytospin, place 1 or 2 drops of sediment on slide, allowing drops to form one large drop. Do not spread the fluid. Air-dry or place on warmer to dry.
Interpret CSF gram stains immediately.
Any bacteria seen are considered significant. Notify the physician immediately and document the notification in Cerner.

INOCULATION

Process specimen as soon as it is received.
Culture should be inoculated with 0.5ml of CSF. Place two or three drops each onto BAP, CHOC. Add MAC if gram negative enteric-like bacilli are seen. Streak in quadrants.
Although the stain and culture can be performed with as little as 0.5 ml of fluid, larger volumes are preferred since culture are concentrated by centrifugation before culture.
When > 1.0 ml of fluid is received, the fluid should be centrifuged (1.500 x g for 5 min) and the sediment used to inoculate media.
If >1mL is available from a ventricular source or shunt, inoculate 1mL to BHI broth.
If insufficient specimen is received for centrifugation/concentration (<1ml), the report must note that culture results may be compromised by the limited volume of specimen received.

If a CSF specimen appears empty or contains only 1 to 5 drops of fluid and more specimen is not available in the laboratory, proceed as follows,
If one drop is available, use a sterile pipette and prepare a smear for Gram stain from a portion of the specimen.
Using a sterile pipette, place 0.5mL BHI broth medium into the specimen tube and invert to mix the contents, then use the broth to inoculate media.
Anaerobic culture is appropriate for shunt fluid only. Inoculate an anaerobic broth such as thioglycolate (THIO) or brain heart infusion (BHI).
See AFB, Mycology, or Anaerobic Manuals pertaining to these types of requests
Save some CSF at 4C for 1 week for other subsequent requests.

INCUBATION

Incubate BAP and CHOC, at 35-37C in 5% CO2. Alternatively, use a CO2-generating system to provide the proper atmosphere if a CO2 incubator is unavailable.
Incubate BHI broth, if indicated for anaerobic culture, at 35-37C in ambient air for 6 days.

CULTURE EXAMINATION

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Examine all aerobic plated media for growth at 24 hours.
If there is no visible growth, re-incubate.
Read all plates daily for four days.
Broth enrichment should not be used routinely. *P. acnes* may be the cause of infection in patients with indwelling CSF shunts. Examine broth media daily for 4 days and hold for 6 days before discarding.
NOTE: *P. acnes* is a slow-growing organism that can be isolated only after prolonged incubation

Cultures with growth

Notify physician and/or licensed caregiver of positive culture findings.
Identify all organisms.
Perform catalase and gram stains of organisms growing on BAP and CHOC
Perform oxidase test on gram negative diplococci. If positive, identify using MALDI or Vitek NH card.
Perform indole and oxidase on gram negative rods. Identify using MALDI or VITEK GNI card.
If an organism is determined by the physician to be a probable contaminant, complete workup may not be needed.
Coagulase negative Staphylococci and Corynebacteria sp. may cause infection inpatients with CNS shunts.
For all Staphylococci, perform tube coagulase for confirmation of slide or latex coagulase results.
Perform AST on gram negative rods, enterococcus, S. pneumoniae, Streptococcus agalactiae, Staphylococcus aureus, and other significant Staphylococci.
Hold positive culture plates for 7 days.
ORGANISMS IN ACUTE MENINGITIS
Neonate

<2 months ***Escherichia coli, Listeria****, Group B Streptococcus,*
<10 years Viruses, ***Haemophilus influenza, Strep.***
Pneumonia,
N. meningitidis
Young adult Viruses, ***Strep. Pneumonia, N. meningitidis***
Adult **Strep. Pneumonia, *N. meningitidis***
Elderly ***Strep Pneumonia, Listeria,*** Gram negative rod
AIDS Patient ***Cryptococcus neoformans***
ORGANISMS IN CHRONIC MENINGITIS
Mycobacteria tuberculosis
Cryptococcus neoformans
Coccidiodes immitis
Histoplasma Capsulatum
Blastomyces dermatitidis
Candida spp.
Nocardia spp.
Actinomyces
Treponema pallidum
Brucella spp.
Salmonella spp.
Rarely parasites: ***Toxoplasma gondii, Cysticercus, Paragonimus westermanii, Trichenella spiralis***

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REPORTING RESULTS

Report gram stain results as soon as possible.
Report probable genus and species as soon as preliminary tests are completed.
Telephone all positive results to the physician or licensed caregiver taking care of the patient.
Document physician or licensed caregiver notification

INTERPRETATION

Generally, a positive culture indicates infection with the organism.
Lack of WBCs in CSF does not rule out infection, especially in listeriosis.
The most common cause of community acquired meningitis is S. pneumoniae. Performance of rapid tests on all alpha hemolytic streptococci seen in Gram stain is vital to a rapid diagnosis.
Isolation of enterococci from CSF is a cause for concern. The presence of the organism may be an indication of strongyloidiasis
If insufficient specimen is received for centrifugation/concentration, the report must note that the "Culture results may be compromised by the limited volume of specimen received."

LIMITATIONS

False positive results can result from contamination of the specimen or the culture with skin microbiota.
False negative results can be caused by low numbers of organisms, prior antimicrobial therapy, or

the fastidious nature of the organism.

REFERENCES

Baron, Ellen Jo, et al, **Diagnostic Microbiology,** 9th edition, The C.V. Mosby Co., St. Louis, Mo, 1994, pp. 210-218

Forbes, Betty, et al, **Diagnostic Microbiology,** 10th edition, The C.V. Mosby Co., St. Louis, Mo., 1998, p.329

Koneman, **Color Atlas and Textbook of Diagnostic Microbiology,** 6th ed., 2006, Lippincott, William and Wilkins, pp. 16 and 27.

Leber Amy L. editor in chief, 4rd ed. **Clinical Microbiology Procedure Handbook,**2016, 3.7.1 to 3.7.10, ASM Press, Washington D.C.

Murray, Patrick, et al, **Manual of Clinical Microbiology,** 7th edition, ASM, Washington D.C., 1999, p.68.


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Policy Owner	Linda Conboy: Supervisor-Microbiology, Laboratory Services	3/1/2026
Policy Owner	M. Anwar Molani: Medical Director, Laboratory Services	2/28/2026

Policy Owner	Erlinda Roxas: Director, Laboratory Services	2/28/2026

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L.MIC.7.21 Skin, Soft Tissue, and Wound Cultures

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PRINCIPLE:

The skin serves as a barrier between the internal organs and the external environment.
In some infections, such as staphylococcal scalded skin-syndrome, the toxins produced by the bacteria cause skin lesions. In others, lesions can result from the host's immune response to microbial agents.
Skin infections can arise from the invasion of certain organisms from the external environment through wounds made be trauma or bites (exogenous), complications of surgery or foreign body implants (endogenous) or from organisms that reach the skin through the blood as part of a systematic disease (hematogenous). Many different bacteria, fungi, and viruses may be involved. Also, these infections can result from one or several causative agents.

SPECIMEN:

Skin: macule, papule, nodule, pustule, vesicle, scales, ulcer, bulla
Hair follicles: folliculitis, furuncle (boil), carbuncle
Epidermal & dermal layers: erysipelas, erythrasma, impetigo, cellulitis, dermatophytosis, hidradenitis, pilonidal tuft cyst or hairs
Muscle fascia: Necrotizing fasciitis, myositis
Wounds: Post-operative, bites, burns
Acute: External damage to intact skin, e.g. surgical, bite, burn, cut laceration, etc.
Chronic: Internal (endogenous) damage to skin usually over extended time, e.g. decubitus ulcers
Soft tissue: As a result of vascular and neurologic problems, sinus tract and fistulas, systemic infections with skin manifestations

SPECIMEN COLLECTION:

Tissue: Deep biopsy after initial debridement and cleaning of superficial debris gives the best sample.
Fluid: Aspirate from deeper pockets beneath skin surfaces
Aspirated pus: Collect up to 5ml
Excised tissue: Minimum of several grams from base or edge (if surface disinfected may be appropriate for anaerobic culture)
Note: Tissues taken during surgery or aspirates obtained through intact skin are the best types of specimens to obtain for routine and anaerobic cultures. Interpretation of microbial cultures taken from open skin or abscesses may be compromised since these lesions are often colonized.

REJECTION CRITERIA

Do not accept specimens for microbiological analysis in containers with formalin.
If >15 / LPF squamous epithelial cells are present on the Gram stain, especially from swab specimens, request a recollection if there is evidence of infection**.**

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GRAM STAIN:

Make smear according to the consistency and the nature of the specimen.
Tissue: Imprints on homogenized tissue
ESwabs: Vortex swab and use pipette to drop sample onto slide.
Air dry the slide and methanol fix (avoid heating and precipitating protein which makes reading difficult.

GRAM STAIN READING:

Note: The quality of a wound specimen can be assessed by the Gram stain.
The presence of organisms in the Gram stain of an appropriately collected specimen correlates with a clinically significant count of bacteria and should be used to guide the extent of the microbiology testing. The presence of PMNs is an indication of an inflammatory or infectious process, while the presence of epithelial cells indicates surface contamination. If the patient is immunocompromised or has poor vascular supply, inflammatory cells may not be present in the specimen as a guide to the extent of workup of the culture**.**
Cells: PMNs, macrophages, epithelial cells – quantitate
Many epithelial cells indicate possible contaminated specimen. Limit work-up
Many PMNs means more extensive work up
Bacteria and fungi – Quantitate and note predominant morphotype
Note: Based on the Gram stain interpretation, telephone or report results to the appropriate caregiver (RN or Physician) immediately in a surgically collected specimen from a normally sterile site.
Some examples include: Clostridium like organisms on specimens of soft tissue, CSF, numerous

PMNs and bacteria seen on brain abscesses and gram positive cocci suggestive of Streptococcus sp. from endometrial tissue or placenta.

MEDIA:

BA, MAC, CNA, MTM (when indicated)
Add THIO for Tissue Biopsies and Surgical aspirates when anaerobic culture is ordered.
Broth cultures inoculated as an adjunct to direct plating of wounds and fluid samples have been shown to seldom yield results thatwould alter patient management and could be omitted for most specimens with our compromising patient care.
Swabs are not suitable for inoculation into THIO broth.

INOCULATION:

Note: For safety reasons and to protect specimens from environmental contamination, place specimens and media in a biological safety cabinet to perform specimen preparation and inoculation.
If transport swab specimen is submitted, put both swabs in 1 ml sterile saline or 1 ml THIO broth and vortex for 20 seconds. Media may then be inoculated, and smear made from saline or broth.
Inoculate ANA media as per anaerobic protocol if anaerobic culture is requested.

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INCUBATION:

Incubate THIO (if tissue, surgical aspirate for anaerobic culture) in aerobic incubator at 35 degrees C.
Incubate BAP, CHOC, MAC, CNA and MTM (when indicated) in CO2 at 35 degrees C
Incubate ANA media in an anaerobic environment at 35 degrees C

CULTURE WORK-UP CONSIDERATIONS:

BITE WOUND INFECTIONS

Human, cat, dog, other animal origin
Mouth flora, including anaerobes may be involved
Most important pathogens: *Staphylococcus aureus, Capnocytophaga, Eikenella, Pasteurella multocida.*

BURN WOUND INFECTIONS

Infection is considered major complication
75% of deaths related to infection
Most important pathogens: *Pseudomonas aeruginosa, Staphylococcus aureus, Escherichia coli, Klebsiella sp., Candida sp*

DIABETIC FOOT ULCERS

Plantar ulcers associated with diabetes mellitus
Inability of PMNs to kill organisms
Foot infection diagnosed primarily on clinical grounds
Most important pathogens: *Staphylococcus aureus, Beta streptococcus, Pseudomonas aeruginosa, Clostridia sp.*

SKIN ULCER IN INJECTION DRUG USER (IVDA)

Skin popping – injecting of drugs into the skin and subcutaneous tissue.
Frequently polymicrobial
Most common organisms*: Staphylococcus aureus, Beta hemolytic streptococcus*, *Gram Negative (Pseudomonas aeruginosa, Klebsiella sp, E. coli, Proteus sp)*, Normal flora for oropharynx

DECUBITUS ULCER

Develop due to continuous skin pressure over bony prominences leading to skin erosion, local tissue ischemia, and necrosis. 25% have underlying osteomyelitis.
Colonization by aerobic and anaerobic bacteria is frequent.
Management is aggressive: Surgical debridement and broad-spectrum antimicrobial therapy.
Swab samples of superficial wounds are not acceptable. Use the number of squamous epithelial cells/lpf as an indication of quality of specimen.

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REPORTING RESULTS:

Report results and update results whenever available as preliminary results.
Report quantity along with organism name.

CULTURE EXAMINATION:

24 hours old

Examine all plated and broth media for growth.
If no visible growth is observed, re-incubate.
Culture with growth.
Semi-quantitate growth on plated media.
Gram stain morphotype when indicated.
Report individually those organisms that are always considered to be pathogens.
Beta hemolytic Streptococcus
Staphylococcus aureus
Pseudomonas aeruginosa
Clostridium perfringens
Refer to Micro 5.0 for anaerobic culture procedure

48 hour and older

Examine culture daily for two days.
Examine culture daily for four days if anaerobic culture is also in progress
If anaerobic culture set up and/or surgical specimen, hold for 6 days.

EVALUATE PATHOGENS AS INDICATED

Evaluate the culture with the guidance of Table 1.
Generally, identify up to three organisms if the following is true:
PMNs were present on the direct smear.
The specimen was collected from a normally sterile site.
The specimen was of good quality.
Identify clinically relevant (up to 3 isolates) with the guidance of Table 1.
Identify any number of organisms that only grow on CHOC, and not on BAP.
Identify *Streptococcus pyogenes or Streptococcus agalactiae*
Identify ***Staph aureus***, perform AST, and notify Infection Control and patient's caregiver (documenting all notifications on report) if MRSA and there is not previous history.
Identify *Pseudomonas aeruginosa;* perform AST.
When *Coagulase Negative Staph* are present in pure culture, report "Susceptibilities not performed. Contact Microbiology department if susceptibilities are indicated. Organism held until M/D/Y.

Identify *Streptococcus viridians group and Enterococcus sp* if:

a. Surgically or invasively collected specimen.
b. The organism is the single or predominant pathogen and PMNs were seen on the direct Gram stain.

For Gram positive rods, if specimen is from a normally sterile site or biopsy sample, rule out *Listeria, Erysipelothrix, Bacillus cereus, Bacillus anthracis, Archanobacterium, Corynebacterium ulcerans, Nocardia, rapid growing Mycobacterium sp and Actinomyces.* Identify other gram positive rods if numerous are seen as predominant on Gram stain.
Identify yeasts only if they are from sterile body site or predominant.
Identify Enteric Gram negative rods if
Organism was isolated from an invasively collected procedure.
The organism is predominant
PMNs were seen on the direct Gram stain
Rule out *Salmonella sp., Shigella sp., Campylobacter sp and Yersinia sp* from abdominal abscesses.
Gram negative rods that are not of the Enterobacteriaceae family
Rule out organisms that are always considered to be pathogens
(Brucella sp., Haemophilus sp., Pasteurella sp., Francisella sp)
Stenotrophomonas Maltophilia
If in pure culture or significant amounts

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Gram stain suggests an infective process
Identify oxidase positive, indole positive organisms which are likely to be *Aeromonas or Vibrio*.

POLYMICROBIAL CULTURE COMMENTS

"**MGI**" "Mixed normal Gastrointestinal Bacteria. Performance of antimicrobial susceptibility testing is not indicated.
"**MMGI**" "Note: Performance of antimicrobial susceptibilities ……..
"**MMNSK**" "Mixed Normal flora for skin."
"MMSKEN" Mixed Normal skin and enteric bacteria
"MCONTSOFT" Note: When cultures contain a variety of enteric rods,
When multiple morphotypes are present, report with minimal identification.
Example: "Culture yields growth of >3 colony types of enteric gram-negative bacilli. No further work-up."
"**MBNR**": Organisms seen on smear and not recovered aerobically.
"Multiple organism morphologies seen on Gram stain that were not recovered aerobically may be possible anaerobes. Please submit anaerobic culture if surgical specimen obtained in the future."
"MCWC" Greater than 15 squamous cells per low power field on Gram Stain.
"Note: Numerous epithelial cells indicate surface contamination of specimen; therefore culture results are of questionable accuracy in the diagnosis of the infectious process

REFERENCES:

Brown, William PhD., (ABMM), F(AMM), Professor Emeritus of Pathology and Immunology/ Microbiology, Wayne State University School of Medicine, "Skin and Soft Tissue Infections-2006 Guidelines for Polymicrobic Culture Work-Up. CMPH, 1992, Vol. 1, pages 1.16-1.16.14

Forbes, Betty A., et al, Bailey & Scott's Diagnostic Microbiology, 11th edition, 2002, ASM., Washington D.C., pages 972-983

Koneman, Color Atlas and Textbook of Diagnostic Microbiology, 6th edition, 2006, Lippincott, Williams, and Wilkens, pages 16 and 27

Schreckenberger, Paul, PhD., Lowering Laboratory Costs: Practical Guidelines for the Testing and Work-up of Specimens in Clinical Microbiology, Hardy Diagnostics Educational Seminars, January 9, 2004. Torrance Memorial Medical Center, Torrance, Ca. pages 16-20.

COPY

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Attachments

Micro 7.21a Tables.pdf

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Hospital Administration	Jason Arimura: Associate Hospital Administrator, VCMC & SPH	3/2/2026
Policy Owner	Linda Conboy: Supervisor-Microbiology, Laboratory Services	3/1/2026
Policy Owner	M. Anwar Molani: Medical Director, Laboratory Services	2/24/2026
Policy Owner	Erlinda Roxas: Director, Laboratory Services	2/24/2026

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Policy Area	Laboratory Services - Microbiology

L.MIC.8.1 Handling of Microbiology Supplies, Reagents, Disks, Media and ID Kits

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POLICY:

Inspection of Media Shipment

1. Upon receipt, it is the responsibility of the laboratory personnel to visually inspect all media, reagents, disks, and ID kits breakage, contamination, appearance, and evidence of freezing or overheating. Handle promptly as indicated.
2. Find and remove the packing slip
    a. Check off the items received on the packing slip. Date and initial the packing slip.
    b. Compare the items received on packing slip with the purchase requisition found in the Microbiology Orders folder. Date and check off the items received. Those items not received on the purchase requisition may be backordered or being sent directly from the manufacturer rather than the vendor. If the order is incomplete, place the purchase requisition back in the Microbiology Orders folder.
    c. If all items on the purchase requisition are received, plate this on the Microbiology Supervisor's desk.
    d. After checking off packing slip, photocopy two copies, one for Microbiology and one for Lab to be filed. The original packing slip will be forwarded to Accounts Payable.
3. Locate the copy of the purchase order (P.O0 in the Order Folder. Write in date received, place back into the Order Folder.

4. Stamp date received on all items received. Do not cover pertinent information such as item name, lo member, and expiration date. If unable to stamp directly onto item, stamp date onto a label, them attach label onto the item. If item requires QC before use, stamp date of receipt on the red (Do not use this lot number" sticker.
5. If indicated, log in date of receipt, lot number, the expiration date for reagents, disks, media, and identification onto the appropriate Reagent/Disk log.
6. See the following list for QC requirements and items to be pulled for QC before use. Bring to the attention of a technologist.
7. Upon the opening, write date opened with the initial of the person opening the item. Example op5/29/01 JG
8. If the date of receipt is only stamped on the box, do not discard the box until all of the contents is depleted. Do not consolidate items with different lot numbers into the same box.

When the items pave passed QC and are cleared for use, attach the green "THIS LOT IS READY FOR USE" label just slightly under the date received of the red label after the date and initial of person certifying its use.

Media QC-Purchased

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1. Media or reagents received in the laboratory will not be released for use until they pass quality assurance testing.
2. A sample from each lot and shipment of each purchased medium is checked before or concurrent with initial use for each of the following:
    a. Sterility
    b. Ability to support the growth of organisms intended to be isolated on the media by means of stock cultures or by parallel testing with previous lots and shipments.
    c. Biochemical reactivity, where appropriate
3. Upon successful completion of test, affix "Ready for Use" green stickers to each package.
4. If, at any time, media or reagents do not meet stated quality assurance limits, they are to be immediately withheld or removed from use. Patient test results obtained in an analytically unacceptable test run or since the last acceptable test run must be reevaluated to determine if there is a significant clinical difference in patient results. Reevaluation may or may not include retesting patient samples, depending on the circumstances. Even if patient samples are no longer available, test results can be re-evaluated to search for evidence of an out-of-control condition that might have affected patient results.
5. The microbiology Supervisor will be notified of discrepant results.
6. Quality Assurance tests will be repeated.
    1. If quality assurance tests are passed the second time, the discrepant results

obtained at first testing must be explained before the media or reagents may be released for use.

2. If quality assurance tests fail the second time, the media or reagents will be withheld or removed from use and the manufacturer notified.

7. A corrective action from must be completed and countersigned by the Microbiology Supervisor.

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Attachments

REF SUPPLIES TO BE TAGGED.XLS

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L.MIC.8.2 Reagent Preparation

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POLICY:

1. **BLEACH SOLUTION, 10% (MADE DAILY); 0.5% Sodium hypochlorite**
   - A. 30 ML HOUSEHOLD BLEACH IS PRE-DISPENSED IN PLASTIC TUBES.
   - B. 30 ML HOUSEHOLD BLEACH IS ADDED TO 270 ML TAP WATER FOR 300 ML TOTAL VOLUME. SEE FILL TO LINES ON BLEACH SQUEEZE BOTTLE.

ALL REAGENTS MUST BE PROPERLY LABELLED WITH THE FOLLOWING ELEMENTS:

- Content and quantity, concentration or titer
- Storage requirements
- Date prepared, filtered, or reconstituted by laboratory
- Expiration date

Note: Reagents in the laboratory which have not been assigned an expiration date by the manufacturer will be assigned a five (5) year expiration date from the date of receipt (*L.33 Laboratory Instrument Utilization*)

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Owner	Samah Meshreky: Supervisor-Hematology, Laboratory Services
Policy Area	Laboratory Services

L.UA 1.1 Specimen Rejection, Acceptability and Stability Criteria - Urinalysis

COPY

PRINCIPLE:

Specimen integrity is extremely important in accurately testing and reporting patient results by laboratory personnel. To ensure consistent reliable results, all specimen requirements should be strictly followed regarding the preservation of urinalysis specimens.

PROCEDURE:

Before patient testing occurs all specimens should be evaluated and rejected if:

- Specimens are found to be unlabeled or incorrectly labeled. For proper label requirements refer to VCMC General Phlebotomy: **Procedure 5.2 - Specimen Labeling Requirements.**
- Specimens received are in the incorrect container or with preservative.
- Specimens are found to be insufficient or unsuitable for procedure(s): **If the quantity received is not sufficient** for test requirements,
    - Minimum volume for Urinalysis testing is approximately 4 mL (exceptions for neonates ONLY) Urine samples containing **less than about 3 mL** can only be tested for the urine dipstick only.
    - **For NEONATES ONLY,** sample volumes under 3 mL, the dipstick will be tested using backup urine analyzer and strips and if sample is more than 2 mL, manual microscopy should be performed.
    - **ALL microscopic** testing for samples under 2 mL (including neonates) should be canceled as QNS.
- Tube received broken or leaking, or incorrect specimen is received for ordered test.

- Specimens spun/centrifuged before received by testing personnel.
- Specimens collected in expired tubes or non-sterile containers.
- Specimens received past testing stability limit.

Any re-allocation of specimens such as aliquots, transfers or dilutions from primary container **MUST** be visibly labeled with two patient identifiers (preferably patient Name and Medical Record Number.)

PROCEDURE NOTES:

ONLY the following specimen containers are accepted for the following tests:

- **Urinalysis and Urine Eosinophil Orders**
  - Sterile urine vacutainer collection cup
  - Yellow UA top tube (no additives)
- **Neonatal Urinalysis (NUA)**
  - Sterile urine vacutainer collection cup
  - Yellow UA top tube (no additives)
  - Syringe capped (with cotton soaked urine) (No needles attached)
- **Urinalysis Reflex Orders:** for urine culture orders see Microbiology specifications
  - Sterile urine vacutainer collection cup
  - Yellow UA top tube (no additives) and Grey top tube (C&S preservative)

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Acceptable Containers for Urinalysis Testing

Test	Sterile Urine collection cup	Yellow top UA tube	Syringe w/ cotton	Grey top tube (C&S preservative)
Urinalysis Orders (Urine dipsticks, microscopy and eosinophils)	√	√		
Neonatal Urinalysis (NUA)	√	√	√	
Urinalysis Reflex Orders (Yellow top MUST be received in addition to Grey top tube)	√	√①		√①

①**NOTE:** The grey top tube should be received in addition to the sample required for Urinalysis testing. A grey top tube can NOT be used for urinalysis testing. Similarly a yellow top tube can NOT be used to fill a grey top tube for reflex testing. If a Grey top tube is NOT received the order should be canceled and reordered.

LIMITATIONS:

Stability for Urinalysis Testing

Test	Stability
Urinalysis Orders & NUA (MUST be received AND tested within 2 hours of collection)	2 hours after collection at room temperature (18-30°C). 24 hours after collection when refrigerated at 2-8°C. Must be brought to room temperature before testing.
Culture Reflex Testing Orders (Grey Top tubes)	48 hours after collection at room temperature (18-30°C) or refrigerated at 2-8°C.

Specimen containers received past listed stability should be cancelled and ordering physician or designated nursing personnel should be notified and notification documented.

- NOTE: If authorization is needed to proceed testing questionable samples, consult with pathologist and indicate approval on test comments.

REFERENCES:

A Handbook of Routine Urinalysis, Sister Laurine Graft, JB Lippincott Company, ISBN 0-397-52111-1.

Clinical Diagnosis and Management by Laboratory Methods, 19th Edition, John Bernard Henry, MD, WB Saunders, ISBN 0-7216-6030-4.

CAP Accreditation Program – Urinalysis Checklist 07.28.2015

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CAP Checklist Requirements

URN.22300 Urine Preservation

URN.22400 Urine Preservation

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L.UA 3.1 Urine Eosinophil's

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PRINCIPLE:

Urine eosinophil's can be increased in a variety of diseases including acute interstitial nephritis, cystitis, prostatitis, pyelonephritis and glomerulonephritis. Eosinophiluria is also seen in other acute disorders of the genitourinary tract.

This procedure outlines the method used for identifying eosinophils in urine samples.

SPECIMEN:

Fresh voided urine

EQUIPMENT:

Centrifuge

Coulter DxH SMS (Slidemaker/Stainer)

Aerospray Cyto-centrifuge

MATERIALS:

Cytopro microscope slides

Cytopad chambers (tan), with caps

Disposable transfer pipettes

PROCEDURE:

1.	Upon receipt of specimen, refer to procedure **L.UA1.1 - Specimen Rejection, Acceptability and Stability Criteria** to verify specimen acceptability and stability. **NOTE:** Any samples not acceptable for specimen testing should be canceled and reordered. Refer to **L.HEM 1.5 - Canceling & Reordering Tests for Unacceptable Specimens** procedure for guidelines.
2.	Samples received refrigerated must be brought to room temperature before analysis (do NOT incubate cold specimens). Frozen specimens are NOT acceptable. **NOTE:** Urine samples containing visible amorphous sedimentation may be poured into a 16x100mm disposable glass tube and gently swirled in 56-64°C water bath to dissipate sediments. Do NOT leave urine in water bath.
3.	Spin urine sample at 2500 - 3000 for 5 minutes. Decant urine supernatant and resuspend the urine sediment/pellet.
4.	Label a microscope slide and place 1-2 drops of well-mixed sediment into the tan cytospin sample chamber, making sure that the urine goes into the bottom of the funnel. **NOTE:** 1-2 drops of 22% albumin solution may be added to the sample chamber to aid in cell to slide adhesion and decrease cellular distortion from the centrifugal force.
5.	Assemble slide and Cytospin chamber into the cyto-centrifuge and spin under Program 1: (1000 rpm for 5 minutes at low acceleration).
6.	Remove slides from chambers and allow to air dry.
7.	Place dried slide in the SP50, or Aerospray back up stainer drawer to stain with Wright Giemsa.
8.	After slide is stained, scan the entire microscope slide for urine eosinophil's under high power field (50x).
9.	Use the UA Eosinophil patient testing worksheet to record results.
10.	Under Accession Result Entry, enter patient results and file the worksheet. **NOTE:** Worksheets printouts are filed daily and kept for a minimum of two years in storage boxes.

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REPORTING RESULTS:

Select one the following from drop down menu:

Test	Results	Interpretations
UA Eos	None seen	No Eosinophils seen
	Present	Eosinophils Present: If ANY Eosinophils are seen on cytospin slide. Any semi-quantitative analysis may be placed as a result comment if clarifications are needed (i.e. 20% Eos seen, many Eos seen).

PROCEDURE NOTES:

There are no established reference ranges for urine eosinophil testing. However, these cells are not

normally seen in urine, and the finding of more than 1% eosinophils among the leukocyte population present is significant.

LIMITATIONS:

If the urine has less than 10 WBC cells/µL, eosinophil's may be missed on slide review.

REFERENCES:

McPherson and Pincus. Henry's Clinical diagnosis and Management by Laboratory methods. 22nd edition. 2012

Hansen and Hiene. The Cyto-Centrifuge and Cerebrospinal Fluid cytology. ACTA Cytologica, Vol 18, #3. 1974

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Laboratory Service Dept	Samah Meshreky: Supervisor-Hematology, Laboratory Services	2/24/2026
Laboratory Service Dept	M. Anwar Molani: Medical Director, Laboratory Services	2/23/2026
Laboratory Service Dept	Erlinda Roxas: Director, Laboratory Services	2/23/2026

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Owner	Samah Meshreky: Supervisor-Hematology, Laboratory Services
Policy Area	Laboratory Services

L.UA 3.4 Cerebrospinal and Serous Fluids Cell Count- IRIS iQ200

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PRINCIPLE:

WBC and RBC cell counts provide extremely important information for the diagnosis and treatment of diseases involving CSF and serous fluids. Infections, hemorrhages, and malignancies are the primary concerns.

Cell counts for cerebrospinal fluid (CSF) are obtained to assist in diagnosing central nervous system infection, tumors or vascular accidents. Serous fluid (pleural, peritoneal, pericardial, etc.) cell counts results are used to decipher between a transudate due to increased hydrostatic or decreased plasma oncotic pressure; and an exudate secondary to a wide variety of pleural diseases, e.g. increased capillary permeability, infection, infarction, rheumatoid disease, collagen disease; or secondary to malignancy.

Cell counts at VCMC laboratory may be performed by manual or automated methods.

SPECIMEN:

Acceptable specimen types for IRIS iQ200 cell counts are collected without anticoagulant or with EDTA:

Cerebrospinal Fluid (CSF), Ventriculostomy or Shunt fluid

Serous Fluids: Ascites, Peritoneal, Paracentesis, Pleural, Thoracic, Pericardial, etc.

NOTE: No other specimen types have been validated to provide accurate reportable cell counts with this automated method, and thus should NOT be tested using this system, namely joint & synovial fluids.

EQUIPMENT/INSTRUMENT:

IRIS - iQ 200 Elite

iQ Body Fluids Module Key Disc (must be inserted in the computer drive for testing to run)

REAGENTS/MATERIALS:

Body Fluid 10mL plastic conical bottom tubes

iQ Lamina

iQ Body Fluid Racks

Iris Cleanser

Iris Diluent

iQ Body Fluid Lysing Reagent

QUALITY CONTROL:

performed every 24 hours of patient testing.

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PROCESSING SPECIMENS:

If the specimen received is a CSF fluid, distribute as follows:

1. For all CSF fluids, record the total volume of the specimen received.
2. Mix the sample for homogeneity.
3. CSF is typically collected in sequential order. Tubes are labeled in the order drawn. Depending on the amount of CSF tubes received proceed with the following:

Containers	**Send outs / Serological Tests**	**Chemistries**	**Microbiology Cultures**	**Cell Counts, Differentials and Cytology**
One tube received	First, give sample to Microbiology department, then aliquot remaining specimen into the appropriate containers for the ordered testing.			
Two tubes received	**Tube 1**		**Tube 2**	
Three tubes received	**Tube 1**		**Tube 2**	**Tube 3**
Four tubes received	**Tube 1**	**Tube 2**	**Tube 3**	**Tube 4**

- Cell Counts are **ONLY** performed on the last collected tube and should not be performed on combined tubes or counted on any additional tubes.

PROCEDURE:

RUNNING PATIENT SPECIMENS (PART ONE: Loading Specimens)

1.	Upon receipt of specimen, refer to procedure **L.HEM 1.1 - Specimen Rejection, Acceptability and Stability Criteria** to verify specimen acceptability and stability. **NOTE:** Any samples not acceptable for specimen testing should be canceled and reordered. Refer to **L.HEM 1.5 - Canceling & Reordering Tests for Unacceptable Specimens** procedure for guidelines.
2.	Visually inspect all specimens for clots. If any clumps, debris or clots are seen, do **NOT** perform automated cell count testing. See manual cell count procedure.
3.	If specimen is acceptable mix specimen thoroughly to evaluate fluid color and clarity. Enter the fluid type, macroscopic analysis AND methodology in Cerner to ensure that results transmit appropriately. For methodology, use: • **Automated:** for IRIS testing & Sysmex XN3100 • **Manual:** for manual hemocytometer testing Select **PERFORM**. **NOTE:** Not performing the macroscopic evaluation in Cerner first, or selecting verify first for the macroscopic results, will cause the additional testing parameters to **NOT** be triggered.
4.	If the fluid type is CSF, Xanthochromia and total fluid volume should be resulted. Select **PERFORM**.
5.	Before running the patient specimen, the background count must be evaluated. Prepare 3 tubes for background (or used saved background from daily QC run): **Background (BFQC) Rack:** • **Position 2** → pour ~8mL of Iris Diluent in tube • **Position 3** → pour ~8mL of Lysing Reagent in tube, label with ***Background Label*** (located in **BFQC** kit) • **Position 4** → pour ~8mL of Iris Diluent in tube, label with ***Background Label***
6.	Review results and ensure background count passes before using the diluent and lysing fluids with the patient sample. See **steps 13 - 15.** (Except, do not add image to report)
7.	Using the iQ Body Fluids Dilutions and Barcode Chart & Binder, determine by the fluid appearance which dilution and barcode labels will be used.
8.	To run the patient specimen, obtain the BF sample (SAMP) rack & five body fluid conical tubes. Arrange as follows: **BF SAMP**: *Body Fluid patient sample rack* • **Position 1** → pour a minimum of 2mL of Iris Diluent in tube (NO LABEL) • **Position 2** → pour a minimum of 2mL of Iris Diluent in tube (NO LABEL)

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- **Position 3** → pipette (from background rack) (Lysing Reagent + Sample) volumes tap gently to mix, then label with ***Patient Accession barcode & LYS dilution Labels***
- **Position 4** → pipette (from background rack) (IRIS Diluent + Sample) volumes tap gently to mix, then label with ***Patient Accession barcode & TOT dilution Labels***
- **Position 5** → pour a minimum of 2mL of Iris Diluent in tube (NO LABEL)

BF SAMPLE Rack	1	IRIS Diluent
	2	IRIS Diluent
	3	Lyse + Sample
	4	Dil + Sample
	5	IRIS Diluent

NOTE: Barcode labels should be oriented with the number reading down.
NOTE: Lysing reagent or Diluent MUST be placed in the tube **FIRST**. With the sample, then being pipetted DIRECTLY into the diluting fluid. Specimens added incorrectly will result in inaccurate counts. Additionally, **NEVER** pipette Diluent or Lyse from the original bottles. This can cause contamination of reagents and specimens!

9. Load background rack before the BF SAMP rack on the right side of iQ Sample Transport Module and press the Start button.
NOTE: Run background racks before and after running any patient samples.

RUNNING PATIENT SPECIMENS (PART TWO: Reviewing & Categorizing BF Cell Counts)

10. Classify cell categories in background and patient results.

11. Display the **Work List**, by selecting **Work List** located on the top right side of the screen. The Work List screen allows you to quickly identify specimens with flags or needing operator review and only contains unreleased results.

12. Double-click the specimen row, to review a specimen, or select the row and select Specimens.

13. Start by double clicking the Total Cells category. Unlike with urines, review EACH image, like a manual cell count, and move all "non-intact cells" to the Artifact category.

14. Right click any one cell in Total Cells that best represents most of the cells counted. Select **add image to report**. Select Next button to proceed to the next category.

15. Review the ART (Total) images, moving any mischaracterized cells into the Total cells category.

16. Repeat **steps 13 - 15.** for Nucleated Cells.
NOTE: For examples of Body Fluids images, review **iQ200 series Image Encyclopedia Resource Guide**.

17. After particle images, have been reviewed, select **Results**, ensure that all categories are as acceptable, then select **Accept** to release the results.
NOTE: Any flags or abnormal results must be addressed and cannot be reported. Additionally,

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	this testing is not approved for any additional dilutions or calculations. Any grossly bloody or higher than linearity cell counts should be tested using the Sysmex XN3100
18.	Cell count results will transmit to Cerner. Ensure you print a copy of the patient's instrument results and file. **NOTE:** Body Fluid patient result printouts are filed daily and kept for a minimum of two years.

REPORTING RESULTS:

VCMC IRIS iQ200 Reporting Linear & Reportable Range

Parameter	Linear & Reportable Range
RBC	0 - 100,000 cells/µL
TNC (CSF)	0 - 300 cells/µL
TNC (Serous)	0 - 50,000 cells/µL

- Grossly bloody or high concentration samples should perform cell counts on Sysmex XN3100 instrument.

Body Fluid Cell Count Reference Ranges

Fluids	RBC	TNC
CSF (Neonates)	0 – 10 cells/µL	0 – 30 cells/µL
CSF (Adults)	0 – 5 cells/µL	0 – 5 cells/µL
Serous Fluids (Pleural, Thoracic)	0 – 1,000 cells/µL	0 – 1,000 cells/µL
Serous Fluids (all others)	0 – 100 cells/µL	0 – 150 cells/µL

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PROCEDURE NOTES:

VCMC Fluid Reported Color and Clarity

Color	Clarity
Colorless	Clear
Pale yellow	Slightly hazy
Yellow	Hazy
Pink	Cloudy
Red	Turbid
Other	Bloody

Xanthochromia: Xanthochromia is coloration of the cerebrospinal fluid (CSF) which distinguishes in vivo hemorrhage from a traumatic tap. Xanthochromia can only be determined from a spun specimen. Since cell counts cannot be performed from spun specimens, xanthochromia may be determined from spun chemistry aliquots.

NOTE: For CSF, append comment **L1BL4** (first collected tube is visibly bloodier than the last collected tube) if tube 1 is visible bloodier than tube 4.

iQ Body Fluids Dilutions & Barcode Chart

Appearance	Fluid Type	Dilution	Dilution Labels	Sample Volume	Diluent/Lyse Volume
Clear / Colorless	CSF	1:3	CSF 0, CSF 8, CSF 9	450 µL	900 µL
	Serous	1:5	SER 5	250 µL	1000 µL
Lt. Yellow or Lt. Pink/ Sl. Hazy or Hazy	CSF	1:5	CSF 1	250 µL	1000 µL
	Serous	1:10	SER 2, SER 6	150 µL	1350 µL
Yellow or Pink or Orange/ Hazy or Sl. Cloudy	CSF	1:10	CSF 2	150 µL	1350 µL
	Serous	1:20	SER 3, SER 7, SER 8	100 µL	1900 µL
Red / Cloudy	CSF	1:20	CSF 3	100 µL	1900 µL
	Serous	1:50	SER 4, SER 9	60 µL	2940 µL
**Bloody/Turbid	CSF	1:50	CSF 4	60 µL	2940 µL
	Serous		SER 4, SER 9		

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LIMITATIONS:

- Cells in body fluids may undergo cell lysis if the following resting time is permitted:
  - Sitting after dilution >10 minutes
- If the specimen contains significant clots or tissue fragments, cell count will be compromised. Confirm with a pathologist before performing the cell count. If cell count is to be performed, it should be performed manually and append comment (**LRQ** – Results Questionable Due to Specimen Condition) and specify that the specimen was clotted.

REFERENCES:

iQ200 Operator's Manual: Iris Diagnostics.

Fascicle VI, Patient Preparation & Specimen Handling, Chemistry/Clinical Microscopy, Cerebrospinal Fluid, analysis, routine – color and appearance, cell count and differential, College of American Pathologists. CAP.5M293

Fascicle VI, Patient Preparation & Specimen Handling, Chemistry/Clinical Microscopy, Peritoneal Fluid Analysis, College of American Pathologists. CAP.5M293

Modified from Davidson, Israel and Henry, John B.: Todd-Sanford Clinical Diagnosis by Laboratory Methods, 15th edition, Philadelphia, 1974, W.B. Saunders Company.

KJeldsberg, Carl R., Knight, Joseph A. **Body** Fluids - **Laboratory** Examination of **Amniotic**, Cerebrospinal,

Seminal, Serous & Synovial Fluids, econd edition, American Society of Clinical Pathologists, Chicago, 1986

Kreig AF, Kjeldsberg CR. Cerebrospinal fluid and other body fluids. In: Henry JB, ed. Clinical Diagnosis and Management by Laboratory Methods, Philadelphia PA: W.B. Saunders Co.;1991:445-473

CAP Accreditation Program – Hematology and Coagulation Checklist 07.28.2015

CAP Checklist Requirements

HEM.35319Diluting Equipment

HEM.35414Background Checks – Automated Counts

HEM.35452Acceptable Limits

HEM.35471Cell Clumps/Debris – Automated Counts

HEM.35490Stabilized Controls

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All Revision Dates

2/24/2026

Approval Signatures

Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator, VCMC & SPH	2/24/2026
Laboratory Service Dept	M. Anwar Molani: Medical Director, Laboratory Services	2/24/2026
Laboratory Service Dept	Samah Meshreky: Supervisor-Hematology, Laboratory Services	2/24/2026
Laboratory Service Dept	Erlinda Roxas: Director, Laboratory Services	2/24/2026

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Next Review	3/1/2028		

L.UA 4.1 Maintenance Protocol UA Bench (Au-11)

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PRINCIPLE:

To ensure that the instrument can function in its best state, it is necessary to perform scheduled maintenance. Perform maintenance according to the schedule below and record performance on the UA Bench Maintenance Log sheet.

EQUIPMENT:

Siemens Clinitek 500

MATERIALS:

Soap & Water

Sani-Cloth (or napkins & alcohol)

USE OF INSTRUMENT:

- When performing maintenance work or inspection, use specified tools and parts.
- Do not use substitute parts, or modify the instrument. It is hazardous.
- Do not bring your body or clothes without proper PPE close to the instrument.
- Those who have no or only limited experience in using reagents should have guidance or assistance by those with sufficient experience.
- If the instrument has developed a trouble by any chance, take steps within the range specified in the Operator's Manual or (instructions for use) IFU. For extended troubleshooting contact manufacturer's service representative for repair.

SCHEDULE:

Daily	Wash Aution Eleven(AE4022) Platform & Empty Waste
	Clean Aution Eleven(AE4022)Touchscreen
	Perform UA QC & Check Reagent Strips
As needed	Add Water to Water Bath
	Empty, Clean & Refill Water Bath

DAILY PROCEDURES:

Wash Aution Eleven(AE4022) Platform & Empty Waste

1. Remove the push bar by tilting it slightly upwards and pulling straight out.
2. Remove the waste bin liner and discard used reagent strips. Replace waste bin liner as needed.
3. Remove the fixed platform by pulling the entire assembly towards you.
4. Remove the moving table in the same manner.
5. Remove the holddown plate from the fixed platform by pressing up against the tab at the back of the plate then pull the other end from its retaining hole.
6. Using soap and water clean the push bar, platform, hold down plate, moving table and waste liner.
7. Rinse each piece and leave to air dry, or wipe dry using a napkin.
8. Reinstall all parts of the instrument in the same order it was removed.
9. Record on Maintenance Log.

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Clean Aution Eleven(AE4022) Touchscreen

1. Using a Sani-cloth or a napkin with alcohol, clean Clinitek touchscreen and body.
2. Record on Maintenance Log.

Perform UA QC & Check Reagent Strips

1. Perform UA Daily QC, see L.UA **2.1 - Daily Quality Control Aution Eleven (AE4022) Procedure** for instructions.
2. Ensure two reagent strip containers are QC'd and record any changes in lot numbers on the maintenance log.

AS NEEDED PROCEDURES:

Add Water to Water Bath

1. Check water bath level. If low, add water until water bath is 90% filled.
2. Record on Maintenance Log

Empty, Clean & Refill Water Bath

1. Unplug water bath, empty any water into the sink.
2. Clean water bath with soap and water. Rinse. (do not wet or wash power cord area)
3. Dry water bath with a napkin and plug power cord into the electric outlet.
4. Fill water bath with water until 80-90% filled.
5. Wait 30 minutes, then check to ensure temperature is 56 -64°C. If the temperature is not 56 -64°C, monitor temperature every 10 minutes thereafter until it is within desired range.
6. Record on Maintenance Log

All Revision Dates

3/2/2026

Approval Signatures

Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator, VCMC & SPH	3/2/2026
Laboratory Service Dept	Samah Meshreky: Supervisor-Hematology, Laboratory Services	3/2/2026
Laboratory Service Dept	M. Anwar Molani: Medical Director, Laboratory Services	3/1/2026
Laboratory Service Dept	Erlinda Roxas: Director, Laboratory Services	2/28/2026

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Policy Area	Laboratory Services

L.UA.4.2 Maintenance Protocol – IRIS (Arkray AX-4030 and iQ Elite)

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PRINCIPLE:

To ensure that the instrument can function in its optimal state, it is necessary to perform scheduled maintenance. Perform maintenance per the schedule below and record performance on the IRIS Maintenance Log Worksheet.

EQUIPMENT:

IRIS Systems (AX-4030 & iQ Elite)

REAGENTS

1. Arkray Concentrated Washing Solution 3
2. Iris System Cleanser
3. Deionized(dI) Water or Reagent Grade Water (RGW)
4. Arkray AUTION Sticks
5. Arkray S.G. Calibrator
6. DRI Gravity-Detect Level 1 Control
7. iQ Calibrator Pack

MATERIALS:

1. Paper towels/ gauze

2. Kim Wipes
3. Blower brush
4. 16 x 100 Disposable Polystyrene tubes
5. Sample Filter Flush kit
6. Cotton swabs
7. Wash Solution Filter

USE OF INSTRUMENT:

- When performing maintenance work or inspection, use specified tools and parts.
- Do not use substitute parts, or modify the instrument. It is hazardous.
- Do not bring your body or clothes without proper PPE close to the instrument.
- Those who have no or only limited experience in using reagents should have guidance or assistance by those with sufficient experience.
- If the instrument has developed a trouble by any chance, take steps within the range specified in the Operator's Manual or (instructions for use) IFU. For extended troubleshooting contact manufacturer's service representative for repair.

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SCHEDULE:

Daily	Empty & Clean Strip Waste Box **(AX)**
	Clean Sample Transport Modules (STM) **(AX & iQ)**
	Clean Instrument Surfaces **(AX & iQ)**
	Run Urine QC's **(AX & iQ)**
	Run Body Fluid QC's **(iQ)**
Three Days	Dust/Clean Strip Feeder **(AX)**
	Clean Test Strip Stopper & Roller (**AX)**
	Clean Introduction & Transport Trays **(AX)**
Weekly	Change Wash Solution **(AX)**
	Perform S.G. Cell Wash **(AX)**
	Change/Flush Sample Filter Tip **(iQ)**
Monthly	Replace wash solution Filter & Stopper **(AX)**
	Clean wash bath **(AX)**
	Clean air filter **(AX)**
	Perform S.G. Calibration **(AX)**
	Perform Instrument Calibration **(iQ)**

DAILY PROCEDURES:

Empty and Clean Strip Waste Box

1. On the AX-4030 screen, press **Stop** to put the analyzer in Standby.
2. Pull out waste box tray located on the left of the AX-4030 instrument (between the two analyzers).
3. Remove waste box from the tray and discard the used strips.
4. Clean the waste box with soap and water. Wipe box to be completely dry.
5. Holding the waste box tab facing forward, return the waste box to the tray and slide back into the instrument.

Clean Sample Transport Module (STM)

1. Make a 1:10 dilution of Iris System Cleanser with dI or RGW.
2. Moisten paper towels with diluted Iris Cleaner and clean STM's on both the analyzers.
3. Without Excessive stretching or pulling, try to clean under the belts as much as possible.
4. Wipe again using distilled water, then wipe dry.

Clean Instrument Surfaces

1. Moisten paper towels with Iris System Cleaner diluted 1:10 and clean instrument surfaces on both instruments.
2. Wipe again using distilled water, then wipe dry.

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Run Urine and Body Fluid QC's

1. See procedure ***HEM 3.2.1 – Daily Quality Control - IRIS*** for instructions.
2. Record daily maintenance performance on Maintenance Log.

3-DAY PROCEDURES (AX ONLY)

Clean Strip Feeders

1. On the AX-4030 screen, press **Stop** to put the analyzer in Standby.
2. When "Ready for measurement" appears on the screen, turn off the power by pressing the green button on the front of the analyzer.
3. Unlock and open the cover of the strip feeder.
4. Remove remaining strips using a Kim Wipe and set aside strips or if few, discard.
   NOTE: Urine strips are only valid for 3 days once exposed in the instrument. If performing **Check Measurement,** or performing <3 days ago, save strips in Kim wipe.
5. Lock the feeder covers.
6. Open the four AX-4030 instrument covers in the following order:
   i. The Maintenance cover on the front-right side of the analyzer by pulling forward.

ii. The Feeder Protective cover on top by lifting the piece upward.

iii. The Side cover on right side of the analyzer by pulling it downward and slide it forward, or to the left to get it off the hinges.

iv. The Front cover on the front-left side of analyzer by pulling it towards you.

7. Perform Clean Strip feeders, Clean Test Strip Stopper & Roller, and Clean Introduction and Transport Trays maintenance.
8. Pull the whole feeder unit to the right.
9. Unlock each feeder cover and use the blower brush to clean each strip feeder. ****Do not use canned air**
10. Lock the feeder covers.

Clean Test Strip Stopper and Roller

1. Loosen the silver screw on the test strip stopper and open sideways.
2. Slide the stopper toward the front of the instrument to remove it.
3. Using the blower brush, blow dust off the stopper and the grey roller inside the feeder unit.
4. Reinstall the test strip stopper, close the stopper, and tighten the silver screw.

Clean Introduction Tray and Transport Tray

1. Locate the black ***Introduction tray*** at the bottom of the instrument and pull it toward the right. Then carefully lift the tray up at an angle and completely remove it. ****Avoid impact with the introduction arms.**
2. Remove smaller black ***Transport tray*** located further inside the instrument by sliding it to the right. Carefully pull the tray out of the instrument.
3. Clean both trays with soap and warm water. Rinse well with water. ****Do not scratch the trays or use hot water to clean.**
4. Both trays must be completely dry before reinstalling.
5. Reinstall the Transport tray by inserting the two tray guides into the slots and press until you feel it click into place.
6. Install the Introduction tray by inserting it along the grooves until the tray is sitting flat. Slide it to the left until the arrow marks are completely visible and you feel it click into place.
7. Turn the whole feeder unit back upright and press down until the latch clicks and unit locks into place.
8. Close all 4 covers. Load no more than ½ - 1 bottle of AUTION Sticks into the strip feeder.
9. Turn analyzer back on by pressing the green button on the front of the AX-4030.
10. Record 3-day maintenance performance on Maintenance Log.

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WEEKLY PROCEDURES:

Replace Wash Solution

1. On the AX-4030 screen, press **Stop** to put the analyzer in Standby.
2. Prepare the new Wash solution:
    a. First, fill backup Wash Solution bottle up to the 1800mL mark with deionized water.
    b. Pour 200mL of Concentrated Washing Solution 3 using the mark on the bottle.
3. Cover bottle or seal the top with parafilm and **gently** invert the bottle to mix.
4. Replace newly prepared Wash Solution with current analyzer wash solution.
5. Discard the remaining wash solution and rinse bottle with deionized water.
6. Leave empty bottle out to dry, then store for use for the following week.

Perform S.G. Cell Wash

1. Standby screen must be displayed.
2. Make a 1:10 dilution of Iris System Cleanser with dI or RGW
3. Fill a 16x100 tube with 2mL of the 1:10 Iris Cleaner dilution.
4. Load tube into the STAT port and push it in forward making sure its locked into place.
5. Go to **Main Menu > #5 Maintenance > #1: SG cell washout,** then press **Start.**
   NOTE: If warning "W002" occurs, it means the sample tube may be incorrectly placed. Reload tube correctly and press **OK** to clear warning.
6. When washing is completed, ~ 5 mins, press **Go back** twice to return to Standby screen.
7. Take the tube out of the STAT port.

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Change/Flush Sample Tip Filter

1. Put the iQ200 into **Standby > Instrument > Go Offline**, then turn off by pressing the On/Off button on the front of the instrument, then and open the front panel.
2. With one hand, hold the sample filter firmly in place.
3. With the other hand, carefully unscrew the top green fitting counter-clockwise.
4. Then unscrew the bottom green fitting.
5. Install the clean/dry alternate filter. Make sure the arrow on the filter is pointing up.
6. Turn the instrument back on by pressing the On/Off button on the front of the iQ200.
7. Soak the removed filter in a tube with Iris Cleanser for 15 minutes.
8. After soaking, fill the sample filter flush syringe provided in the kit with dI water and connect the syringe to the notched end (opposite the arrow direction) of the filter and push water through.
   NOTE: It must be done in this direction **FIRST** to prevent filter from getting clogged.
9. After, remove filter from syringe and refill syringe with dI water and connect the syringe to the

other end (same as arrow direction) of the filter and push water through.

10. Leave out to dry, then store for use for the following week.
11. Record weekly maintenance performance on Maintenance Log.

MONTHLY PROCEDURES:

Clean the Wash Bath (AX only)

1. On the AX-4030 screen, press **Stop** to place the analyzer in Standby.
2. From Standby screen, press **Menu > #5 Maintenance > #2 Clean washing bath and tray.**
3. Press the green button on the front of the AX-4030 to turn the power off.
4. Open the front cover of the instrument.
5. Move probe unit back, towards the back of the instrument.
6. Using a cotton swab moistened with deionized water:
    a. Wipe the washing bath and port. **Do not touch the metal probe.
    b. Clean the two level detection sensors
7. Close the front cover of the instrument.

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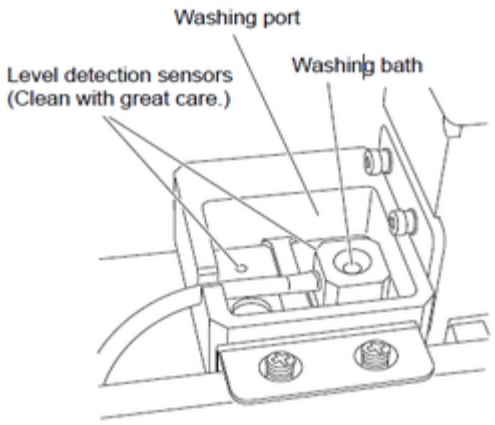
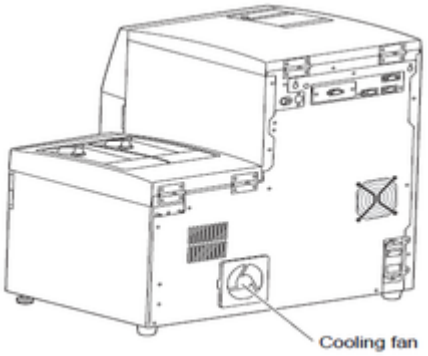


Clean air filter (AX only)

1. Ensure the AX-4030 instrument is turned off.
2. Wait until the cooling fan located on the back side of the instrument comes to a complete stop.
3. Pull off the cover of the cooling fan and remove the air filter.
4. Remove dust from the air filter and wash thoroughly under running tap water.
5. Gently wring out water from the filter and dry well.
6. Reassemble the air filter and cover. The tabs on the cover should be the left and right sides. Press until you hear the tabs click into place.



Replace the Wash Solution Filter and Rubber Stopper (AX only)

1. Ensure the AX-4030 instrument is turned off.
2. On the AX-4030 Wash solution bottle, locate the white filter holder on the tubing.
3. Unscrew the filter holder to disassemble and carefully remove the filter with tweezers.
4. Discard old filter and red rubber stopper.
5. Gently place a new filter into the filter holder, and use a new red rubber stopper.
6. Reassemble the filter holder and tighten.
7. Turn AX-4030 back on by pressing the green button on the front of the instrument.
8. During warm-up, check the filter holder connection for leaks. If found, tighten the filter holder.

Perform S.G. Calibration (AX only)

1. Make sure no patient samples are run during this procedure.
2. On the AX-4030 screen, press **Stop** to place the analyzer in Standby.
3. Turn on the AX-4030 printer before starting calibration:
    a. Press **Menu > #3 Initial Settings > #2 Printer Setup.**
    b. "No use" is highlighted. Press the Minus (-) button on the keypad to change to "Use". Then press **OK** twice, then **Go back** twice to get to the standby screen.
4. In a Sample rack, prepare the low and high S.G. solutions:
    a. Position 1 (Low): pour RG or dI water into a sample tube to the 1st fill line (~2mL)
    b. Position 2 (High): pour Arkray S.G Calibrator solution into tube up to the 1st fill line.
5. Load the sample rack on the AX and slide the rack all the way toward the instrument.
6. From the standby screen, press **S.G. Cal.** Use the numeric keys to enter the S.G. values for the **Low** (**Water S.G. = 1.000**) and **High** (**Arkray Calibrator S.G.** = value is located in package insert) solutions:
    a. Type the S.G. values and press Enter button ↵ to accept.
    b. Press **OK** to save the values.
7. Make sure the sample rack is correctly loaded and press **Start**.

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8. When the calibration is complete, the message "Measurement completed" will appear.
9. Press **Go back** to return to the standby screen.
10. "Calibration ok" should print on the thermal paper.
11. If Calibration passes, then prepare the orange "UA Chem only" rack #23 with the following:
    a. Position 1 – reagent grade water filled to the 1st fill line on the rack.
    b. Position 2 –Level 2 liquichek Control filled to the 1st line on the rack.
12. Check that the results passed:
    a. The result for the water should be 1.000 ± 0.002.
    b. The result for Level 2 liquichek Control should be the same from that day's QC run ± 0.002.
13. If the results pass for all three, then press the feed button on the printer and tear off the thermal printout. This is the ***only*** documentation that the calibration was performed, so you must ***make a photocopy and file in the Maintenance binder***.
14. Turn AX-4030 printer off before resuming patient testing:
    a. Press **Menu > #3 Initial Settings > #2 Printer Setup.**
    b. "Use" is highlighted. Press the Minus (-) button on the keypad to change to "No use". Then press **OK** twice, then **Go back** twice to get to the standby screen.

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Perform iQ Instrument Calibration (iQ only)

1. Take iQ Calibrator Pack and iQ Control/Focus Set out for at least 15 -20 minutes to warm to room temperature.
2. Using the **iQ QC Rack**, to load the following materials:

Position	Volume	Contents	Barcode
1	3mL	Iris System Cleanser	No
2	3mL	Iris Diluent	No
3	3mL	Iris Diluent	No
4	Leave this position empty		
5	6mL	iQ Focus	Yes

3. Load the rack onto the iQ sampler and press Start button the iQ.
4. Make sure the Focus passes before continuing.
5. Place 10 tubes in the **iQ CAL rack**.
6. **Label ONLY the Position 1 tube** with a Calibration barcode located in the iQ Calibration reagent box.
7. Mix the iQ calibrator by holding the bottle upside down and give 5 hard shakes followed by 5 gentle inversions. Let the bottle sit 1 minute for air bubbles to disperse.
8. Pour iQ calibrator in all 10 tubes to the second fill line on the rack.

9. Load the rack on the right side of the iQ analyzer and press the iQ Start button.
10. When complete, a new REF number will be displayed on the computer screen.
11. Quality control must be run (Positive and Negative) after calibration. See procedure ***HEM 3.2.1 – Daily Quality Control - IRIS*** for instructions.
12. If Calibration passes or fails:
    a. If the **calibration and QC pass**, then discard the entire IQ Calibrator bottle (only stable for 24 hours once opened).
    b. If the **calibration passes, but QC fails,** Rerun QC before attempting to recalibrate.
    c. If **Calibration fails**, rerun using the same bottle of calibrator. If calibration fails again, calibrate using a new bottle. If this is not resolved, contact Beckman Coulter.
13. Record monthly maintenance performance on Maintenance Log.

All Revision Dates

2/24/2026

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Attachments

PREV MAINT LOGS HEMO 3.18.26.xlsx

Approval Signatures

Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator, VCMC & SPH	4/9/2026
Laboratory Service Dept	M. Anwar Molani: Medical Director, Laboratory Services	4/9/2026
Laboratory Service Dept	Erlinda Roxas: Director, Laboratory Services	4/8/2026
Laboratory Service Dept	Samah Meshreky: Supervisor-Hematology, Laboratory Services	4/8/2026

Status Active PolicyStat ID 20346592

Origination	1/12/2024
Last Approved	4/9/2026
Effective	4/9/2026
Last Revised	4/9/2026
Next Review	4/8/2028
Owner	Evan Gamad: CLS III
Policy Area	Laboratory Services

L.118 Quality Management System Clinical Laboratory Ventura County Medical Center Santa Paula Hospital

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Vision

Setting the standard in health care excellence. Healthy people in healthy communities throughout Ventura County.

Mission Statement

Provide comprehensive, cost-effective, compassionate healthcare for our diverse community, especially those facing barriers, through an exceptional workforce, education, and forward-thinking leadership.

Quality Statement

Quality is essential in our services, our workplace environment and in our people. Through our qualit y program the clinical laboratories at the Ventura County Medical Center and Santa Paula Hospital are committed to accurate test results and high quality-cost effective patient care. Both laboratories will consistently strive to meet and exceed our customers' expectations through our co mmitment to quality.

Scope

The laboratory will comply with the requirements of the College of American Pathologists (CAP), federal, and state regulatory agencies and continually improve its quality management system.

The Clinical Laboratory will comply with all laws, rules, and regulations, as is consistent with the *Code of Conduct* and *Code of Ethics* for the Ventura County Medical Center and Santa Paula Hospital. The regulating agencies for the clinical laboratory include College of American Pathologists (CAP), the Centers for Medicare and Medicaid Services (CMS), the Clinical Laboratory Improvement Act (CLIA), Joint Commission, and the State of California. Compliance with local laws and regulations will also be adhered to, as is applicable.

The Laboratory permits performance of accreditation inspections by accrediting agencies. Accrediting agencies may review results of evaluations by publicly recognized bodies. The Laboratory provides accurate information throughout the accreditation process.

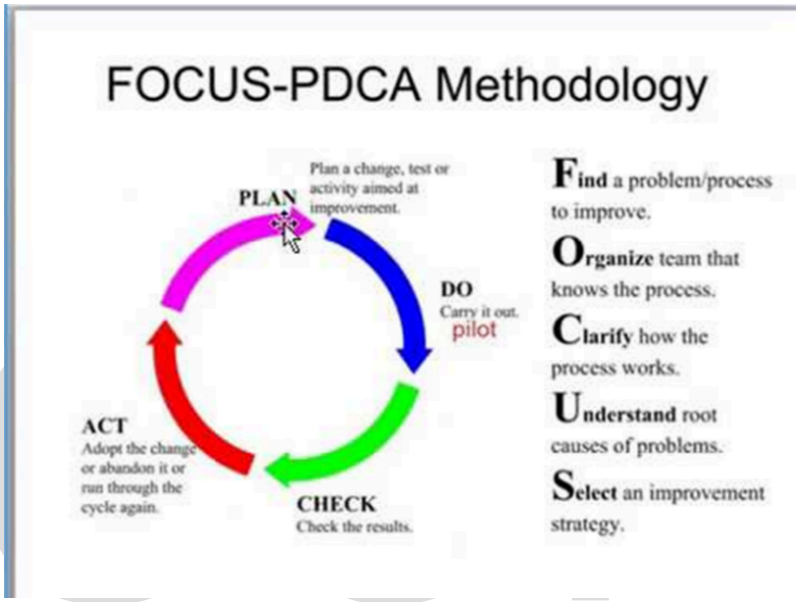
This policy is not meant to include an all-inclusive list of the regulations but serve as a guideline for the commitment to comply with the regulations set forth by each agency and directions for finding the specific rules and regulations.

Quality Policy

In support of this policy both laboratories will fully operate to documented standards within the

scope. Each laboratory section Clinical Laboratory Scientist
III will ensure compliance to Laboratory Policies and Procedures.

- Provide a clear focus on priorities through the establishment of quality objectives.
- Make available the necessary resources for the effective functioning of the quality ma nagement system and the achievement of its quality objectives
- Communicate the Quality Policy and objectives to all lab employees.
- Provide the necessary training and skills to lab employees.
- Operate a closed loop performance measurement system by identifying areas for improvemen t and implementing the necessary corrective actions and preventive measures.

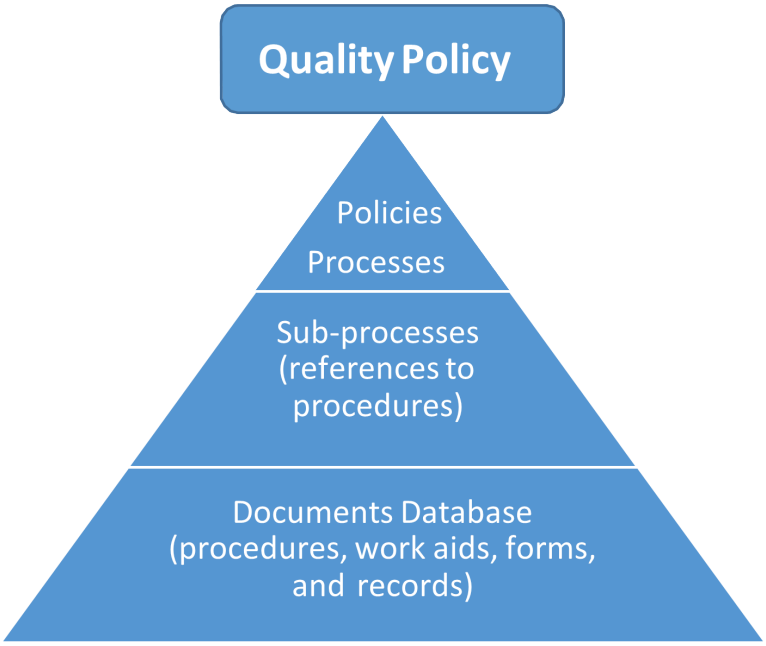


The Quality Management System is annually reviewed by the Quality Assurance/Performance Improvement CLS III, the section CLS III, the director of laboratory services, or designee, and clinical laboratory medical director.

The Quality Management System
is assessed through the Internal Quality Audits and Management Review Meetings to reaffirm its con tinued suitability and conformity. Initial training of laboratory staff is done within 90 days of hire.

The quality management system and the structure of the documentation are organized by the follo wing configuration.

Topic	
Quality Policy	
A.Scope of Services	
B. Quality Objective and Metrics	
C. Roles and Responsibilities	
D.Quality System Overview	
E. Ethical Conduct	
F. Management Commitment	
H. Implementation and Monitoring	



Scope of Services

Types of Services Provided

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The laboratory offers a full range of clinical laboratory and anatomical pathology services. Testing requiring technology not available within the hospital is forwarded to accredited reference laboratories approved by medical staff. The monitoring of quality for reference laboratories is part of the overall Quality Management System.

- Hours of Operations:
  - 24/7 Laboratory Services (Phlebotomy and Diagnostic Testing)
  - 0800 to 1630(Anatomical Pathology Services)
  - 0700 to 1530

Service	Description
General Laboratory Testing of Individual Laboratory Tests	Perform analytical testing classified by testing methodologies and medical disciplines: Hematology, Urinalysis, Routine and automated chemistry, Immunochemistry, Serology, Coagulation, Transfusion Medicine/Blood Bank, and Toxicology.
Pathology and Cytology Services	Anatomic pathology and Cytopathology (non-gynecologic). Services include autopsy, biopsy,PAP test, interpret fine-needle aspirate, frozen section analysis, pathology consultations, histology processing/ staining, and surgical pathology.
Microbiology Testing	Perform services for bacteriology, mycology and molecular testing.
Transfusion Service/Blood Bank	Maintains full-service hospital transfusion service with an active blood management program.

Complexity of Patient Care Needs

Hospital services: Newborn through adult patients of all acuity levels, including those requiring the intensive care involved in emergency services, Level II trauma, neonatal, cardiac and oncology services.

Outpatient services: Specimen collection and POCT is available at outpatient locations. The laboratory serves as referral laboratory to physician offices in the community.

Specific Services Provided

A. Quality Objectives and Metrics

Clinical Laboratory Scientist III, Performance Improvement/Quality Assurance Supervisor, Laboratory Manager, Director of Laboratory Services monitor and measure performance of processes within their area(s) of responsibility. Each lab section will establish measurable operation level improvement indicators consistent with the quality policy. The following are examples:

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Element of Quality Policy	Quality Objective	Metrics
Meeting Customer Needs	Timely test results.	A. STAT turnaround times for Inpatient and emergency department (ED). B. Routine Early Morning Collection. C. Turnaround Time (TAT) for BMP, PT/ INR/PTT, CBC, and Troponin-I in ER D. Lactate Turnaround Time (TAT) E. Unacceptable Specimens
	Meet and exceed customer satisfaction.	A. Satisfaction Surveys B. Monitoring and the Resolution of Notifications
	Cost effectiveness	A. Blood Utilization (Usage and Wastage, Crossmatch: Transfusion Ratio) B. Test Utilization
Accurate Test Result	Maintain or improve scores in Proficiency Testing	Proficiency testing survey evaluation trending.
	Perform all defined quality control measures.	A. Blood Culture Contamination Rates B. Corrected Results Report C. Computer Calculation Checks. D. Evaluations of suppliers of critical reagents.
	Retain qualified and competent staff	A. Employee Satisfaction Survey B. Training/Competency Completion Audit C. Professional Development Plans
High Quality Patient Care	Accurately identify all patient and patient samples.	A. Labeling Errors B. Requisition Aud completeness
	Call all defined critical results to an approved health care provider in a timely manner.	A. Critical Value R B. Critical Value Documer C. Frozen Section
	Accurately report test results.	A. Data transmiss B. Resulting Cleric

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	Reduce Nosocomial Infections	MRSA/CDIFF testing su audits.
Maintain a safe work environment.	Ensure Employee Safety and Regulatory Safety Requirements are met.	A. Occupational In B. Environmental

B. **Roles and Responsibilities**

Overall Quality Management System responsibilities for ensuring compliance with the QMS is described below:

Position	Responsibility
Chief Operations Officer and Chief Quality Officer	Responsible for quality affairs at the senior executive level.
Associate Hospital Administrator (Ancillary Services)	Responsible for executive sponsorship of laboratory management and laboratory quality providing oversight and alignment within the Health Care Agency.
Laboratory Medical Director	Responsible for the clinical aspects of laboratory testing, which includes approval of the new tests, test procedures, reference ranges, report format, clinical interpretation, and consultation. Responsible for the approval of overall QMS activities.
Director of Laboratory Services/Laboratory Manager	Responsible for the business management and strategic direction of the laboratory in support of overall quality management. Responsible for activities involved in laboratory operation such as testing, reporting, logistics, facilities, and environmental health and safety. Also, responsible for QMS planning and the provision of resources needed to implement and improve the QMS.
Section Clinical Laboratory Scientist III	Responsible for planning and controlling QMS processes within their area(s) of responsibility, including the implementation of Quality Management objectives and the provision of resources needed to implement and improve these processes. Clinical Laboratory Scientists are responsible for corrective action of product or process non-conformities. Develops a budget for the laboratory and maintains control of laboratory costs.
Quality Assurance/ Performance Improvement (CLS III)	Delegated responsibility for ensuring that QMS is established, implemented,monitoring, documenting and continuously improving quality. Also,responsible for periodical reviews by Senior Management for effectiveness and continuing suitability. The Quality Assurance/Performance Improvement (CLS III) provides guidance for staff to develop and document appropriate operational procedures for department activities.
Clinical Laboratory Scientist III	Responsible for supervising the activities of the QMS. Ensures performance of standard biological, microbiological, and chemical tests to ensure their delivery in an accurate and timely fashion using proper safety precautions. Evaluates quality control and quality assurance statistics and maintains policies and procedures. Investigations and root cause analyses for the management of occurrences.
Staff	Responsible for the quality of individual work and the development and implementation of the policy and procedures applicable to the processes performed. Identifying and reporting occurrences.

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C. **Quality System Overview**

All employees are responsible for the quality system. Individual policies and procedures further define specific employee responsibilities. The quality system includes a formal system of planned activities. The quality manual is maintained current by the Quality Assurance/ Performance Improvement CLS III to reflect changes to the system. The laboratory defines the key components of quality in a separate quality improvement process document.

The laboratory defines policies for each applicable standard in the quality manual or the general policy manual . Laboratory policies are maintained in a document control system and approved by the Laboratory Medical Director. The laboratory departments have documented procedures that further describe how the specific policy objectives and goals are implemented within the department.

Technical work instructions are maintained in each department's manuals. The technical procedures specify t he equipment, and the required resources needed to produce quality work. Department policies and procedure s are maintained in the document control system by each department leadership, section director, and approv ed by the laboratory medical director.

D. **Ethical Conduct**

The hospital has a Compliance Program which requires all dealings to be conducted in a lawful and ethical manner. Through adherence to the Code of Conduct all staff members will conduct themselves to protect and promote organization-wide integrity.

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E. **Management Commitment**

Laboratory management provides evidence of commitment to the development and implementation of the quality management system and continually improves its effectiveness by the following activities:

- Laboratory management establishes the quality policy and reviews biannually. Communication to emp loyees of the quality policy is documented during laboratory training/ orientation and reviewed annually. It is understood, implemented, and maintained by employees at all l evels. This is documented by management through the employee evaluation process and training proc edures. The internal audit process and the management review process demonstrate compliance.

- The department leaders and section directors should ensure department policies and procedures are understood and implemented by testing personnel. Documentation is documented through tra ining/competency and maintained in the employee file.
- Laboratory communication is accomplished through Departmental and Quality Management Meetings. Documentation of meetings is maintained.

Implementation and Monitoring

The following calendar has been established to identify when QA reviews should be performed. Each item identified under the QA Review heading must be reviewed at a minimum of once a year.

January	February	March	April
A. Monthly reviews B. Annual evaluation of QMS	A. Monthly reviews B. Annual review of safe work	A. Monthly reviews B. Annual Water Quality Check	A. Monthly reviews B. Competency #1 OSHA Training/

C. Staff Performance Evaluation	practices, evaluation of accident/ injury	C. Annual review of emergency preparedness policy D. Cancer Committee	PPE/Fire Safety C. Annual review of infection/ exposure plan/PPE usage
May A. Monthly reviews B. Annual review of policies and procedures	**June** A. Monthly reviews B. Annual review of chemical hygiene plan C. Biennial review of technical policies and procedures by lab med director	**July** A. Monthly reviews B. Instrument checks/ Noise level checks C. Cancer Committee	**August** A. Monthly reviews B. Competency #2 Technical procedures (TS/Micro/ Chem)
September A. Monthly reviews B. Self-inspection C. Vendor qualification reviews by lab medical director	**October** A. Monthly reviews B. Annual review of ergonomics policy/ assessment	**November** A. Monthly reviews B. Customer feedback C. Cancer Committee	**December** A. Monthly reviews B. Competency #3 Technical Procedures (Hema/UA/ Coag/ Serology) C. Purge documents (2 years old)

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DEPARTMENTAL MONTHLY QA REPORTS

- QUALITY CONTROL LOGS
- MONTHLY STATISTICS CALCULATION
- PREVENTIVE MAINTENANCE LOGS
- PROBLEM LOGS
- QUALITY ASSURANCE REVIEWS: INDICATORS, INCIDENT REPORTS, CERTIFICATIONS AND LICENSES
- EVALUATIONS OF EFFECTIVENESS OF CORRECTIVE ACTIONS TAKEN OF INVESTIGATIONS AND NON-CONFORMING EVENTS
- CALIBRATIONS/CALIBRATION VERIFICATIONS
- PARALLEL TESTING/LOT-LOT CORRELATIONS

- VALIDATIONS OF NEW TEST/METHOD
- SURVEILLANCE LOGS
- PENDING LOGS
- UNCOLLECTED SPECIMENS LOG
- EXCEPTION REPORTS
- RESULTS REVIEW

QUALITY ASSURANCE Reviews

Pre-Analytical Metrics

Patient Preparation, Specimen Collection, & Handling

(GEN.40016, GEN.40032, GEN.40050, GEN.40100, GEN. 40490. GEN.40491, GEN.40499, GEN.40535)

- Is patient identity properly confirmed prior to collection? (GEN.40490)
- Are specimens only collected when patients have been properly prepared?
- Are specimens properly labelled? (GEN.40491)
- Are appropriate specimen collection containers and procedures followed?
- How is specimen integrity maintained if testing cannot be performed right away?
- If specimens require special preparation or handling prior to testing, is this performed properly?
- If specimens must be transported to another location for testing, are procedures followed to ensure specimen integrity is maintained? If specimens are not suitable for analyses, are they rejected and appropriate notifications made? How are they communicated to clients? (GEN.40535).
- Are preventive measures being applied to decreased the recurrence of errors in the proper collection of specimens? Is accurate documentation of incident details the aid of investigation and counselling of collecting personnels? Are competency, remedials and re-training being practiced to ensure patient safety and reliability of results are achieved? (GEN.40499).
- Are policies and procedures (existing and/or modified) reviewed by the lab medical director or designee at least every two years?

When:	Daily reviews of specimen logs, send out logs, referral lab reports, batch reports
How:	Specimen integrity, reviews of requisition slips
Acceptable Target for Performance:	100% of samples submitted shall be appropriately labeled and packaged for transport, requisitions shall have identical patient information on the specimen label.

Test Ordering & Requisitions

(GEN.40700, GEN.40725, GEN.40750, GEN.40825, GEN.40900, GEN.40930, GEN.43900)

- Do all specimens accompanied by an adequate requisition? (GEN.40700)
- How does the laboratory know what tests have been ordered on which patients, by which health care provider?
- Are orders reviewed to identify any inconsistencies related to age, gender, diagnosis, or relationship with other test requests or results?

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- Are all surgical pathology/cytology specimens accurately labeled with source and test requisition
- What serves as the laboratory's test requisition for inpatient and outpatients?
- How does the laboratory evaluate test requisitions to ensure completeness of required information needed for test interpretation? (GEN.40750)
    - If information is missing are proper procedures followed to obtain the needed information?
- Are test requisition data elements entered accurately into the laboratory information system? (GEN.40725)
- How are requisitions stored?
- How long are requisitions retained?
- Can the laboratory produce original or exact copies of requisitions throughout the entire time period for retention?

When:	Daily Checks, Monthly Reviews
How:	Upon receipt of specimen packages, test requisitions are reviewed for completeness and are checked against specimen collection vials submitted. Clerical checks of specimen labels. When and if discrepancies are discovered, the specimens are quarantined and held for investigation.
Acceptable Target for Performance:	• All manual requisitions submitted with the specimens shall have an authorized physician and patient signature (as applicable) • Patient demographics are complete • Clinical information and diagnosis are indicated on the requisition • Site of the biopsy is clearly identified

Communication Breakdowns

(GEN.20325, GEN.40535, GEN.61750, GEN.61800)

- How does the laboratory communicate changes in specimen collection requirements, testing, or reporting to health care providers? (GEN.40535)
- Is there any feedback from providers, which indicates a communication problem between the provider and the laboratory may have occurred?
- How were these investigated and resolved?

When:	When there are changes
How:	Laboratory staff will create a memo or a bulletin and have the laboratory medical director approve and sign documents
Acceptable Target for Performance:	All changes pertaining to specimen collection requirements, testing or reporting, including manufacturer recalls, will be communicated to clients within 72 hours of changes or discoveries of recalls.

Analytical Metrics

Performance Specifications

- Have performance specifications been completed for all non-waived test systems? NOTE: If you have multiple units of the same instrument, each must have performance specifications completed independently.
- Is there any evidence that a test system may no longer be meeting expected performance specifications including accuracy, precision, reportable range? *(This may include discrepancies in the relationship or distribution of test results, discrepancies between in house test results and those obtained by other laboratories, questions or complaints from ordering*

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practitioners regarding test results, patterns related to repetitive maintenance, calibration, or QC issues for a given test/test system.)

- You must complete performance specifications on "loaner" instruments.

When:	Annual
How:	Calibration verification
Acceptable Target for Performance:	100% compliance

Instrument and Equipment Record Review

(COM.04200, COM.30550, COM.30575, COM.30600, COM.30625, COM.30650, COM.30675, COM.30680, COM.30680, COM.30685, COM.30700, COM.30725, COM.30750, 30775, COM.30600, COM.30810, COM.30820, COM.30830)

- Is the preventive maintenance performed as scheduled?
- Is there an appropriate corrective action performed for the problems identified?
- Performance verification is performed on all instruments and equipment prior to initial use, after major maintenance or service, and after relocation to ensure that they run according to expectations
- Start-up, operation, and shutdown instructions for all instruments and equipment are available at the workbench or work area

When:	Monthly
How:	Laboratory Director or Designee reviews and assesses instrument and equipment maintenance and function check records. If problems are identified, the reviewer must record corrective action. The review of the records related to tests that have an approved individual quality assurance plan (IQCP) is included in the assessment of whether further evaluation of the risk assessment and quality control plan is needed based on the problems identified.
Acceptable Target for Performance:	100% compliance

Reference Ranges for In House Testing

- How are reference ranges established for all tests performed by the laboratory?
- If a change in test methodology has been implemented, did the laboratory verify the reference range for the new methodology?
- Does the laboratory serve a patient population with characteristics that affect the expected normal range for a given test? *(For example pediatrics, geriatrics, ethnic variations, altitude, etc..)*
- Have you compared results for a sample of "normal" patients from your practice to your established reference range?
    - Does this comparison indicate the need for further review or potentially adjustment of laboratory reference ranges?
- If any need for adjustment of reference ranges was identified, were ordering practitioners notified of the change and reporting methods updated to reflect the new range?

When:	Annual
How:	Monthly statistical analyses of patient data
Acceptable Target for Performance:	100% compliance

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Corrective Actions for QC and Calibration

(GEN.30000)

- Is laboratory staff identifying out of range results for QC or calibration?
- Is laboratory staff documenting corrective actions taken when out of range results are obtained?
- Are the corrective actions taken appropriate?
- Can you observe any patterns related to the frequency of out-of-range results, the staff members involved, the cause of out-of-range results?
- *If patterns are identified, further investigation is needed to determine the root cause and identify actions that can be implemented to prevent future occurrences.*

When:	Daily review of QC by testing personnel, monthly QC reviews
How:	Testing personnel, prior to testing patients, will review QC data, investigate out-of-control, perform corrective action
Acceptable Threshold:	100% QC/calibration are within acceptable range, performance of appropriate corrective actions

Proficiency Testing

(COM.01000, COM.01100, COM.01200
Review of Activity Menu (COM.01200)
PT Attestation Statement (COM.01400)
On the most recent PT event:

- Has the laboratory received any PT scores for any test that were not within the allowable range? (NOTE: the laboratory may pass the PT challenge for a given analyte even though an out-of-range result was received for 1 of the PT samples.)
  - If so, investigate to determine the reason for out-of-range results and take corrective action as needed.
- Were any tests not graded or evaluated?
  - If so, review the PT report to determine the reason it was not graded. If the target values expected for the samples are provided, compare your results to the target. If not within range, conduct split sample analysis to verify the accuracy of your test results.
- Is there a record of actions taken to investigate any PT failures and the above situations?
- On-going evaluation of PT by laboratory director or designee with appropriate corrective action taken for each unacceptable result. (COM.01700)

Compare Current PT Performance to the Two Preceding Events:

- Are there any patterns for a given test? (out of range results, un-graded results)?
  - If so, has performance improved in the most recent PT event?
  - If not, is further investigation and corrective action warranted to ensure accuracy of patient results?

When:	When performance evaluations from each PT event are received.
How:	Quality Assurance/Performance Improvement CLS III or designee will distribute PT evaluations to respective CLS III who will evaluate performance adhering to policy and procedure related to proficiency testing.
Acceptable Target for Performance:	• 80% for all analytes, see CMS changes • 100% for transfusion medicine

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Individualized Quality Control Plans

For each test utilizing IQCP:

- Evaluate the effectiveness of the IQCP by reviewing the following:
    - Has the laboratory received any feedback questioning test results?
    - Has the laboratory received any unsatisfactory or unsuccessful PT scores?
    - Have any QA Reviews identified concerns with the given test?
- Review the prior Risk Assessment based on any problems identified and any changes that may have occurred in the past year. This may lead to either an increase or a decrease in the future risk of an incorrect result.
    - Changes related to the specimen, collection and its handling?
    - Changes related to testing personnel?
    - Changes related to the testing environment?
    - Changes in reagents used for testing?
    - Changes to the test system or its components?
        - Re-assess the potential risk for any changes or identified problems.
- Review the QC Plan.
    - If the risk has increased, determine what additional actions can be implemented to reduce the risk.
        - Add these actions to the QC Plan.
    - If the risk has decreased, determine whether the prior actions in the QC Plan to address the risk should remain or be altered.
        - Make any adjustments to QC plan as needed.
- Approve all changes to the IQCP and re-train staff in the revised IQCP.
- If no changes are needed, record the review noting that the IQCP was determined to be effective.

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When:	At least once per year
How:	List of IQCP will be reviewed by responsible CLS III and/or QA/PI CLS III, add or delete as necessary, risk assessment performed for new test, identify risks and implement risk mitigation steps.
Acceptable Target for Performance:	100% adherence to standard

Relationship of Patient Results

- Does the laboratory have a mechanism to detect inconsistencies in the distribution of patient results across your stated reference ranges?
- Does the laboratory have a mechanism to detect inconsistencies in patient results based on relationship with other test results?
- Does the laboratory have a mechanism to detect inconsistencies in patient results based on relevant information such as gender, age, time of collection, symptoms, treatments, diagnosis, clinical history.

For each of the above:

- What inconsistencies have been identified?
    - What actions were taken to investigate the cause of any inconsistencies?
    - What corrective actions were taken?

◦ How was the situation communicated to ordering practitioners?	
When:	Testing event
How:	• Reviews of anion gaps, delta checks, H/H mismatch, etc. • Pathology correlation reports (monthly/quarterly/semi-annual/annual reports
Acceptable Target for Performance:	100%

Patient Test Results/Reports

- How does the laboratory report test results?
- How does the laboratory monitor corrected and amended reports?
- How does testing personnel report critical results to healthcare providers?
- How does the laboratory monitor reports for completeness (all required elements are present)?
- Do reports include the name of the laboratory director of the laboratory performing the test?
- Is there any feedback that would indicate a potential problem with content of reports or their distribution?
- How long does the laboratory maintain test reports?
    - Can the laboratory produce the original or an exact copy of test reports throughout the entire time period?
- How does the laboratory evaluate staff compliance with procedures for reporting critical values?
- How does the laboratory evaluate staff compliance with procedures for issuing corrected reports?

When:	Test Results: Daily reviews of departmental activity reports Test Reports: Biennial (Every two years)
How:	VCMC and SPH laboratory provide electronic reports to ordering physicians.
Acceptable Target for Performance:	100% compliance

Laboratory Information System

- How does the laboratory evaluate data entry processes (manual & automated) for patient information?
    - Are there any indications of problems with the accuracy of patient information?
    - Are there any indications that some patients or some information may be missing from the lab information system?
- How does the laboratory evaluate data entry processes (manual & automated) for test results?
    - Are there any indications of problems with the accuracy of test results including any interpretive comments?
    - Are there any indications that some test results may be missing from the lab information system?
- Does the Lab Information System perform any calculations?

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(The following items are provided as potential examples of calculations that might be performed: converting birth dates to age groups for evaluating normal values, INR calculations, Anion gap, ratios to compare selected test results (BUN/Creatinine, Total Cholesterol/HDL),and/or conversion of any results to different units or percentages).

- How does the laboratory validate the correctness of any calculations performed by the LIS?

- How does the laboratory protect the LIS against loss of data?
- Is the laboratory able to retrieve data from the past in a timely manner?
- How far back can the laboratory retrieve data?

When:	Annual
How:	Periodic validation and maintenance of LIS hardware, software, calculations, etc. Transfusion Services: BC Solutions
Acceptable Target for Performance:	100%

Monitoring Turn-Around-Time

In house:

- Has the laboratory established turn-around times for reporting results based on the needs of ordering practitioners?
- How does the laboratory monitor its ability to meet the established turn-around times?
- Has the laboratory received any feedback regarding turn-around time?
- How does the laboratory ensure that all results are reported within a clinically useful period?

Send outs:

- Does the laboratory have a negotiated turn-around time with outside laboratories?
- How does the laboratory monitor the turn-around time?
- Does the laboratory provide feedback to the outside laboratory regarding turn-around time?
- How does the laboratory ensure that reports are received within a clinically useful period for all tests sent to an outside laboratory?
- Does the referral laboratory adhere to all requisition, collection and handing specifications of the referral laboratory?

When:	Daily reviews Tracking CMP, CBC with Differential, PT/PTT, Troponin, Lactate Monitoring tests-not-performed reports from referral laboratories
How:	• Specimen tracking for all in-house and outpatient draws, referral lab reports • Participation in hospital-wide and laboratory Throughput Committee • Participation in ED TAT Committee
Acceptable Target for Performance:	90% (60 minutes from order time, 45 minutes from door time (CODE STROKE, CODE SEPSIS)

Customer Feedback

Does the laboratory have a method for obtaining feedback regarding laboratory services from patients and ordering providers?

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How is this feedback reviewed and acted on? Does the laboratory have a protocol for handling complaints? Have all complaints been investigated? Have corrective actions been taken, as appropriate? Are there any patterns related to the number or type of complaints received?	
When:	Annual
How:	Distribution of customer satisfaction survey Review of the NRC reports techsupport@nationalresearch.com
Acceptable Target for Performance:	Customer (patient and physician) feedback is reviewed, evaluated and corrective action performed within 72 hours of receipt

Water Quality and Glassware Has the laboratory defined the specific type of water required for each of its testing procedures and water quality is tested at least annually? Have corrective actions been taken, as appropriate?	
When:	Annual
How:	Biomed checks
Acceptable Target for Performance:	100% compliance

Safety Rounds Policy and procedure current and available to staff, staff training Work practices, occupational injury/illness tracking and monitoring For any occupational injury or illness that required medical treatment, further evaluate laboratory leadership's responses, corrective actions, follow-up procedures, and additional measures taken to ensure safety in the workplace	
When:	Weekly
How:	Weekly rounding in all areas of the laboratory at SPH and VCMC using the hospital's Patient Safety Rounding Tool, weekly report provided by PI/QA
Acceptable Target for Performance:	90% compliance

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Attachments

A. Quality System Management Calendar

B. Performance Improvement Dashboard

C. Annual review of quality management system

References

1. Accreditation Checklists, College of American Pathologists, September, 2021.
2. Clinical and Laboratory Standards Institute (CLSI). A *Quality Management System Model for Laboratory Services*. 5th ed. CLSI guideline QMS01. Clinical and Laboratory Standards Institute, Wayne, PA; 2019.
3. Valenstein P. Quality Management In Clinical Laboratories. Chicago, IL: CAP Press, 2005.

4. Jhai Q, Siegal GP. Quality Management in Anatomic Pathology. Northfield, IL: CAP Press, 2017
5. ISO Standards compendium: ISO 9001:2015, Quality management systems -- Requirements. Geneva, Switzerland: International Organization for Standardization, 2015.
6. ISO 15189:2012 Medical laboratories -- Requirements for quality and competence. Geneva, Switzerland: International Organization for Standardization, 2012.

All Revision Dates

4/9/2026, 3/27/2026, 3/3/2026

Attachments

Clinical Lab Investigation Form.pdf

Approval Signatures

Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator, VCMC & SPH	4/9/2026
Laboratory Services Department	Evan Gamad: CLS III	4/9/2026
Laboratory Services Department	M. Anwar Molani: Medical Director, Laboratory Services	4/9/2026
Laboratory Services Department	Erlinda Roxas: Director, Laboratory Services	4/8/2026

Status **Active** PolicyStat ID **20004057**

Origination	2/27/2026	Owner	Evan Gamad: CLS III
Last Approved	2/27/2026	Policy Area	Laboratory Services
Effective	2/27/2026		
Last Revised	2/27/2026		
Next Review	2/27/2028		

L.86 Laboratory Test Add-On

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PRINCIPLE:

When lab work is ordered and reported, a physician may request additional testing. A lab test may be added on to an existing specimen if the integrity and stability of the specimen allows for the test to be run.

POLICY:

1. The Central Specimen Processing Coordinator taking the add-on call will verify from the Laboratory Information System (LIS) if the test ordered may be added to a previously drawn sample. However, the appropriateness of performing the test is a technical decision for each department, not that of the Central Specimen Processing Coordinator.
2. The Central Specimen Processing Coordinator receiving the verbal or the phone order, confirms the order by reading back the entire order to verify the accuracy of the transcription.

PROCEDURE:

When an “add-on” label prints to add on tests to a specimen that has already been drawn:

1. From the **LIS** choose the **Department Order Entry icon** from the application bar code (*app bar*):
    a. Select the **Accession Add-On icon** and enter the accession number. Data for accession number will populate the fields. There will be a field to enter the name of the ordering physician. The order date and time will default to the original information.
2. Enter the test to be added. Type the first few letters and select … to bring up a list of tests. Select **Add Order to Scratch Pad icon.** Select **Submit Orders icon** to add the tests.

3. Make a note of the accession number and select **Label Reprint icon** to print a bar code label on the appropriate label printer.
4. The label(s) with the added test and the specimen is then taken to the appropriate department and the Clinical Laboratory Scientist (CLS) informed.
5. The “add-on” accession number can then be cancelled with the reason “combined orders”. An order comment is added noting the accession number to which the test was added.
6. If the add-on tests cannot be run because the quantity of the specimen is not sufficient (QNS), an inappropriate sample (i.e. wrong tube or wrong anticoagulant) was drawn, or the specimen is beyond stability (too old), the CLS will make the determination and inform the Central Specimen Processing Coordinator that the test cannot be added on and a new draw is needed.
7. The physician or nurse will then be called with an explanation of why the test(s) cannot be added on and asked if the patient can be redrawn. If the patient is in-house, orders can be placed with the next draw so that the number of venipunctures to the patient is minimized. If no other tests are scheduled to be drawn or the patient is an outpatient, ask the physician or nurse if the patient should be contacted to return to the lab for a new draw.
    a. Document dialogue in specimen comment section of the appropriate accession.

REFERENCE

COPY

All Revision Dates

2/27/2026

Approval Signatures

Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator, VCMC & SPH	2/27/2026
Laboratory Services Department	M. Anwar Molani: Medical Director, Laboratory Services	2/26/2026
Laboratory Services Department	Evan Gamad: CLS III	2/26/2026
Laboratory Services Department	Erlinda Roxas: Director, Laboratory Services	2/26/2026

Status **Active** PolicyStat ID **20004071**

Origination	3/2/2026	Owner	Evan Gamad: CLS III
Last Approved	3/2/2026	Policy Area	Laboratory Services
Effective	3/2/2026		
Last Revised	3/2/2026		
Next Review	3/1/2028		

L.98 Blood Collection By Skin Puncture

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INTRODUCTION:

When blood cannot be obtained from a vein, or when conditions indicate it, blood may be collected by skin puncture, either from a heel in babies <3 months old or from a finger in children one year or older or adults with Unistik 3 lancets. (See Manufacturers description that follows. Gauge: 18G, Depth: 1.8 mm)

Also referred to as capillary or fingerstick.

The factors that contribute to a successful draw are:

1. **A well prepped patient:**

Cleanse the puncture site properly.

Warm the site properly to increase blood flow.

For adults, choose the middle or ring finger. Avoid fingernail and calloused areas.

For infants, always handle heel and toe sites carefully to avoid damage and discomfort.

2. **Good blood flow:**

Using the correct equipment to puncture a finger or heel optimizes the effectiveness of the puncture. If the blood flow is poor, squeezing can cause tissue fluid to contaminate the specimen.

Use the correct lancet depth.

3. **Fast collection and mixing:**

Discard the first drop of blood (can be diluted with interstitial fluid).

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Avoid "milking": Forceful squeezing can cause hemolysis (rupturing of red blood cells) and contaminate the specimen.

Clotting is triggered immediately upon skin puncture and represents the greatest obstacle in collecting quality specimens, especially when whole blood is required.

Specimen collection that takes more than two minutes will frequently result in poorer quality specimens and higher incidence of micro clotting in EDTA and heparin tubes. The tubes that contain additives should be filled to volume lines so that the correct additive to blood ratio is maintained.

All microtainers should be inverted 8-10 times to assure anticoagulation or clot activation.

Materials:

1. Alchol pad
2. Gloves
3. Single-use lancet
4. Gauze
5. Specimen collection tubes

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Order of collection:

1. Blood gases (usually drawn by respiratory therapy).
2. Slides/smears
3. EDTA tubes
4. Other additive tubes
5. Serum tubes
6. Coagulation tests cannot be performed on specimens collected by skin puncture.

REFERENCE:

Reference: Becton Dickinson "Successful Specimen Collection", 1991.

All Revision Dates

3/2/2026

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Approval Signatures

Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator, VCMC & SPH	3/2/2026
Laboratory Services Department	M. Anwar Molani: Medical Director, Laboratory Services	3/1/2026
Laboratory Services Department	Evan Gamad: CLS III	3/1/2026
Laboratory Services Department	Erlinda Roxas: Director, Laboratory Services	2/28/2026

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Status **Active** PolicyStat ID **20180047**

Origination	3/2/2026
Last Approved	3/27/2026
Effective	3/27/2026
Last Revised	3/27/2026
Next Review	3/26/2028

Owner	Christian Press: Supervisor-LIS, Laboratory Services
Policy Area	Laboratory Services - Lab Information Systems
References	GEN.43150, GEN.43200

L.LIS.04 User Authentication, User Authorization Privileges, Unauthorized Software Installation, and Intake Procedure

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PRINCIPLE:

This document fulfills CAP guidelines GEN.43150 and GEN.43200 by defining who may access computer systems, how access is obtained, how security is maintained, and how unauthorized software installation is controlled. This policy defines authorized users for any computer, laboratory information system application, or analyzer system at Ventura County Medical Center and Santa Paula Hospital Laboratories.

Access privileges are restricted by job role within individual applications in Cerner Millennium and other laboratory systems, limiting user access to only those functions necessary to perform assigned responsibilities. User access is granted according to the principle of least privilege and is reviewed periodically to ensure appropriateness for current job responsibilities.

This policy also provides instructions for obtaining new user access to computers, Cerner Millennium, and other required applications. User authentication is unique to each individual, shared accounts are prohibited, and application assignments may be modified with Laboratory Director approval. Access requests are submitted through the Help Desk at **(805) 677 5119**.

POLICY:

User Access Issuance

Employees of the Ventura County Medical Center and Santa Paula Hospital Laboratory Departments receive computer and network access upon hire or after an internal transfer. HCA IT Security assigns unique user names and passwords for approved computers and the secured Ventura County network. Accounts are deactivated when personnel leave the organization or no longer require access.

- **Accounts lock after five failed login attempts.**
- **Passwords must be changed periodically and must meet current complexity requirements.**
- **For password rule updates, contact the Help Desk at (805) 677 5119.**

Access Governance

Control of the following is managed by IT, Informatics, or the LIS vendor, not the Laboratory Department:

- **• Physical entry to data centers housing the LIS**
- **• Access to server operating systems hosting the LIS**
- **• Access to software systems that comprise the LIS**

Laboratory leadership coordinates with Information Technology and Informatics to ensure access is appropriate, approved, and compliant with CAP requirements. User access is reviewed periodically and adjusted when job duties change.

Application Access by Role

The following positions receive access to Cerner Millennium, Microsoft Office, and any other systems required for their job duties:

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- **Laboratory Medical Director**
- **Laboratory Director**
- **Assistant Laboratory Director**
- **Pathologist (Not a position managed by the laboratory staff)**
- **Pathologist Assistant**
- **Clinical Laboratory Scientist**
- **Medical Laboratory Technician**
- **Histology Technician**
- **Histologist**
- **Certified Phlebotomy Technician**
- **Medical Office Assistant**
- **Pathology Transcriptionist**

Assignment of application access is based on job role, training, competency, and operational need. Not all users receive the same functionality within the same application.

Password and Workstation Security

Password sharing is prohibited. Users shall not disclose passwords, post passwords at workstations, or use another individual's credentials to access laboratory systems.

If delayed documentation becomes necessary during urgent operations, the work performed must remain traceable to the actual performing user through appropriate documentation, such as:

- Assay results that include an internal note identifying the performing user, or
- A signed analyzer printout that includes the performing user's initials, date, and time, when applicable.

All staff must log out of or secure their workstations whenever they step away from direct view. Workstations shall not be left open and unattended in a manner that allows unauthorized viewing or access to patient information. Workstations automatically lock after 10 minutes of inactivity.

New Account Creation

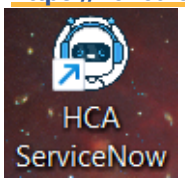
To request a new account with access to Windows, Microsoft Office, and Cerner Millennium, follow the instructions outlined below.

New hires at VCMC and SPH follow a standardized intake process that provides consistent onboarding and ensures they receive foundational training on employee resources, laboratory operations, the laboratory information system, analyzers, and middleware technologies used at VCMC and SPH.

Over time, applications may be added to user roles based on operational need, training, competency, and approval for additional duties. Below is a general outline of applications for each main job classification in Cerner. All access additions or changes must be approved and documented through the appropriate workflow.

A. The Laboratory Director, Assistant Laboratory Director, or other manager in charge of hiring will notify the appropriate party of the start date of any new hire **at least one week prior to start date**. Two weeks' notice or more is ideal.

B. **Contractor Accounts:** Upon notification, the party in charge of ordering an account creation will create an account using the account creation order form on the HCA ServiceNow Portal: **https://vchca.service-now.com/esc**



1. From the main ServiceNow Portal page type: **"**Contractor Onboarding**"** into the search bar.

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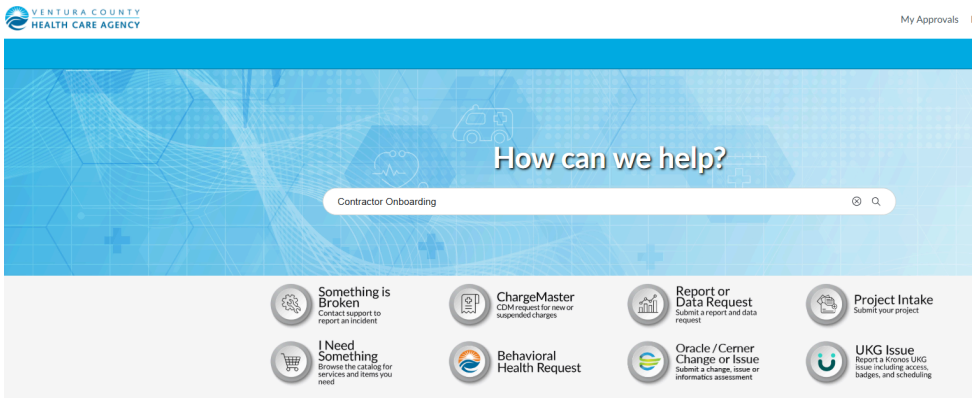
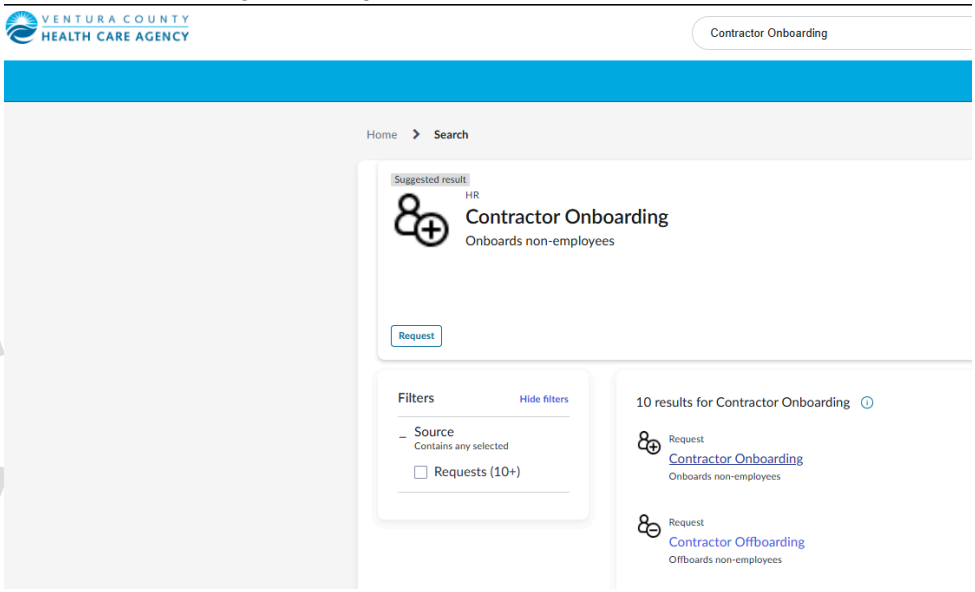


2. **Click on/offboarding and complete the form.**



C. **Employee Orientation -** After the employee arrives for the first day of work, the Laboratory Director or designee will provide or arrange a tour of the hospital and laboratory. The orientation shall include the elements required for a proper safety orientation. Safety features reviewed during the tour shall include eye wash stations, fire alarms, fire extinguishers, emergency exits, and information regarding commonly announced emergency codes.

D. The next phase of the staff members' training will be either **Laboratory Information System (LIS) Training** or **Policy and Procedure Review** to increase their base knowledge prior to starting. Regardless of which training phase is completed first, both are required training phases before the staff can treat patients.

E. **LIS Training** - Must be coordinated 2 weeks prior to the desired date. The training is completed by the Informatics Department and appointments can be created by emailing the Help Desk at **HCA.Helpdesk@ventura.org. The following two points shall be considered.** The length of training will vary depending on whether the new hire has prior experience with Cerner.

The new hire will be signed off for the Cerner applications relevant to the position and will attest to the required knowledge.

F. **Policy and Procedure Review** takes place in front of the Laboratory Director's Office, or at the new

hire's desk/office if they are assigned one. The full review should take no more than 1 to 3 days depending on the new hire's experience with VCMC and SPH.

G. If the new hire is for SPH, the policies and procedures specific to SPH are present in the Pathology Office at SPH Laboratory and/or on PolicyStat. However, the VCMC policies and procedures will apply when SPH must send samples to VCMC, so it is important to be familiar with both.

H. The employee may now proceed to assigned training rotations respective to their job position.

Assignment of Applications

Laboratory staff may require working knowledge of multiple Cerner applications. Depending on the needs of the hospital, staff can take on new applications as needed. Therefore, positions may be assigned the following applications, as applicable to job duties and operational need:

Below is a general outline of applications that may be assigned for each main job classification in Cerner.

Certified Phlebotomy Technician I/II/III
Collection List
Collections Inquiry
Container Inquiry
Department Order Entry
Label Reprint
Modify Collections
Order Result Viewer
Pending Inquiry
PowerChart
Specimen Log-In
Storage Tracking
Transfer Specimens
AP Transcriptionist/Histotechnician/Histologist
Collection List
Collections Inquiry
Container Inquiry
Department Order Entry
Label Reprint
Modify Collections
Order Result Viewer
Pending Inquiry
PowerChart
Specimen Log-In
Storage Tracking
Transfer Specimens
Transcription
Online Review
Case Management

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Document Scanning
Medical Laboratory Technician
Accession Result Entry
Batch Result Entry
Charge Viewer
Collection List
Collections Inquiry
Container Inquiry
Daily Reports
Department Order Entry
Explorer Menu
Label Preprint
Label Reprint
Modify Collections
Multiple Accession Result Verification
Order Result Viewer
Pending Inquiry
Point of Care Result Entry
PowerChart
QC Inquiry
Quality Control Result Entry
Report Selection
Specimen Log-In
Storage Tracking
TAT Monitor
Transfer Specimens
Worklist Request
Clinical Laboratory Scientist I/II
Access Management Office
Accession Audit
Accession Result Entry
Batch Result Entry
Charge Viewer
Collection List
Collections Inquiry
Container Inquiry
Correct Inventory
Daily Reports
Department Order Entry
Dispense and Assign Products
Explorer Menu
Final Disposition
Generate Tags and Labels (BB)
Instrument Accession Queue Viewer
Instrument Activity Monitor

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Inventory Search
Label PrePrint
Label Reprint
Label Verify
Lot Maintenance
Media Label Reprint
Modify Collections
Modify Crossmatch
Modify Products (BB)
Multiple Accession Result Verification
Order Result Viewer
Patient Product Inquiry
Pending Inquiry
Point of Care Result Entry
PowerChart
Product History Review
QC Inquiry
Quality Control Result Entry
Quarantine Products (BB)
Receive Products (BB)
Release Products
Report Selection
Result Entry Blood Bank
Result Entry Microbiology
Return Products
Specimen Log-In
Storage Tracking
TAT Monitor
Transfer Specimens
Worklist Request

Clinical Laboratory Scientist III
Access Management Office
Accession Audit
Accession Result Entry
Batch Result Entry
Charge Viewer
Collection List
Collections Inquiry
Container Inquiry
Daily Reports
DB Collection Requirements Inquiry
DB QC Maintenance
DB QC Patient Data Monitoring

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DB QC Reference Build
DB QC Templates
DB Worklist Build
Department Order Entry
Explorer Menu
Instrument Accession Queue Viewer
Instrument Activity Monitor
Label PrePrint
Label Reprint
Modify Collections
Multiple Accession Result Verification
Order Result Viewer
Pending Inquiry
Point of Care Result Entry
PowerChart
QC Inquiry
Quality Control Result Entry
Report Selection
Specimen Log-In
Storage Tracking
TAT Monitor
Transfer Specimens
Worklist Request
Document Scanning

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Plus any other respective department-specific applications available in Cerner

Adding Applications to the Appbar

AppBar -> Customize -> Buttons -> Sort -> View all available apps for department

A. Click the "**A**"

B. Click **Customize** → **Buttons** → Click **Product** to sort the applications by Department.

C. View Sorted Applications by department. Note that many applications are shared and will not be in a department specific location. But for a department supervisor, this step will help them ensure that they have all relevant applications at their disposal.

D. Click **OK** to save application display changes.

If the new hire is for SPH, the policies and procedures specific to SPH are present in the Pathology Office at

SPH Laboratory and/or on PolicyStat. However, the VCMC policies and procedures will apply when SPH must send samples to VCMC, so it is important to be familiar with both.

The employee may now proceed to assigned training rotations respective to their job position.

Access to laboratory workstations (PCs) and laptop devices is granted only to the following:

- Current authorized Ventura County employees.
- Current authorized Ventura County contracted employees.

Access to laboratory is granted only to the following:

- Current authorized Ventura County employees.
- Current authorized Ventura County contracted employees.
- Individuals or representatives of organizations authorized by management to enter the laboratory.

Access to laboratory analyzers is granted only to the following:

- Current Qualified Ventura County employees
- Current Qualified Ventura County contracted employees
- Current authorized and qualified Ventura County contracted analyzer vendor technical support personnel, when necessary and approved.

For detailed application assignment by job role, the Informatics Department supports application assignment within Cerner in coordination with management. Requests for information may be submitted through the Help Desk at (805) 677 5119.

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All Revision Dates

3/27/2026, 3/2/2026

Approval Signatures

Step Description	Approver	Date
Hospital Administration	Jason Arimura: Associate Hospital Administrator, VCMC & SPH	3/27/2026
Laboratory Services Department	Erlinda Roxas: Director, Laboratory Services	3/26/2026

Laboratory Services Department	M. Anwar Molani: Medical Director, Laboratory Services	3/18/2026
Laboratory Services Department	Christian Press: Supervisor-LIS, Laboratory Services	3/18/2026

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Medical Executive Committee Document Approvals

April 2026

a. Policies & Procedures / Clinical Practice Guidelines / Forms / Orders

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Current Status: *Pending* **PolicyStat ID:** *19191767*

VENTURA COUNTY HEALTH CARE AGENCY

Origination:	*1/1/2001*
Effective:	*Upon Approval*
Last Approved:	*N/A*
Last Revised:	*3/30/2026*
Next Review:	*3 years after approval*
Owner:	*Sherri Block: Associate Chief Nursing Executive, VCMC & SPH*
Policy Area:	*Administrative - Patient Care*
References:	

100.077 Newborn Surrender

PURPOSE:

The Safely Surrendered Baby (SSB) Law responds to the increasing number of newborn infant deaths due to abandonment in unsafe locations. First created in January 2001, the Safely Surrendered Baby law was signed permanently into state law in January 2006.

The SSB law requires the child be taken to a public or private hospital, designated fire station or other designated site, as determined by the local County Board of Supervisors. Designated sites shall post a sign displaying a statewide logo that has been adopted by the State Department of Social Services that notifies the public of the location where a minor child 72 hours old or younger may be safely surrendered. Under the law, a parent or individual who has lawful custody of the child can safely surrender a baby, confidentially and without fear of prosecution (pursuant to Section 271.5 of the Penal Code California), protecting surrendering individuals from prosecution of abandonment as long as the baby is safely surrendered to an actual individual on duty at the safe-surrender site.

According to the SSB law "no person or entity that accepts a surrendered child shall be subject to civil, criminal, or administrative liability for accepting the child and caring for the child in the good faith belief that action is required or authorized (California Health and Safety Code, section 1255.7), including, but not limited to, instances where the child is older than 72 hours or the person surrendering the child did not have lawful physical custody of the child."

POLICY:

~~In accordance with California State Law (Senate Bill 1368 - Brulte), Ventura County Medical Center (VCMC) and Santa Paula Hospital (SPH) will accept physical custody of newborns up to 72 hours old who are voluntarily surrendered by a parent or other person with legal custody. According to the law "no person or entity that accepts a surrendered child shall be subject to civil, criminal, or administrative liability for accepting the child and caring for the child in the good faith belief that action is required or authorized by the bill, including, but not limited to, instances where the child is older than 72 hours or the person surrendering the child did not have lawful physical custody of the child".~~

Ventura County Medical Center (VCMC) and Santa Paula Hospital (SPH), hereby referred to as The Hospital - is a designated Safe-Surrender site, and as such, shall abide by the SSB law regulations as follows:

A. Accept temporary physical custody of voluntarily surrendered child in specified circumstances, until the

department of Children & Family Services (CFS) can take custody.

B. The Emergency Department is the designated location for a parent or individual who has lawful custody of the child to surrender a baby. The child will be accepted by a Registered Nurse in the Emergency Department, though any VCMC/SPH personnel may accept a surrendered newborn, including a clinic employee, via to the Emergency Department SSB guidelines.

C. The Hospital does not need the consent of the parent/other relative in order to provide a medical screening examination, necessary newborn screening tests, and any required medical care to the child. In addition, a child surrendered in accordance with this law is eligible for Medi-Cal.

D. At the time of surrender, qualified Hospital personnel shall accept physical custody of the child, place the unique SSB coded confidential ID bracelet/band on the baby and provide a duplicate band to the surrendering person [example images below], in addition to providing the voluntary SSB Medical Questionnaire; specific procedures are delineated below, under Procedures.

   - Refer to **Procedures** section **A.** for **Emergency Department Newborn Surrender**

E. If the person who surrendered the newborn requests return of the child, CFS must be consulted before returning the child to the person as requested. This will be reported per Hospital policies and procedures (Administrative policy 107.050).

F. If a birthing parent arrives in active labor and only discloses desire to surrender her baby *after* birth occurs, Maternal-Child Health (MCH) Department personnel are to proceed with Voluntary Relinquishment/Surrender Algorithm [see attachment A].

   - Refer to **Procedures** section **B.** for **MCH Department Newborn Surrender**

DEFINITIONS:

I. For purposes of this policy, "**parent**" means a birth parent of a minor child who is 72 hours old or younger.

II. For purposes of this policy, "**personnel**" means a person who is an officer or employee of a safe-surrender site or who has staff privileges at the site.

III. **Safe Surrender**: State law that allows a parent or someone with legal custody to anonymously and legally surrender a newborn (72 hours old or younger) at designated sites (hospitals, fire stations) without fear of prosecution. Personal identifying information that pertains to a parent or individual who surrenders a child shall be redacted from any medical information provided to child protective services or the county agency providing child welfare services. Requires specific baby band placement per the SSB kit, as delineated in this policy (100.007 Newborn Surrender).

IV. **Relinquishment/Adoption**: Relinquishment or termination of parental rights (TPR), is the voluntary legal process where a parent severs all ties, rights, and obligations to a child, allowing another party (adoptive parents or an agency) to assume full legal responsibility, often for adoption, ending duties like child support and rights to custody or visitation. The parent has the option to place their child in an *open* (retains relationship) or *closed* (retains some degree of relationship) adoption of the child. Requires routine baby band placement, per Hospital newborn admission policy (Infant Identification MCH.07).

PROCEDURE:

~~The Emergency Department is the designated department for the parent to surrender their infant. The~~

~~newborn will be accepted by a Registered Nurse in the Emergency Department. Any VCMC/SPH employee may accept a surrendered infant including a clinic employee. (If an abandoned newborn is found on Hospital grounds or surrendered in a department other than the Emergency Department it will be immediately taken to the Emergency Department).~~

~~The Registered Nurse will place a confidential coded identification ankle bracelet on the newborn, and make a "good faith effort" to give the person surrendering the baby a copy of the bracelet, in order to facilitate reclaiming the child. The Registered Nurse or designee will make a "good faith" attempt to have the person surrendering the newborn complete a family medical history questionnaire. However, the person surrendering the infant may decline to complete the questionnaire. The Registered Nurse will be sensitive to the fact that the person may not want to stay and answer questions. If necessary, the medical history questionnaire will be provided with a return stamped envelope that can be completed and returned. The questionnaire shall not require any identifying information about the child or the parent. However, the confidential code must be documented on the form, to allow for matching to the baby.~~

~~A Medical Screening exam will be performed in accordance with Administrative policy 100.068. Necessary newborn screening and medical care will be given. The consent of the parent is not required.~~

~~Children and Family Services Agency will be contacted as soon as possible. Once the contact is made, the Agency will assume temporary custody of the newborn. The Agency will investigate the circumstances of the case and notify the State Department of Social Services. The Agency will file a petition in juvenile court to declare the infant a dependent of the court.~~

~~If the person who surrendered the newborn requests return of the newborn, Children and Family Services must be consulted before returning the child to the parent as requested. This will be reported per Hospital policies and procedures (see Administrative policy 107.050, ER Procedure A.2).~~

A. Emergency Department Newborn Surrender

1. Accept the newborn from the parent/person and obtain the Safe Surrender Packet/Kit located in ED Triage-Charge RN Desk [contents of the packet attached to this policy].
    i. English/Spanish packets available for either Boy/Girl
2. Place a [premade] coded, confidential ankle bracelet/band on the child for identification (ID) with naming convention “Safe Surrender Baby Boy / Girl”, infant's Date of Birth and Date of Surrender; and Medical Record Number (MRN) if available.

1. Provide, or make a good faith effort to provide to the parent or other individual surrendering the child, a copy of the unique, coded, confidential bracelet/band ID in order to facilitate reclaiming the child later. However, possession of the ID band, in and of itself, does not establish parentage or a right to custody of the child (a parent or person with lawful custody has up to 14 days from the time of voluntary surrender to reclaim the child). Each set of bands has its own individualized identification number which should be documented in the Hospital electronic medical record (EMR).
2. Provide, or makes a good faith effort to provide to the parent or other individual surrendering the child a SSB Medical Questionnaire, which may be declined, voluntarily filled out and returned at the time the child is surrendered, or later filled out and mailed in the envelope, provided for this purpose (with a return

address for The Hospital's Social Services Department). This medical information questionnaire shall not require identifying information about the child or the parent or individual surrendering the child, other than the identification code provided in the ankle bracelet ID that was placed on the child.

3. Facility notifications:
    i. Hospital: Administration, Social Services, and Nursing Supervisor.
    ii. Children and Family Services (CFS): Hotline reporting of 'Safe Surrender Baby' .
        1. As soon as possible, but in no event later than 48 hours after the physical custody of a child has been accepted, Hospital personnel shall call in a report. *No personal identifying information that pertains to the parent/person who surrendered the newborn can be given out.*
        2. CFS to provide Hospital personnel with ongoing direction and information, such as, appropriate naming convention for the newborn (i.e., "SSB Boy/Girl XVI") for documentation, state screening forms, etc.
        3. CFS to provide direction for legal placement of the infant for purposes of discharge planning.
4. A Medical Screening exam will be performed in accordance with Administrative Policy 100.068. Necessary newborn screening and medical care will be given (the consent of the parent is not required).
    i. If a SSB first presents to SPH, infant is to be banded via the SSB Kit, initial medical screening exam conducted and patient stabilized, followed by transfer to VCMC for ongoing pediatric services.
5. ED Attending to consult with Pediatric Attending and/or NICU Attending as to the most appropriate location for the newborn's admission.
    i. *Inter-facility transport*: Newborn to be transferred via infant car seat by Hospital personnel per Hospital transport policy guidelines.
    ii. *Intrahospital transport*: Newborn to be transferred via isolette by Hospital personnel per Hospital transport policy' guidelines.
6. REQUEST FOR RETURN OF NEWBORN: The SSB law provides that the person who surrenders custody of a newborn may request to reclaim custody within 14 days. If the parent/person who voluntarily surrendered the newborn requests that the newborn be returned to him/her, notify Hospital Administration, Social Services, and the Maternal-Child Health (MCH) Director. *CFS must be consulted before returning the child to the person as requested.* This will be reported per Hospital policies and procedures (Administrative policy 107.050).

B. MCH Department Newborn Surrender

1. If a birthing parent discloses a desire to surrender her baby *after* birth occurs, Maternal-Child Health (MCH) Department personnel will:
    i. Immediately notify the OB Attending/managing physician, place an urgent Social Services consult order, and contact the hospital Social Worker on duty.
    ii. Understand that the birth parent retains all decision-making rights while with the newborn, unless determined otherwise by CFS (this includes nutrition and medication administration decisions).
    iii. Notify the CFS Hotline in the event the parent declines to care for the newborn or is discharged, leaving the newborn [abandoned] in the Hospital.

iv. Follow the Voluntary Relinquishment/Surrender Algorithm to provide the birth parent with appropriate options for relinquishing of the newborn [see attachment A].

1. **Relinquishment/Adoption**: mother has the option for an *open* (retains relationship) or *closed* (retains some degree of relationship) adoption of the child. Routine baby band placement, per Hospital newborn admission policy.

2. **Safe Surrender**: child and birth parent have no documented relationship [anonymity must be maintained in all documentation]; placement of de-identified baby bands from the SSB kit.

   a. If maternal desire to surrender her baby is *known prior* to calling the baby to Admitting Dept., obtain the Safe Surrender Packet/Kit located in OB Triage Desk and follow the Safe Surrender ED protocol above [Procedure sect. A].

   b. If maternal desire to surrender her baby is *not known prior* to calling the baby to Admitting Dept., the charts will need to be de-identified/break the relationship – notify MCH Director. *Replace previous hospital baby bands with SSB Kit bands on newborn AND birth parent*, and follow the Safe Surrender ED protocol above [Procedures sect. A].

      i. When bands require replacement, document a note indicating the prior band ID number, new band ID number, and reason for replacement [maintaining anonymity of the surrendering party].

REFERENCES:

- Safe Surrender Baby
- California Code, HSC 1255.7
- More Child Welfare Services – Human Services Agency
- Adoptions

All revision dates: 3/30/2026, 3/1/2016, 5/1/2006, 1/1/2005

Attachments

- Attachment A - Reliquishment vs Safe Surrender Algorithm.pdf
- HSA Adoption Brochure - English.pdf
- HSA Adoption Brochure - Spanish.pdf
- HSA-CFS Brochure - English.pdf
- HSA-CFS Brochure - Spanish.pdf
- Medical Questionnaire-SOC861.pdf
- Medical Questionnaire-SOC861SP.pdf
- Safe Surrender Brochure - English.pdf
- Safe Surrender Brochure - Spanish.pdf

Approval Signatures

Step Description	Approver	Date
Medical Executive Committee	Stephanie Denson: Manager, Medical Staff Office	pending
Hospital Administration	Minako Watabe: Chief Medical Officer, VCMC & SPH [AB]	4/2/2026
Hospital Administration	Osahon Ekhaese: Chief Operating Officer, VCMC & SPH	3/30/2026
Nursing Administration	Danielle Gabele: Chief Nursing Executive, VCMC & SPH	3/30/2026
Nursing Administration	Sherri Block: Associate Chief Nursing Executive, VCMC & SPH	3/30/2026
Policy Owner	Sherri Block: Associate Chief Nursing Executive, VCMC & SPH	3/30/2026

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References:	

100.111 Secure Text Messaging of Protected Health Information (PHI)

POLICY:

TigerText (TigerConnect) is a secure messaging application that allows real time, HIPAA-compliant communication between two or more authenticated users. This policy provides guidelines and defines accepted practices for the transmission of Protected Health Information (PHI) via secure messaging between authenticated users, to ensure that PHI is transmitted in compliance with HIPAA standards. Text messaging is a form of informal communication that can be beneficial to improve communication between healthcare team members.

PROCEDURE:

Authenticated User – anyone that has been granted access to the TigerText application by the Ventura County Health Care Agency.

TigerText is the approved application for communicating PHI via text message between authorized users at Ventura County Health Care Agency (VCHCA)

A. TigerText is the only approved, HIPAA-compliant text messaging solution for communication of PHI by the VCHCA, and should be used when sending text messages containing patient name, date of birth, medical record number (MRN), social security numbers, photographs, video, or financial account information.

B. Secure text messaging is considered *informal* communication.

C. Only persons licensed for the Ventura County Health Care Agency TigerText system are accessible within the Ventura County Medical Center TigerText account.

D. Sharing of PHI via TigerText must comply with all federal (HIPAA) and state laws and regulations regarding confidentiality of records; i.e. only individuals who are permitted to access a particular patient's PHI may obtain that PHI via TigerText.

E. Professional behavior and standards are required of all TigerText users. Users shall adhere to all applicable policies in their use of TigerText.

F. Text messages are not stored or considered part of the patient's permanent record. If there is a need to archive communications, this should be done separately in the Electronic Health Record.

GUIDELINES

A. Retention of Records
The content of each TigerText message is swept from all devices (individual accounts and servers) after no more than five (5) days.

B. Safeguards and Texting Etiquette

1. Personal devices must be equipped with a passcode or method of authentication of the owner.
2. Clinical pictures, video, voice files, and other files must be taken and sent *within* the secure messaging application. They should not be taken or stored outside of the secure application.
3. The TigerText application shall never be used to create, display, store, or transmit illegal, inappropriate, derogatory, harassing, or offensive material.
4. If your Personal Device is lost, stolen or if there is interception of transmission of electronic PHI by an unauthorized person, you must notify the hospital immediately. Disposal or sale of your Personal Device should not be done until all hospital related content, including the TigerText application, is completely removed.
5. If employment is terminated, you must remove all hospital related content, including the TigerText application, from your Personal Device.

C. General Use Guidelines

1. TigerText should be used for non-emergent, non-urgent communication
2. Message status definitions
    a. A "sent" status indicated that the message has not yet been delivered to the recipient.
    b. A "delivered" status indicates that the message has been delivered to the recipient's active account, but not yet read.
    c. A "read" status indicates that a message has been received and read by the recipient.
    d. If a message is "read" by the recipient, or if the recipient does not respond to the message in an appropriate amount of time, the sender will contact the recipient through alternate means to verify the communication was received.
3. Message composition
    a. To avoid confusion when communicating about patients, include as much identifying information about the patient as possible. Consider using the following format: [Patient First and Last name]: [Medial Record Number]: [Room#]:[Issue to be communicated]: [Sender's name]: [Call back #]

D. Emergencies

1. **Do not use TigerText in an emergency.** If a true emergency arises, handle communication as you would without TigerText, and as clinically appropriate; e.g., call a code blue or rapid response (RRT), interact face-to-face or communicate via real-time voice telephone call.

E. TigerText Orders

1. Per Joint Commission standards, orders MAY NOT be conveyed over text messaging.
2. Nursing staff will utilize the TigerText algorithm to evaluate texts versus phone calls (See Attachment 1).

F. Inclusion in Medical Record

1. If information transmitted via TigerText needs to be part of the medical record, the appropriate healthcare professional who created or received the information has the duty to make an entry in the medical record documenting the pertinent information.

All revision dates: 2/27/2026, 3/9/2021, 9/1/2016

Attachments

Tiger Text Algorithm.pdf

Approval Signatures

Step Description	Approver	Date
Medical Executive Committee	Stephanie Denson: Manager, Medical Staff Office	pending
Hospital Administration	Osahon Ekhaese: Chief Operating Officer, VCMC & SPH	3/30/2026
Hospital Administration	Minako Watabe: Chief Medical Officer, VCMC & SPH [AB]	3/10/2026
Nursing Administration	Sherri Block: Associate Chief Nursing Executive, VCMC & SPH	3/7/2026
Nursing Administration	Danielle Gabele: Chief Nursing Executive, VCMC & SPH	3/7/2026
Policy Owner	Todd Flosi, MD: Associate Chief Medical Officer, VCMC & SPH	3/7/2026

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102.018 Peer Review

POLICY:

Peer review is an ongoing evaluation of the performance of clinical privileges at Ventura County Medical Center (VCMC), Santa Paula Hospital (SPH), Inpatient Psychiatric Unit (IPU) and the Ambulatory and Behavioral Health Clinics. The goals of the peer review process are:

1. Preserve and continuously improve the safety and quality of patient care;
2. Provide ongoing review and evaluation of care provided by practitioners exercising privileges in the hospital and/or clinic setting;
3. Identify significant trends by analyzing aggregate data that may impact the safety and quality of patient care;
4. Provide recommendations and specific feedback to practitioners;
5. Identify opportunities for process and systems improvements;
6. Identify educational opportunities / Continuing Medical Education (CME) recommendations;
7. Improve completeness and quality of the medical record.

PROCEDURE:

A. Peer review is a case-based evaluation of a practitioner's performance of clinical privileges, directed towards issues which impact patient safety and the quality of patient care. Peer review is performed by individuals from the same discipline (e.g., physician to physician, dentist to dentist, etc…) with similar qualifications, experience and training. Review shall be designed to evaluate whether a practitioner's patient care falls within acceptable standards of safety and professional practice as defined by the Medical Staff.

B. At the discretion of the Department Chief, a Quality Medical Director or a Medical Director, peer review may be performed when any of the following is identified involving a member of the Medical Staff or Allied Health Practitioner (AHP) exercising clinical privileges in the hospital or clinics:

   1. Occurrences which meet Medical Staff Department approved peer review quality indicators;
   2. Statistical analysis and aggregate data reflecting levels of performance, utilization or patient outcomes which varies significantly and undesirably from professional standards;
   3. Significant adverse patient events and/or safety risks with the potential for patient harm;

4. Risk Management concerns involving quality of care;
5. Reports by Medical Staff or AHP Staff members, Hospital healthcare team, or patient/family involving a quality of care issue which may indicate a substantial deviation from the standard of care;
6. Notices from regulatory bodies, accreditation agencies or third party payors involving quality of care.

C. Code of conduct issues, physician health and well-being, and issues related to professional behavior are not part of the peer review process, unless they directly impact patient care. These issues shall be directed to the Chief of Staff, Chief Medical Officer or any Medical Staff Officer including Department Chiefs for management as specified in the Medical Staff Bylaws.

D. All activities related to peer review are protected by California Evidence Code §1157 and will remain confidential. All documentation will be maintained within the Medical Staff Services Department to maintain confidentiality in accordance with the Medical Staff Bylaws.

E. Actions taken according to this policy are not considered a formal investigation and do not invoke section 805 reporting requirements if a member withdraws requests for privileges or terminates membership or privileges. If the Medical Executive Committee (MEC) concludes that corrective action may be warranted, a formal investigation shall be initiated pursuant to Article 13 of the Medical Staff Bylaws.

F. Practitioner specific peer review results will be considered during the credentialing and privileging recommendations and, as appropriate, may be utilized in the organization's performance activities.

G. Notwithstanding the terms and provisions of this policy and procedure, corrective action or disciplinary action, including but not limited to summary suspension, may be instituted at any time in accordance with the Medical Staff Bylaws.

H. Each clinical department shall establish and approve peer review indicators which will be tracked in order to identify potential problems with patient care.

I. The Quality Assurance Performance Improvement Department (QAPI) shall screen Hospital cases utilizing these peer review indicators and notify the Medical Staff Services Department to initiate the peer review process.

J. Practitioners providing care solely in an Ambulatory or Behavioral Clinic are subject to the same quality standards and care concerns identified will be assigned for review through the electronic peer review process, and reviewed by the appropriate Medical Staff Department in which the practitioner holds clinical privileges.

K. Reviewers shall be notified by the Medical Staff Services Department of the charts assigned for review and their responsibility to participate in peer review activities.

L. A reviewer may be recused and another reviewer assigned if:
1. The reviewer was involved in the care or treatment of the patient(s); or
2. A conflict of interest exists which may compromise the reviewer's objectivity.

M. Practitioners being reviewed will be given an opportunity to provide additional information or feedback, whenever reasonably possible, regarding the case reviewed, which may include an invitation to attend the Department meeting in which the case will be discussed.

N. Peer review shall be conducted as soon as reasonably possible. In general, the medical record shall be completed prior to the case being assigned for peer review. It is the goal of the Medical Staff to have peer review finalized within 120 days from the date the occurrence was identified for peer review, although this time frame may be extended for good cause.

O. Practitioners will be notified by the Department Chief or his/her designee in writing of all peer review findings that were found to deviate from the standards of care and given an opportunity to respond, request additional review or provide information not available at the time of review that may have relevance on the peer review rating.

P. All cases not meeting the standards of care will be trended for Ongoing Professional Practice Evaluation (OPPE) and recredentialing. Practice trends towards substandard patient care may, at the discretion of the Department Chief, invoke Focused Professional Practice Evaluation (FPPE) as described in the Medical Staff Bylaws.

Q. Circumstances which may require external peer review include but are not limited to:

1. There is insufficient local expertise to adequately and objectively review the practitioner's care. This would include situations in which the only peers on the Medical Staff are partners, associates or direct competitors of the practitioner under review and the potential for conflict of interest exists.
2. There is a known conflict among practitioners which would impact the objectivity and fairness of the review.
3. When there are conflicting recommendations from internal reviewers or Medical Staff committees.
4. As requested by the Medical Executive Committee or Governing Board.

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Attachments

No Attachments

Approval Signatures

Step Description	Approver	Date
Medical Staff Office	Stephanie Denson: Manager, Medical Staff Office	pending
Medical Staff Office	Minako Watabe: Chief Medical Officer, VCMC & SPH	pending
Policy Owner	Tracy Chapman: Director, HCA Medical Staff Administration	4/2/2026

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102.043 Medical Staff Continuing Education (CME/CEU) Requirements

POLICY:

The Medical Staff is responsible for ensuring that all practitioners granted membership and/or privileges complete continuing medical or professional education (CME/CE) in accordance with licensing requirements applicable to their specialty, as outlined in Article 2 of the Medical Staff Bylaws under section 2.6.17, Basic Responsibilities of Medical Staff Membership, and policy 102.033 Allied Health Professionals.

PROCEDURE(S):

Documentation:

To reduce documentation requirements on practitioners, the Medical Staff Office will accept an attestation in lieu of CME certificates. Compliance with CME/CE requirements will be monitored through annual audits.

Annual Audits:

The Medical Staff will identify no less than 5 initial appointments and 10 reappointments at random annually to undergo an audit of CME/CE documentation. When a practitioner is notified they have been identified to be audited, documentation must be provided within no longer than 7 days. If a practitioner fails to respond to the audit request or is unable to provide documentation of CME/CE within the requested time frame, noncompliance will be reported to the appropriate credentialing committee for further action.

Exceptions:

All practitioners are expected to maintain documentation of CME/CE within the past 2 years for the purpose of this audit. This requirement is waived for recent graduates within the past 2 years and recently board certified within the past 4 years.

REFERENCE(S):

A. Medical Staff Bylaws

B. 102.033 Allied Health Professionals

All revision dates:

Attachments

- CE Psychology Requirements.pdf
- CE_NP and CRNFA Reporting Form 9.2024.pdf
- CME_Attestation Form Physician_PA_.pdf

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Medical Staff Office	Stephanie Denson: Manager, Medical Staff Office	pending
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Policy Area:	*Administrative - Environment of Care*
References:	

106.034 Emergency Management Plan

POLICY:

It is the policy of Ventura County Medical Center (VCMC)/Santa Paula Hospital (SPH) and Licensed Hospital clinics to develop, maintain and continually update an Emergency Management Plan. The purpose of the Emergency Management Plan is as follows:

A. Designed to support the Hospital Incident Command System (HICS), which is a modification of the Incident Command System (ICS). ICS is the standardized and official emergency response organization adopted by city, county, and state organizations, to permit improved understanding and communications between various government agencies. VCMC/SPH joins an expanding number of health care organizations, by adopting HICS, which will permit improved coordination between other health care facilities and local government agencies.

B. To provide for effective actions which will minimize injuries and loss of life among patients, employees, volunteers, vendors, visitors and contractors during a state of disaster or extreme emergency.

C. To provide procedures for optimal use of our resources during a state of disaster or extreme emergency.

D. To provide a plan, through EMS, of mutual assistance with other hospitals, organizations and agencies for the prompt transfer of victims that we are unable to manage.

The VCMC/SPH Emergency Operations Plan (see attachment) is modeled after the HICS format. The goal is to provide a simplified disaster plan for common response by all departments and units. The specific duty for implementations of these plans is the responsibility of each department manager or supervisor. Plans are tailored to the specific needs and resources of each department.

PROCEDURE:

The Emergency Operations Plan is designed to work in conjunction with the Ventura County Sheriff Office of Emergency Services (OES), Ventura County Emergency Medical Services (VCEMS) Agency and Public Health. In the event of a large-scale disaster, VCMC/SPH will participate in the coordination between other healthcare facilities, as directed by the Ventura County Sheriff's OES Multi-Hazard Functional Plan and the EMS Agency. The Ventura County Medical Network (REDDINET) system will be used to assist in coordinating emergency response and hospital availability. The HICS plan will also support the medical needs of the surrounding communities.

The Emergency Operations Plan is also designed to activate the resources of Ventura County Ambulatory Care (AC) as needed. If an emergency situation occurs that necessitates assistance by AC, the Incident

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Commander will contact the AC Administrator-on-Call to initiate the AC Emergency Operations Plan. According to the plan, the Administrator-on-Call will determine whether to assign an AC Liaison to the VCMC ICC who will coordinate the limited mobilization of AC resources or to initiate the Ambulatory Care Incident Command Center to mobilize and coordinate massive resources, in which case an Ambulatory Care liaison would be assigned to the VCMC ICC to facilitate collaboration and coordination.

To permit optimum response and minimize the impact of the emergency on normal operations, the response effort must grow with the threat and then needs to be reduced as soon as emergency conditions permit. This requires rapid assessment of the problem, and the resources available to contain and resolve the emergency. Quickly obtaining current and accurate information enables the incident management team to estimate the potential impact on the facility and initiate plans to meet both facility and community needs.

This Emergency Operations Plan shall be prepared in compliance with the California Administrative Code, Title 17, Title 9 and The Joint Commission, which requires that all hospitals have a written Emergency Operations Plan.

A trauma surgeon from the trauma panel must be included as a member of the hospital's Emergency Management Committee and be responsible for the development of a surgical response to a mass casualty event. The surgical response is detailed in policy *T.13 Multiple Casualty Incident*, and outlines the critical personnel, means of contact, initial surgical triage (including subspecialty triage when appropriate), and coordination of secondary procedures.

Any fire service, law enforcement agency, public health agency or hospital may notify the Ventura County Sheriff's Office of Emergency Services and/or Ventura County Emergency Medical Services (EMS) Agency of any disaster that is known to have produced, or is likely to produce, multiple causalities.

AUTHORITY

A. The Environment of Care Executive Committee appoints a chairperson to be responsible for the management, monitoring and reporting regarding the Emergency Operations Plan (EOP).

B. The Chairperson of the Emergency Management Committee has immediate and complete access to all records that become necessary in carrying out the EOP.

HAZARD VULNERABILITY ANALYSIS

Hazard Vulnerability Analysis is conducted every two years, or sooner as needed.

Results of the Hazard Vulnerability Analysis are obtained through the collaborative efforts of the Emergency Management Committee.

Both natural and man-made disasters could affect this hospital at any time. It is an inherent obligation of those charged with the responsibility for the care of the sick and injured to provide an effective Emergency Operations Plan. This program should ensure the maximum safety and well being of all patients and staff.

DEFINITIONS

Disasters may be "Internal" or "External" to the hospital. Disasters shall be paged over the hospital intercom system and phone page system as "CODE TRIAGE" (15 or more patients/victims, regardless of mechanism or acuity i.e. trauma, chemical exposure, radiation exposure etc., are expected or received for emergency care in the Emergency Department), followed by "External or Internal," (location), (ETA if known) "All visiting hours are now ended, visitors please exit the hospital."

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Disasters are defined as follows:

A. **External**
An External disaster occurs outside the hospital complex which affects the local community and which would result in a sudden influx of acutely sick and/or injured patients needing emergency care. Disasters of this type could result from fire, major accident, earthquake, flood, explosion, electrical failure, gas leakage, etc.

B. **Internal**
A disaster occurring within the bounds of the hospital complex with acute injuries, facility damage or significant disruption of service or the threat of potential injuries, due to a major calamity. Disasters of this type could result from fire, explosion, electrical failure, flood, gas leakage, earthquake, threat of an employee walkout, etc.

C. **Bioterrorism/Hazardous Substance**
Bioterrorism is the deliberate release of pathogenic microorganisms (bacteria, viruses, fungi or toxins) into a community. Most likely diseases include smallpox, anthrax, botulism, plague and tularemia, but viral hemorrhagic fever viruses such as Lassa, Marburg and Ebola may also be deliberately introduced. With the exception of smallpox, VHR and the encephalitis viruses, all bioterrorism agents can be treated with antibiotics or toxin antagonists if promptly diagnosed.

The key to rapid intervention and prevention is to maintain a high level of vigilance. Early identification of an outbreak from an unnatural source is essential. Suspicious indicators include increasing numbers of otherwise healthy persons with similar symptoms seeking treatment over a period of several hours, days or weeks, a cluster of previously healthy persons with similar symptoms who live, work or recreate in a common geographical area; an unusual clinical presentation; an increase in reports of dead animals; lower incident rates in those persons protected; an increase number of patients who expire within 72 hours after admission; any person with a history of recent travel to a foreign country presenting with S&S of high fever, rigors, delirium, rash, extreme myalgias, prostration, shock diffuse hemorrhagic lesions or petechiae; and/or extreme dehydration due to vomiting or diarrhea with or without blood loss.

Decontamination of suspected exposure to a bioterrorism agent or to reduce the extent of external contamination will be coordinated with the Hazardous Materials Team of the Fire Department. The Decon tent will be set-up by our Facilities Dept. as needed.

D. **Emergency Operations Plan**
The Emergency Operations Plan (EOP) is an "all hazards" plan to guide preparations, response, and recovery to emergencies and disaster for Ventura County Medical Center and Santa Paula Hospital. The EOP is a dynamic document that is modified as deficiencies and opportunities for improvement are identified in the evaluation of all emergency response exercises and all responses to actual emergencies.

INITIATION OF CODE TRIAGE

A. Authority to Initiate -- The Hospital Administrator or the Administrator on Duty in conjunction with the Nursing Supervisor and the Emergency Department Charge Nurse have the authority to initiate a Code Triage and activate the Emergency Operations Plan, or other portions of the Plan as deemed appropriate. The person activating the plan serves as Incident Commander until relieved by a Senior Administrator or relinquishes responsibility to another individual.

B. Conditions Necessary to Initiate the Emergency Operations Plan:

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1. Notification of a disaster received from the Ventura County EMS Agency or Office of Emergency Services Emergency Operations Center (EOC).
2. Any condition that brings a significant number of patients to the Emergency Department or seriously disrupts the quality of services that the facility provides to its patients, staff and communities.
3. A significant internal disaster.

C. The Initiation Process:

1. In the event of a disaster, the initial notification will usually be to the Emergency Department. The Emergency Department will immediately notify the Administrator-On-Duty (Administration during the weekdays, Nursing Supervisor all other times).
2. The Administrator, Nursing Supervisor, or Administrator on Duty reviews the need to establish the Command Center to manage the situation and, where appropriate, activates the disaster plan.
3. The Administrator, Nursing Supervisor, Administrator on Duty or the Emergency Department Charge Nurse notifies Communications to overhead announce the disaster code: CODE TRIAGE, ER, EXTERNAL OR INTERNAL, or other code as appropriate; activates the Administrative Disaster Call-back as appropriate; notifies those needing to be informed not accessed by the paging system.
4. Paging, after confirming a complete understanding of the notification requirements, overhead announces:

   "Code Triage, (Internal or ***External), (location) (ETA if known),*** **all visiting hours are now ended, visitors please exit the hospital."**
5. At that time, paging will notify the appropriate personnel via pagers and cell Phones. Paging may also be instructed by Administration to notify those needing to be informed of disaster that is not accessed by the paging system. After 15 minutes, **"Code Triage in process until further notice"** should be announced by Paging.

D. Upon establishment of the Incident Command Center, located in the Large Auditorium or ~~Academic Family Medicine Residency and Specialty Care Center in the Computer Training Center~~the 1st floor Administrative Conference Room at VCMC and the Library or Administrative Conference Room (Alternate Location) at ~~VCMC and the Library or Nursing Office (Alternate Location) at~~ SPH, an Incident Briefing Form will be developed:

1. The Incident Commander (IC) will be responsible for preparing the Incident Briefing Form (HICS 201), a brief written statement about the nature of the problem, anticipated impact on the staff, and general directions for managers to take in response to the situation.
2. Command Staff and Section Chiefs, or Branch/Unit/Team Leaders and Medical/Technical Specialists will report to the Incident Command Center to review the Incident Briefing Form and accept assignment by the IC.
3. The IC will provide updated Incident Briefing Forms for departments as often as appropriate and as the situation permits.

STAFF ROLES AND RESPONSIBILITIES (General)

A. **General Guidance to All Staff and Physicians**: In most cases, clinical and support staff will continue their normal duties when a disaster code is called, depending on the level called, unless otherwise directed, such as being identified as a member of the command center staff. When the code is first called,

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staff should check their fellow staff, patients, families, and visitors; installed utilities and equipment, and if there are no injuries or damage, continue the provision of patient care or report to IC if you are a member of the command center staff. Any injuries or damage must be reported to the command center immediately. All staff and physicians should be prepared for reassignment as directed by their immediate supervisor, depending on the nature of the crisis.

B. **Communications**: The Paging Department staff is responsible for alerting key staff per the procedure and call tree when a Code is called, then providing updates via overhead announcement to all people in the hospital. All staff is responsible to check any communications equipment in their area and report system failures to the command center.

C. **Resources and Assets**: During a crisis, all staff is expected to conserve medical and non-medical supplies to the extent that it can reasonably be done without compromise to patient care. When a disaster code is called, Central Supply is responsible to verify current supply inventories, coordinate with vendors to fill any shortfalls, and be prepared to reallocate supplies as directed by the command center. Disaster Carts will be distributed to the designated areas.

D. **Safety and Security**: All staff and physicians are responsible to communicate any safety or security concerns immediately to the command center, attention the Safety Officer for resolution. All staff and physicians are also responsible in the course of their duties to report to Security anyone claiming to be on staff but without an ID badge and any personnel in, or attempting to enter, areas they are not authorized to enter.

E. **Utilities Management**: All staff and physicians are expected to reasonably conserve the demand on utilities in a crisis, without undue effect on patient care. All staff and physicians are responsible to immediately report any utility failures to the command center. Facilities department is responsible to manage primary and alternate utilities in an emergency, including the inventory of utility support requirements such as fuel, water, oil, etc.

F. **Patient Clinical and Support Activities**: All staff and physicians are responsible to communicate honestly with patients, visitors, and families, with respect to what they know, but should not speculate on events, situations, or plans unknown to them, but direct the question back to the command center.

STAFF ROLES AND RESPONSIBILITIES (Specific)

A. Initiate Department Call-Back Lists as necessary, based upon such information as:
   1. Nature and severity of the disaster
   2. Number of victims
   3. Type of injuries
   4. Time of day
   5. Current staffing
   6. Condition and availability of the facility, its equipment and materials
   7. Need for evaluation (consider number of patients, status, etc)

B. Medical Staff will remain in location and wait for further instruction. Medical Staff Office will initiate the call back roster as directed by the Medical Director.

C. Personnel/Volunteers will check in at the Labor pool (Located in the VCMC Cafeteria ~~Conference~~) at VCMC and the Cafeteria Dining Room~~) at VCMC and Dining Room~~ at SPH as directed.

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D. Physicians/Residents will continue their duties until otherwise assigned by Chiefs of Staff or the Medical Director.

E. The ED Physician and/or Nursing Supervisor will keep the Incident Command Center informed of the need for additional personnel to handle incoming victims and initiate the callback list for physicians and staff. Each department will initiate call back as needed or directed and send available personnel to the Labor Pool (VCMC Cafeteria) at VCMC and (Cafeteria ~~Conference~~Dining Room) at ~~VCMC and (Dining Room) at~~ SPH.

F. Employee Sign-In Section Personnel Time Sheet (HICS 252) to be used for all employees to sign in and out of each Department or Treatment Area.

G. Employee Relief: Schedule employees and assign meal breaks.

H. Resource Use: Document equipment/supplies procured from department and agencies.

I. IC to provide general guidance, resourced in the Incident Response Guide manual (IRG), for the immediate situation.

J. Report Forms: Departments will notify the Command Center within 30 minutes of initial notification, as to their ability to respond, when significant information changes, when fully staffed, and whenever requested by Incident Command.

K. Use of telephones will be limited to immediate needs of the disaster response.

L. Communications to be addressed by IC and the distribution of radios as needed.

M. In a County-Wise Disaster Event or during Off Business Hours, all personnel shall be ready to report when notified by Administration of immediate supervisor.

N. In the event that all telephone contact is out of service, all personnel shall report to the labor pool (located in the VCMC Cafeteria ~~Conference~~) at VCMC and (Cafeteria Dining Room) at ~~VCMC and (Dining Room) at~~ SPH for assignment and further instruction.

O. Should evacuation be required, location for all personnel is the Public Health parking lot on Hillmont ~~Rd~~Ave. to the west of the main hospital at VCMC and Parking Lot E at SPH.

P. All facility employees must wear their authorized employee identification badges at all times while in the facility or on its grounds. Personnel assigned to selected special duties may be required to wear position identification vests, ID tags and/or armbands identifying their disaster job titles.

Q. In the event of a lock-down to the facility or during a disaster, employees will use only the ~~Lab entrance~~Employee Entrance (VCMC) and the front entrance to the Emergency Department (SPH).

R. The Emergency Department Staff will use the Ambulance Bay Entrance (VCMC/SPH).

COMMUNICATION PROCESS AND TRAFFIC FLOW

Refer to Attachment A: Emergency Operations Plan.

EMERGENCY TREATMENT AREA LOCATIONS

Refer to Attachment A: Emergency Operations Plan.

DISASTER CONCLUSION

At the conclusion of the disaster, the Incident Commander will notify paging to overhead announce: CODE

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TRIAGE ER HAS BEEN CLEARED (**to be repeated twice**).

All HICS disaster supplies will be returned to the section chiefs. The section chiefs will ensure the supplies have been restocked and returned to storage.

EMERGENCY MANAGEMENT COMMITTEE

The Emergency Management Committee includes representatives from various key departments. The Chairman of the Committee will report activities to the Executive Environment of Care Committee and the general Environment of Care Committee. The Emergency Management Committee will meet at least quarterly. Written Drill critique will be filed with Environment of Care Executive Committee. Responsibilities of the Emergency Management Committee are as follows:

A. To coordinate and critique disaster events and drills.

B. To review and update the Emergency Operations Plan.

There will be a minimum of two emergency drills per year, at least 4 months apart, to include one that will have victim scenarios going through the system.

PERFORMANCE IMPROVEMENT

A. Immediately, or as soon as possible, following an actual disaster or drill, an informal critique of the incident will be held with major players to identify problems and successes. Location and time of the critique will be announced near the end of the incident.

B. Each department manager will review response to the disaster (drill) with his or her staff. Items to be included in the critique are as follows:

   1. Evaluation of facilities and department disaster plans and responses.
   2. Identification of any problems encountered.
   3. Recommendation of changes to the disaster plan, procedures, supplies and materials.
   4. Communication/coordination problems.
   5. Patient and staff movement problems.
   6. Other issues as appropriate.

C. The Emergency Management Committee will meet to:

   1. Review the critiques.
   2. Recommend updates to the disaster plans, as appropriate.
   3. Make recommendations on further testing on the disaster plan.

EMERGENCY RESPONSE EXERCISES

A. The hospital activates its Emergency Operations Plan at least twice a year at each site included in the EOP.

   1. The trauma program must participate in two hospital drills or disaster plan activations per year that include a trauma response and are designed to refine the hospital's response to mass casualty events.

B. For each site of the hospital that offers emergency services or is a community-designated disaster

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receiving station, at least one of the hospital's two emergency response exercises includes an influx of simulated patients.

1. A pediatric mass casualty incident drill will occur at least every two years.

C. For each site of the hospital that offers emergency services or is a community-designated disaster receiving station, at least one of the hospital's two emergency response exercise include an escalating event in which the local community is unable to support the hospital.

D. For each site of the hospital with a defined role in its community's response plan, at least one of the two emergency response exercises includes participation in a community-wide exercise.

E. Emergency response exercises incorporate likely disaster scenarios that allow the hospital to evaluate its handling of communications, resources and assets, security, staff, utilities and patients.

F. The hospital designates an individual(s) whose sole responsibility during emergency response exercise is to monitor performance and document opportunities for improvement.

G. During emergency response exercise, the hospital monitors the effectiveness of internal communication and the effectiveness of communication with outside entities such as local government leadership, police, fire public health officials, and other health care organizations.

H. During emergency response exercise, the hospital monitors resource mobilization and asset allocation, including equipment, supplies, personal protective equipment, and transportation.

I. During emergency response exercise, the hospital monitors:

1. Safety and Security;
2. Staff roles and responsibilities;
3. Utility systems, and;
4. Patient clinical and support care activities.

J. Based on all monitoring activities and observations, the hospital evaluates all emergency response exercise and all responses to actual emergencies using a multidisciplinary process including license independent practitioners.

K. The evaluation of all emergency response exercises and all responses to actual emergencies includes written documentation to identify deficiencies and opportunities for improvement.

L. Deficiencies and opportunities for improvement are communicated to the multidisciplinary Emergency Management Committee.

M. The hospital modifies its Emergency Operations Plan based on its evaluation of emergency response exercise and responses to actual emergencies.

N. Subsequent emergency response exercise will reflect modifications and interim measures as described in the modified Emergency Operations Plan.

O. Communication and documentation of modifications of the Emergency Operations Plan will be documented in the Emergency Management Committee minutes.

EDUCATION

Staff is trained for the emergency roles in the following ways:

A. New hire staff training: During the New Employee Orientation, emergency procedure policy, codes and responsibilities are presented.

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B. Annual staff training: Staff is required to complete safety training which includes emergency procedure policy, codes and responsibilities.

C. New hire physician training: During the New Physician Orientation, emergency procedure policy, codes and responsibilities are presented.

D. Incident Command System (ICS 100/200 HC) and NIMS (IS 700) training for hospital personnel who would assume a leadership role in the Hospital Command Center (NIMS Element 9 and 11).

E. National Response Plan (IS 800a) training for persons directly responsible for the Emergency Management Program (NIMS Element 10)

If Licensed Independent Practitioners volunteer or are transferred into the hospital, they will be oriented, assigned roles, and then proctored by the medical staff in accordance with the procedures established by the Emergency Management Committee according to the Emergency Operations Plan policy -- Disaster/ Emergency Volunteer Health Professionals Credentialing.

EVALUATION

At least annually the Emergency Operations Plan will be reviewed and revised, if necessary, by the Emergency Management Committee chair and approved by the Emergency Management Committee. The scope, objectives, and effectiveness of the EOP, as well as the effectiveness of the emergency operations planning activities will be reviewed. The Environment of Care Executive Committee and Administration will approve the review.

All revision dates:	3/30/2026, 6/17/2024, 4/17/2024, 12/13/2022, 8/2/2019, 6/1/2016, 2/1/2014, 6/1/2011, 11/1/2010, 12/1/2007, 10/1/2006, 5/1/2006

Attachments

- Emergency Operations Plan
- Emergency Operations Plan Appendix A 96-Hour Critical Supplies and Strategies for Extension
- Emergency Operations Plan Appendix B Hazard Vulnerability Assessment
- Emergency Operations Plan Appendix C Emergency Contacts Directory
- Emergency Operations Plan Appendix D Emergency Supply Inventory
- Emergency Operations Plan Appendix E VCMC HICS Assignments
- Emergency Operations Plan Appendix F SPH HICS Assignments
- Emergency Operations Plan Appendix G Evacuation Plan & Rally Points
- Emergency Operations Plan Appendix H Tarp Tent Set-Up Map

Approval Signatures

Step Description	Approver	Date
Medical Executive Committee	Stephanie Denson: Manager, Medical Staff Office	pending
Hospital Administration	Minako Watabe: Chief Medical Officer, VCMC & SPH [AB]	4/6/2026

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Step Description	Approver	Date
Hospital Administration	Osahon Ekhaese: Chief Operating Officer, VCMC & SPH	4/2/2026
Nursing Administration	Sherri Block: Associate Chief Nursing Executive, VCMC & SPH	3/30/2026
Nursing Administration	Danielle Gabele: Chief Nursing Executive, VCMC & SPH	3/30/2026
Emergency Management Committee	Fernando Medina: Director, Support Services	3/30/2026
Policy Owner	Fernando Medina: Director, Support Services	3/30/2026

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VENTURA COUNTY HEALTH CARE AGENCY

Origination:	*1/1/2003*
Effective:	*Upon Approval*
Last Approved:	*N/A*
Last Revised:	*1/1/2026*
Next Review:	*1 year after approval*
Owner:	*Alicia Casapao: Director of Quality and Performance Improvement*
Policy Area:	*Administrative - Operating Policies*
References:	

107.027 Quality Assessment and Performance Improvement Plan

POLICY:

The Quality Assessment & Performance Improvement (QAPI) Plan is a description of the efforts that are directed towards ensuring the consistent delivery of safe, quality, service-focused, effective health care for the patients we serve at Ventura County Medical Center (VCMC)/Santa Paula Hospital (SPH) and in the licensed hospital, Ambulatory Care (AC) clinics.

We look to achieve this through data assessment, outcomes review, process examination, ~~evidenced~~ evidence-based practice research, as well as the identification of opportunities for change and improvement. This is accomplished by systematically assessing patient outcomes and support processes to identify improvement opportunities, and to act on them in a timely manner.

The intent of the plan is the improvement of key clinical, support, and managerial processes that are most important to the health and safety of our patients. Equally important, is our belief that each patient is entitled to quality health care and that every employee is individually obliged to contribute toward the improvement of patient care and safety. To fulfill this obligation, a plan has been developed, and the organization shall nurture an environment that is supportive of excellence and learning, and one that is conducive to positive change.

GOALS AND OBJECTIVES:

In an effort to improve performance in clinical processes and outcomes, as well as to sustain performance, once it is improved, the primary goal of the QAPI Plan is to provide a comprehensive performance improvement program that will coordinate and integrate performance improvement activities across VCMC/SPH and the AC clinics. The approach to performance improvement is the continuous assessment and revision, when required, to meet the goal of ensuring that patient outcomes are continually improved and that safe care is provided.

The objectives of the QAPI Plan include, but are not limited to:

1. Establish priorities for review, investigation, and implementation of changes. Special consideration will be given to processes with the greatest impact on patient outcomes and those that are of the highest risk to patients.
2. Improve processes utilizing established performance improvement tools and techniques, as well as systems thinking.

3. Maintain a framework for improving performance that includes activities focusing on process design and redesign, while measuring, assessing, and improving performance.
4. Identify, assess, and implement corrective action plans for urgent situations requiring immediate action, such as processes that involve risks, have the potential for medical error, or may result in patient harm.
5. Conduct intensive analysis when significant undesirable performance is detected or suspected.
6. Ensure that accurate, valid data is available to monitor performance, and is used to identify opportunities for change.
7. Collect data designed to monitor the stability of existing processes, identify opportunities and changes that will lead to improvement, and document areas of sustained improvement.
8. Communicate outcomes of reviews and corrective action plans, to facilitate change.
9. Conduct ongoing and systematic assessment and documentation of hospital-wide issues, which have a direct or indirect impact on patient care.
10. Coordinate medical staff quality improvement activities with others within the organization, and integrate efforts whenever appropriate.
11. Maintain compliance with regulatory standards, which include those outlined in the Conditions of Participation (CoPs), via the Centers for Medicare and Medicaid Services (CMS), The Joint Commission (TJC), and the California Department of Public Health (CDPH): Title XXII.
12. Monitor, trend, communicate, and implement interventions to improve the patient's perceptions of care that they received, while hospitalized.

Areas to consider when fostering a culture of improvement ~~includes~~include reducing factors known to contribute to adverse events and poor outcomes. These factors are often predicated on poorly designed systems, unanticipated system failures, and failures in processes.

Opportunities to minimize these factors include, but are not limited to:

1. Recognizing and minimizing risks and/or processes that may lead to adverse events.
2. Communication regarding adverse events, in an effort to reduce future events and develop specific process change(s), to ensure similar events do not ~~reoccur~~recur.
3. Focusing on processes and systems while continuing to hold individuals accountable for their personal responsibilities, which includes fostering an environment that supports the principles of a "Just Culture."
4. Exploring processes, tasks, equipment, and other factors that may have contributed to adverse events.
5. Agreeing that standardized processes will lead to predictable outcomes and that aspiring to become a highly reliable organization requires a deference to operational experience and a predisposition ~~with~~to the fact that failure may occur.

~~THE~~ PERFORMANCE IMPROVEMENT COORDINATING COUNCIL (PICC):

The ~~Performance Improvement Coordinating Council (~~PICC~~)~~ functions as the quality improvement committee for the hospitals and provides a forum for performance improvement (PI) activities, with primary responsibility for the quality assessment and performance improvement (QAPI) programs within the organization, including those related to regulatory compliance.

~~The~~ PICC membership includes, but is not limited to:

1. Executive leadership
2. Representatives of the medical staff
3. Departmental directors and managers, and other members of the health care team.

   Every leader and department participates in PI and safety efforts, with the intent of fostering departmental leadership and encouraging staff participation.

~~The~~ PICC meets no less than 4 times each year, to monitor improvement activities and review quality metrics, in order to identify and prioritize improvement activities. Each meeting includes a review of current and proposed activities within the organization, along with an analysis of data, to demonstrate the extent ~~that~~to which these activities were successful, in achieving the intended outcomes.

The patient and family are the primary focus of every QAPI activity. The QAPI team shares the task of performance improvement with everyone who works at VCMC/SPH and the AC clinics. The QAPI team operates under a set of guiding principles, which include:

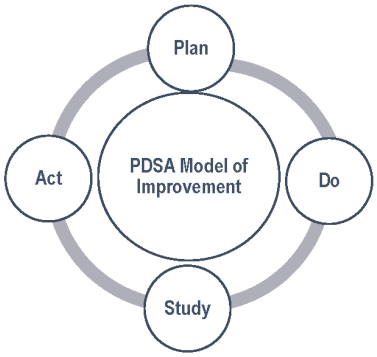
1. Ensuring that data is timely, relevant, and valid.
2. Performance improvement efforts are visible throughout the organization.
3. Collaboration~~, in order~~ - to drive efforts to optimize patient outcomes and improve processes, which are the foundation of all QAPI activities and efforts.
4. Serving as subject matter experts who collaborate with others, ~~in order~~ to continually improve patient safety and serve as performance improvement mentors.
5. Ensuring that evidence-based principles of performance improvement are applied to improvement teams, processes and efforts.

METHODOLOGY AND MODEL OF IMPROVEMENT:

Performance Improvement (PI) methodologies, tools, and strategies are integrated into activities to improve patient outcomes.

The **Plan, Do, Study, Act (PDSA)** is the primary methodology used within the organization:

- **P**lan the improvement and continued data collection
- **D**o Improvement, data collection, and analysis
- **S**tudy the results
- **A**ct to correct identified problem areas or improve performance.



Plan

Performance improvement projects are designed or redesigned to monitor expected performance. Projects are developed to measure, assess, improve, and maintain process improvements.

Performance goals are established through comparison with other "like" facilities, and benchmarking with national and regional results. Comparative data from the National Healthcare Safety Network (NHSN), CMS, TJC, or current/past department performance is utilized as well.

Do

Data collection is the basis of all performance improvement activities and provides a means of measuring performance, through which informed decisions can be made.

Study

Activities are assessed, reviewed, and trended, to determine if process changes, interventions, or policies need to be created or revised. Changes that may need to occur may appear as:

1. System(s): Changes in communication channels, changes in organizational structure, adjustments in staffing, and changes in equipment or documentation;
2. Knowledge Enhancement: In-service education, continuing education, and circulating informational material;
3. Intensive Reviews/Focus Studies: When a medical/health care system, error-related occurrence is identified; proactive risk assessment activities are implemented, including intensive review and/or a focused study. A data collection tool is developed to address processes, functions, and services that can be designed or redesigned to prevent trends that may have contributed to the problem. Once all charts are reviewed, a summary report is compiled to report the conclusions.
4. Root Cause Analysis: An event where a medical/health care error is established as a near miss, a causal analysis is completed to determine the underlying causes of the potential variation, and the outline action plan is implemented.
5. Policy Revisions: Policies are developed or revised for significant organizational issues that are either interdepartmental or mandated to be hospital-wide, by accreditation agencies or state/federal legislation.
6. Proactive Risk Assessment/Failure Mode Effects Analysis: A Proactive Risk Assessment, which is commonly referred to as a Failure Mode and Effects Analysis (FMEA), will be conducted at least once every 18 months on one high-risk, high/low volume, or "error -prone" process. Once potential issues have been identified, the organization will establish processes to improve performance and measures to provide follow-up to ensure that improvement is maintained and that the information learned is communicated.

Act

When opportunities for improving performance are identified, a systematic approach is utilized to redesign the involved process, or to design a new process. When a department or service identifies an opportunity for improvement, the department/service will determine if other disciplines or departments will have an impact on the design/redesign of the process. If other disciplines or departments are involved, the opportunity for improvement will be referred to the appropriate department.

The approach to improving performance at VCMC/SPH and the AC clinics is based upon the following three questions:

1. What are we trying to accomplish?
2. What change can we make that will result in improvement?
3. How will we know that a change is an improvement?

Once those questions are answered, VCMC/SPH and the AC clinics examine “best practice” models that can be adopted and implemented. Results are monitored, rapid cycle changes are made, as indicated, and monitoring continues. The performance improvement model provides:

1. A systematic method for the design of a process.
2. Measurement of the level of performance and stability of important processes.
3. Assessment of the dimensions of performance, as relevant to functions, processes, and outcomes.
4. Development of a plan for improvement.
5. Implementation of the outcomes.
6. Evaluation for additional opportunities for improvement.

Data Collection:

Each clinical professional discipline (hospital staff and medical staff) ~~participate~~participates in the review of patient care/ services it provides. Results and/or findings and actions are reported through the defined reporting structure.

Information obtained through the performance improvement review ~~are~~is, when indicated, a cause for action and a resource for educational programs ~~with the objective of benefiting~~to benefit the patients, staff, hospital, and the community.

Sources of data for PI review activities include, but are not limited to:

1. Review of data related to patient safety events;
2. Performance measures related to accreditation and regulatory agencies, as well as other acceptable databases;
3. Patient throughput;
4. Outcomes measures;
5. Morbidity/mortality review findings;
6. Monitoring activities of the medical staff and hospital departments or committees;
7. Risk management findings;
8. Infection control review: surveillance, prevention, and reporting;
9. Medication use review;
10. Laboratory activities, including blood utilization and autopsy results;
11. Organ procurement activities, including conversion rates;
12. Utilization management review;
13. Staffing effectiveness;
14. Patient and staff satisfaction surveys;

15. Externally generated data received by the hospital;
16. Customer demographics and diagnoses;
17. Information management and medical record reviews;
18. Department -specific indicators and PI team activities.
19. Guidance/direction from regulatory agencies, ie., TJC, CMS, CDPH, etc.

Performance measurement data will be collected, aggregated, and analyzed, to determine if opportunities are identified, to improve safety and reduce risk. If performance improvement opportunities exist, the organization will prioritize those processes that demonstrate significant variation from desired practice, and allocate the necessary resources to mitigate the risks identified. The data will be utilized to:

1. Assess the intended and actual implementation of the process, to identify the steps in the process where there is, or may be, undesirable variation.
2. Identify the possible effects on patients, and how serious those effects could be (criticality of the effect) for each undesirable variation.
3. Conduct a Root Cause Analysis [2] (RCA[2]) for the most critical effects, to determine why the variation led to that result.
4. Redesign the process and/or underlying systems to minimize the risk of that variation, or to protect patients from the effects of that variation.
5. Test and implement the redesigned process.
6. Identify and implement measures for the effectiveness of the redesigned process.
7. Implement a strategy for maintaining the effectiveness of the redesigned process over time.
8. When processes, functions, or services are designed or redesigned, patient safety will be considered as part of the planning and implementation process.
9. Opportunities to reduce errors, which reflect the performance of the individual care provider, are addressed as appropriate, through the Medical Staff Peer Review process or through the organization's Human Resource policy(s).

Examples of data collected and employed interventions, to improve related outcomes (not limited to):

1. Operative or other procedures that place patients at disability or death;
2. Discrepancies between pre- and post-operative diagnosis;
3. Events associated with sedation;
4. Administration of blood and blood components;
5. Transfusion reactions;
6. Resuscitation efforts;
7. Medication errors;
8. Adverse drug events;
9. Patient thermal injuries;
10. Incidents or injuries related to ferromagnetic objects in the magnetic resonance imaging (MRI) scanner room.

In order to reduce the likelihood of patient incidents and negative outcomes, VCMC/SPH and the licensed AC clinics shall track the frequency and type of medical errors and compile them, in order to learn from and prevent future negative occurrences.

The Information Technology (IT) Department provides hardware and software support for the performance improvement activities of VCMC/SPH and the AC clinics. Data sources include, but are not limited to, the following:

Internal Sources

1. Incident Reports from Notification System;
2. Adverse Drug Events and Adverse Drug Reactions;
3. Data from Patient Complaints;
4. Risk Management and Safety Findings;
5. Compliance Findings;
6. QAPI and special study findings, i.e., tracer audits centered around areas such as high-level disinfection practices, ligature risk assessments, and sterile compounding processes;
7. Infectious Disease Information;
8. Operative/Invasive Procedure, Blood Use, Autopsy, Restraint Reviews;
9. Morbidity/Mortality Review Findings;
10. Departmental Indicators;
11. Staff Surveys (includes perception of risk).

External Sources

1. The Joint Commission (TJC) accreditation standards, TJC Sentinel Event Alerts, and TJC ~~FAQs~~FAQ,s as well as communication related to the National Patient Safety Goals;
2. Core Measures Indicators;
3. Accreditation / Regulatory Deficiencies;
4. Patient Satisfaction Surveys;
5. Other Evidence-Based external sources.

Regulatory Reporting

The VCMC/SPH and the hospital clinics ~~collects~~collect, ~~reports and analyzes~~report, and analyze data for submission to the Centers for Medicare & Medicaid Services (CMS) as well as to a variety of other regulatory entities. Data submission includes, but is not limited to:

1. Inpatient Quality Reporting (IQR);
2. Meaningful Use (MU);
3. Electronic Clinical Quality Measures (e-CQM);
4. Hospital Acquired Conditions (HACs);
5. Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS).

Additional Program Activity

Improvement activities may be conducted in partnership with other improvement programs. Every improvement project is driven by measurable performance indicators. Relevant systems and sources of data inform the measurement of improvement. Evidence-based guidelines and current clinical literature provide information to guide improvement focus and measurement. Teams with operational and clinical representation design interventions to achieve targeted outcomes.

Authority, Accountability, and Responsibility

The Oversight Committee has the ultimate responsibility for assuring the quality and effectiveness of patient care services provided by VCMC, ~~SPH~~SP,H and the AC clinics. The Oversight Committee holds the medical staff leadership and hospital administration responsible for the establishment and maintenance of an effective Performance Improvement (PI) program. This includes maintenance of safe and effective care, the provision of PI management, planning PI activities ~~and~~, and the development of PI policies when indicated. The Oversight Committee has responsibility, either directly or through delegation, for the assessment and recommendations regarding the program's efficiency and effectiveness. The Oversight Committee is provided performance improvement updates on a quarterly basis and/or more frequently as indicated by a regulatory agency's activities.

The Chief Operating Officer (COO) has oversight for Performance Improvement, Quality Assessment, and Patient Safety. The COO reports to the Chief Executive Officer (CEO)/Administrator, who in turn reports to the Ventura County Health Care Agency Director. The CCO is responsible for the QAPI Department and will provide reports to the Medical Executive Committee and to the Oversight Committee.

Performance Improvement activities are the responsibility of every department and every employee within the organization. In an effort to minimize patient harm, maximize clinical outcomes, and sustain improvement momentum, the QAPI Department is responsible for coordinating, communicating, ~~integrating~~integratin,g and disseminating performance improvement activities within the organization and to ensure that regulatory compliance is maintained.

Medical Staff

The Medical Staff, through the Medical Executive Committee (MEC), has the responsibility for medical care rendered at VCMC/SPH and the licensed hospital clinics. The Medical Staff departments meet as designated in their rules and regulations to evaluate process and outcomes data. The Department Chair is responsible for reporting, monitoring, and evaluating the outcomes and processes of performance improvement activities for the department. Outcomes and processes are reported up to the MEC and to the Oversight Committee as appropriate. The Medical Staff Rules and Regulations describe the scope of Medical Staff departments.

Each service or department develops a performance improvement plan specific to that department and selects or recommends improvement actions. Each department utilizes the pattern of care demonstrated by the results of the performance improvement monitoring and evaluation activities, as criteria for evaluating the competence of licensed independent practitioners and allied health professionals. These activities include, but are not limited to, patient care review, generic screening case review, utilization review, infection control review, operative and other invasive/non-invasive procedure review, medical record review, blood and blood component review, medication use review, and risk management review.

All information gathered is considered confidential and, as part of the medical staff records, is protected under California Evidence Code 1157. When the findings of the assessment process are relevant to an individual's performance, the medical staff is responsible for determining their use in ongoing professional practice

evaluation, focused professional practice evaluation, peer review and/or any other periodic evaluations of a licensed independent practitioner's competence.

Plan Evaluation

On an annual basis, or more frequently as indicated, the QAPI Plan will be reviewed, evaluated, and revised to incorporate the most current TJC, CMS and CDPH regulatory standards. The review will assess the objectives, scope, organizational ~~effectiveness~~effectivenes,s and appropriateness of the program. The plan will be modified as needed, based on the results of the evaluation or more frequently if indicated. Individual committees and departments will review, evaluate, and revise their performance improvement activities which may be re-prioritized based on significant organizational performance findings or changes in regulatory requirements, patient population, environment of care, or based upon expectations and needs of patients, staff, or the community. Priorities may be reset by the multidisciplinary ~~Performance Improvement Coordinating Council (PICC)~~QAPI/PSC in consultation with senior management, the MEC and/or the Oversight Committee ~~in consultation with senior management, the MEC and/or the Oversight Committee~~.

Confidentiality

The Ventura County Health Care Agency (VCHCA) ensures the privacy and confidentiality of patient records and other protected information. All information generated within or as a result of the Quality and Performance Improvement Program and all peer review discussions and records are confidential and protected by California Evidence Code §1157.

Patient records and information are safeguarded and protected. Health information is shared in accordance with state and federal laws, statutes and guidelines. VCMC/SPH and AC clinics strive to ensure effective coordination of care with other providers and participates in efforts to legally and appropriately share information with partnering organizations to support integrated, patient-centered care for each person as a whole.

Persons receiving health care services have a right to expect that the confidentiality and privacy of individually identifiable medical information of or derived by health service providers will be reasonably preserved. The VCHCA complies with the Confidentiality of Medical Information Act (1982) and releases information pursuant to HIPAA, Lanterman-Petris-Short Act, Title 22, and other applicable state and federal guidelines, statues and laws.

Policies that ensure privacy and confidentiality and appropriate release of medical records include:

1. An Oath of Confidentiality must be signed by all employees as a condition of employment.
2. Proper logging and control of patient records.
3. Controlled access to electronic medical information.
4. Regular security risk analysis to identify and mitigate risks.

APPENDICES:

1. Appendix A - Quality Assessment & Performance Improvement Plan Measures and Metrics ~~2019-2020~~2025-2026

All revision dates: 1/1/2026, 1/10/2023, 11/10/2021, 4/17/2020, 8/1/2015, 9/1/2013, 10/1/2011, 1/1/2011, 5/1/2006, 1/1/2005, 1/1/2004

Attachments

107.027 Appendix A - Quality Assessment & Performance Improvement Plan Measures and Metrics 2025-2026.pdf

Approval Signatures

Step Description	Approver	Date
Medical Executive Committee	Stephanie Denson: Manager, Medical Staff Office	pending
Hospital Administration	John Fankhauser, MD: Chief Executive Officer, VCMC & SPH	3/30/2026
Hospital Administration	Osahon Ekhaese: Chief Operating Officer, VCMC & SPH	2/26/2026
Hospital Administration - CMO	Minako Watabe: Chief Medical Officer, VCMC & SPH [AB]	1/26/2026
Quality Assessment & Performance Improvement	Alicia Casapao: Director of Quality and Performance Improvement	1/1/2026

VENTURA COUNTY HEALTH CARE AGENCY

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Policy Area:	*Laboratory Services*
References:	

L.22 Laboratory Specimen Priority

POLICY

The Ventura County Medical Center/Santa Paula Hospital Laboratory defines turn-around time (TAT) as the time elapsed from the receipt of the request in the Laboratory to the time when the final result is available. Laboratory procedures can be defined as **ROUTINE, TIMED DRAW, OR STAT.**

PROCEDURE

ROUTINE REQUEST

The majority of requisitions fall into this category. Routine requests will be collected Monday to Friday (06:00-17:00) and Saturday, Sunday and holidays (06:00-12:00). The following is a list of protocols for ROUTINE requests:

- Requisitions in the Laboratory by 1:00 am will have results available by 9:00 am (excluding those tests which take longer to perform or are not performed everyday) or within four (4) hours of collection.
- Requisitions in the Laboratory after 4:00 am will be collected on the next routine run. Results will be available as soon as they are verified by testing personnel.

TIMED DRAW

Requisitions for timed draws must be in the laboratory two (2) hours in advance of the specified collection time. Tests will be performed upon receipt in the laboratory and resulted as soon as verified by testing personnel.

STAT REQUEST

STAT requests designate laboratory procedures vital to the immediate medical management of the patient. This is to be determined by the requesting provider.

Laboratory turn-around time for these procedures is approximately one (1) hour.

- STAT testing is available 24 hours a day, 7 days a week, including holidays and weekends.

The following list of tests will be the ONLY tests available as "STAT."

Ordering healthcare providers who deviate from this list must contact the Pathologist on duty and obtain authorization. *Fill out attached "Deviation from Standard Operating Procedure" to document.*

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- Laboratory staff will facilitate this authorization by supplying the pathologist's standby phone number.

BLOOD BANK

- Type, Screen and Hold
- Type and Crossmatch
- HDN Workup

CHEMISTRY

- Acetaminophen
- Acetone
- Albumin
- Alkaline phosphatase
- Alcohol - ethyl
- Ammonia
- Amylase
- Bilirubin - Total and Direct
- BNP (NT-proBnP)
- BUN
- Calcium
- Cardiac Panel
- Creatinine (serum and urine)
- CRP
- Digoxin
- Dilantin (Phenytoin)
- Drug Screens
- Electrolytes
- Fetal Fibronectin
- Fluids
- Glucose
- HCG serum or urine
- Iron
- Lactic Acid
- Lithium
- Magnesium
- Osmolality
- Phenobarbital
- Phosphorus
- Procalcitonin (2 hour turn-around-time)
- Salicylate
- SGOT (AST)
- SGPT (ALT)
- Tegretol (Carbamazepine)
- Theophylline
- Tobramycin
- Troponin
- Uric Acid
- Vancomycin

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- Valproic Acid

HEMATOLOGY

- CBC
- CBC and Differential
- Fluid cell count and differential
- Sedimentation Rate

COAGULATION

- D-Dimer
- Fibrinogen
- PTT
- anti-Xa UNFH
- Anti-Xa LMWH
- Protime
- ROTEM

MICROBIOLOGY

- Blood Cultures
- Gram Stains
- Body Fluid Culture and Gram Stain
- AFB Stain (spinal fluid)
- India Ink Prep (spinal fluid)
- Malarial Smears

URINALYSIS

- Routine Urinalysis
- Urinalysis with Microscopic

IMMUNOLOGY

- HIV - STAT
- Influenza A&B
- MAP
- RSV

EXCEPTIONS

Exceptions to the above policies should be evaluated on an individual basis. When evaluating each case, common sense and patient care should always be considered by everyone concerned. In general, when pathologists are not on site, Clinical Laboratory Scientists (CLS) should attempt to perform the procedure and then refer the problem to the pathologist the next working day. *File a "Deviation From Standard Operating Procedure Form."*

NOTIFICATION OF TESTING DELAYS

When STAT test(s) TAT is expected to be significant for individual patients, it is the responsibility of the Clinical Laboratory Scientist/Medical Laboratory Technician performing the test to use judgment and inform the ordering provider and/or patient's nurse of the delay and to give them an accurate expectation for

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completion of the testing.

This information should be documented in laboratory information system, the specimen result form or on the specimen worksheet.
When STAT test(s) TAT is expected to be significant because of instrument (system) issues, it is the responsibility of the supervisor (or senior CLS) to notify the Emergency Department (ED) and the Nursing Supervisor. The calls to ED and the Nursing Supervisor will be documented on a Notification Form originating in the Laboratory section where the responsibility for that particular instrument/testing resides. Return the form to the Laboratory Manager when the event has been completed and documented.

When test results require repeat testing (re-run or re-draw), immediately notify ordering healthcare provider responsible for the patient by phone and/or TigerText messaging.

When routine testing exceeds expected TAT, the House Supervisor will be notified as indicated above (i.e., CBC's or Basic Metabolic Panels, instruments down, expected time for repairs, backup available for testing, etc.). The House Supervisor will, in turn, notify the nursing units of the situation. In extended downtime or special circumstances, specimens may be sent to other laboratories for testing

All revision dates: 11/15/2024, 7/26/2022, 12/1/2016

Attachments

Deviation from Standard Operating Procedure Form TEMPLATE.doc

Approval Signatures

Step Description	Approver	Date
Medical Executive Committee	Stephanie Denson: Manager, Medical Staff Office	pending
Laboratory Services Department	Gayle Haider: Supervisor-Quality Assurance, Laboratory Services	4/2/2026
Laboratory Services Department	Erlinda Roxas: Director, Laboratory Services	3/26/2026
Laboratory Services Department	M. Anwar Molani: Medical Director, Laboratory Services	3/25/2026

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Owner:	*Erlinda Roxas: Director, Laboratory Services*
Policy Area:	*Laboratory Services - Blood Bank*
References:	

L.BB.42 Reconstitution of Blood for Exchange Transfusions

PRINCIPLE:

Blood for exchange should have a hematocrit~~,~~ which approximates that of ~~the~~a healthy neonate. The hematocrit level and volume required ~~depends~~depend on the gestational age and clinical condition of the baby and will be specified by the Neonatologist. The following formula allows the technologist to calculate the amount of Fresh Frozen Plasma (FFP) needed to achieve the desired hematocrit in the reconstituted blood.

W (FFP) = [(**Hct RBC/Hct RB**) – 1] x W (RBC)
~~**Hct RB**~~

1. **Hct RBC =** Hct of Donor ~~Cells~~Red Blood Cell Unit
2. **W(FFP) =** Vol of ~~FFP~~Fresh Frozen Plasma needed
3. **Hct RB =** Hct of Reconstituted Blood
4. **W(RBC) =** ~~weight of RBC~~Weight of Donor Red Blood Cell Unit

REAGENTS, MATERIALS, AND SPECIAL EQUIPMENT

1. Dietary Scale
2. Plasma Transfer set
3. Hematron Sealer
4. 600 mL transfer bags
5. Donor ~~Cells~~RBC unit (see below for criteria)
6. Group AB Fresh Frozen Plasma Unit, Thawed

DONOR RED BLOOD CELL UNIT CRITERIA

1. Use donor ~~blood~~RBC unit no older than 5 days (excess potassium consideration). If donor ~~blood~~,RBC unit less than 5 days old~~,~~ is not available, have the blood supplier wash the freshest baby unit they have.
2. NOTE: In a grave situation when the baby is ~~subjected~~subject to bilirubin encephalopathy and kernicterus, the physician may waive the need to obtain a RBC unit that is less than 5 days old ~~RBC unit~~

or washed unit (which would avoid the complicationscomplication of hyperkalemic cardiac arrythmiasarrhythmias) and accept the available product on hand (CMV Neg, Irradiated, Hgb S negativeNegative, O Negative RBC) for the exchange transfusion. The Blood Bank CLS will fill out a Deviation fromFrom Standard Operating Procedure form. The CLS will notify the Pathologist, have the pathologistwho will discuss this with the Ordering physician. Once the Ordering physician acknowledges the possible complication of hyperkalemic cardiac arrhythmia via the waiver listed above, the Pathologist will approve it after he discussed with the Ordering physician and the Ordering physician acknowledges his awareness of possible complications of hyperkalemic cardiac arrythmias from such waiver listed abovethe deviation.

3. Donor bloodRBC unit must be compatible with the MomMother:
   a. If the momMother has an antibodyany clinically significant antibodies, the donor unit must be negative for the corresponding antigen(s).
   b. Crossmatch the unit (s) with the MomMother's plasma. If the MomMother's plasma is not available, crossmatch the donor RBC unit with the baby's plasma.
4. Donor bloodRBC unit should be CMV Neg, Irradiated, and Hgb S negativeNegative.

PROCEDURE

1. Mix donor cells well. Express a small amount of the blood into a small satellite bag and perform ameasure the hematocrit. The hematocrit of the donor RBC unit should be between 60%-70in the range of 60-70%.
2. Weigh the parent donor bag. Subtract 55 grams for the weight of thean empty bag or tare the scale accordingly.
3. Do the calculations to determine the volume of Fresh Frozen Plasma (FFP) needed to achieve the desired Hematocrithematocrit.
4. **If the total volume of the reconstituted blood is significantly less than the Doctoramount ordered, it will be necessary to prepare a second bag for transfusionstransfusion. This willmay be the case if a double exchange is being done.**

   EXAMPLE:

   The Physician requests an exchange with a Hctreconstitute blood with a hematocrit of 55%. The donor RBC donor unit weights 300 grams and has a hematocrit of 70%.

   W (FFP) = 70((70/55) – 1) x (300)

   55

   W (FFP) = (1.27-1) x 300 or = 0.27 x 300

   W (FFP) = 81 mL

   Total Volume (TV—) = 300 RBC + 81 FFP

   TV = 381 mL
5. The calculated amount of Fresh Frozenvolume of FFP is added to the red cells using a Plasma is added

~~to the cells using a Plasma~~ Transfer Set (PTS). Any excess ~~Fresh Frozen Plasma~~FFP is discarded. After the addition of the ~~Fresh Frozen Plasma~~FFP, seal the PTS line using the Hematron Sealer. Separate the line at the seal and tape the PTS spike into the red cell unit port.

6. If the volume of the reconstituted blood is significantly greater than ~~that requested by the Physician~~the amount ordered, transfer the excess volume into as many pediatric satellite bags as necessary~~ and label~~. Label each satellite bag. These will be kept in case another exchange is necessary.
7. ***Remember that the expiration date of the reconstituted unit (and all aliquots) is just 24 hours from when the donor ~~red cell~~RBC unit was first entered.***

REFERENCES:

1. Sotelo-Avila, Brovillette, Gould "The Hematocrit of Reconstituted Blood for Exchange Transfusion in Newborn Infants". **The Journal of Pediatrics**, June 1982, pp. 393-398.
2. Funk, Mark K MD, PhD. *Technical Manual.* Bethesda, Maryland: American Association of Blood Banks, Current Edition
3. *Standards for Blood Banks and Transfusion Services*, Bethesda, Maryland: American Association of Blood Banks, Current Edition.

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Attachments

No Attachments

Approval Signatures

Step Description	Approver	Date
Medical Executive Committee	Stephanie Denson: Manager, Medical Staff Office	pending
Blood Usage Committee	Francisco Bracho: MD	3/26/2026
Blood Usage Committee	Kathrina Barcena: Supervisor-Blood Bank, Laboratory Services	2/5/2026
Laboratory Services Department	Erlinda Roxas: Director, Laboratory Services	1/24/2026
Laboratory Services Department	Linda Lee: Medical Director, VCMC Blood Bank	9/30/2025

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Policy Area:	*NICU*
References:	

N.46 Neonatal Preoperative and Postoperative Surgical Care

PURPOSE:

To provide standardized and evidence-based care of surgical neonates with the overall goals of infection prevention, nutritional balance, pain management, achievement of age-appropriate health status, and provision of family-centered care in accordance to California Children's Services (CCS) and Title XXII regulations and quality of care for the infant undergoing surgery.

To outline preoperative and postoperative surgical care of the neonate in the Neonatal Intensive Care Until (NICU).

To ensure safety and quality of care for the preoperative and postoperative infants.

POLICY:

~~To outline preoperative and postoperative surgical care of the neonate in the Neonatal Intensive Care Until (NICU).~~

A. The infant undergoing surgery has pre-operative assessment performed by a registered nurse (RN).

B. Pre-op orders by neonatologist must be documented in Electronic Health Record(EHR).

C. A verbal report using SBAR is given by a NICU RN to an Operating Room (OR) Team nurse using the same criteria as a change of shift report.

D. The (NICU) infant has a RN (trained in neonatal care) stay in the OR throughout the surgical period (including transport to and from the NICU).

E. NICU infant can have a surgical procedure in the OR or in the NICU.

F. Criteria that may indicate the surgery is done in the NICU includes, but is not limited to the following:

1. Physiologically unstable infant.
2. Infant with a communicable disease.
3. Very Low birth Weight (VLBW) infant at increased risk during transport.
4. Infant on an oscillating ventilator.

PROCEDURE FOR PRE-OPERATIVE:

~~The Registered Nurse (RN) physically prepares the neonate for surgery. The physician explains the procedure to the parents/guardian. A "Consent for Surgery" form is signed by the parent/guardian prior to the procedure except in an emergency and the family is unavailable.~~

~~The following procedures may be performed in the NICU: Chest tube insertion, laser eye, patent ductus arteriosus (PDA) , and central nervous system cutdown. Circumcision is performed in the designated area of the Maternal Infant Unit. See related policies and procedures. Other surgeries are undertaken in the Operating Room.~~

~~A.~~ ~~**Preoperative**~~

~~1. Verify signed consent on the chart.~~
~~2. Lab work and diagnostic studies completed. Results on chart.~~
~~3. *If ordered*, unit of pack red blood cells (PRBC) on hold in Blood Bank.~~
~~4. Maintain IV access for surgeries other than circumcision.~~
~~5. Record vital signs, blood glucose, accurate Intake and Output in the chart, bring chart with addressograph plate to the Operating Room.~~
~~6. Neonate is accompanied to the Operating Room by the RN and other health care team member as necessary providing thermal and airway support.~~

~~B.~~ ~~**Intraoperative**~~

~~1. The RN stays with the patient and assists with care of NICU equipment, as necessary.~~

~~C.~~ ~~**Postoperative**~~

~~1. See related guidelines for specific procedures.~~
~~2. Vital signs every 15 minutes X4, every 30 minutes X2, every hour until stable. Then every 2 hours.~~
~~3. Monitor for signs of pneumothorax, perfusion changes, and change in ventilatory needs.~~
~~4. Assist with Chest x-ray, labs, and other procedures as required.~~
~~5. Parents may visit when infant is stabilized.~~
~~6. Assess for pain, offering comfort measures/medication.~~
~~7. Cleanse skin of any remaining povidone iodine solution.~~
~~8. Monitor surgical dressing and site for drainage, hemorrhage.~~

~~DOCUMENTATION~~

~~A. Intake and output, vital signs, Laboratory work document in the Electronic Health Record (EHR).~~
~~B. Procedures and patient tolerance, nursing interventions document in EHR.~~
~~C. Medications, IV/IA fluids: time, route in the EHR.~~
~~D. Surgical Consent, Anesthesia record – file in chart~~

A. PRE-OPERATIVE:

1. The infant's record is reviewed for Physician's pre-op orders.

2. An informed consent for the surgical procedure is signed by the parent/guardian and the physician authorized to do the surgery. Whenever possible, informed consent for surgical procedure is obtained at least 24-hours prior to surgery.
3. An informed consent for the anesthesia is signed by the parent/guardian and the anesthesiologist.
4. NPO status is verified.
5. An IV site is available for medication as ordered. Maintain IV access for surgeries other than circumcision.
6. *If ordered*, unit of packed red blood cells (PRBC) on hold in Blood Bank.
7. A pre-op nursing assessment is completed by bedside nurse taking care of infant prior to infant going to surgery.
8. A pre-op nursing assessment is completed by bedside nurse taking care of infant prior to infant going to surgery.
9. Pre-op documentation of the following is completed prior to surgery, including the following as appropriate for infant to be started 24 hours prior to surgery whenever possible:
    a. Vital signs (T-P-R-BP, and Pain assessment), blood glucose, oxygen saturation within 30 minutes of scheduled surgery.
    b. Current weight
    c. Allergies. NOTE: infants or children with neural tube defects (i.e. Myelomeningocele, Spinal Bifida) are to have “latex precautions” placed under Allergies with Reactions).
    d. Laboratory and radiology results completed (CBC results are to be no older 24-48 hours) in Cerner (EHR).
    e. Isolation. Note the type of isolation required (i.e. contact precautions).
    f. History and physical should be in infant's record.
    g. Infant is wearing an appropriate identification band with name and medical record number.
    h. Pre-op teaching is documented as needed.

B. Surgeries done in the OR

1. Transport the necessary equipment to the OR (i.e. Omni-bed with shuttle/or transport-isolette, ventilator).
2. Hat, warming-pad or chemical mattress for the premature infant to maintain thermoregulation.
3. The surgical site identification on the infant is done by the surgical team.
4. The infant is transported to and from the OR in a transport isolette with temperature control and on a Cardiopulmonary (CP) monitor. Pulse oximeter is required.
5. A RN trained in neonatal care accompanies NICU infant to OR and stays during the surgery and accompanies infant back to NICU. If ventilator support is needed a respiratory therapist (RT) accompanies infant to and from surgery.
6. OR team steps back and assesses that NICU RN has brought the right infant, for the scheduled procedure. OR team completes and documents the “time out” process.
7. Documentation during the surgical procedure is done by the OR team.
8. The role of the NICU nurse during surgery:

a. Visual observation of temperature and vital signs on the monitors (correlate skin temperature with body temperature prior to start of surgery)

b. Visual observation that O2 saturation is maintained within parameters specified by orders written per Neonatologist.

c. Alert surgical team to significant changes in temperature or other vital signs, including blood pressure.

d. Act as infant advocate, especially concerning infant's pain management during surgery.

e. Obtain specific supplies not available in OR or in appropriate size for neonate.

f. If infant is intubated for surgery, infant returns to NICU intubated, unless otherwise indicated by the attending Neonatologist.

C. Surgeries done in the NICU

1. Contact the OR team and coordinate specific time for surgical procedure.
2. Prophylactic antibiotics ordered as one-time doses prior to surgery.
3. The surgical area in the NICU is prepared as follows:
   a. Clear infant's room of extra equipment and supplies and remove trash cans from surgical area completely. Provide three bedside tables for use during surgery; one for the surgical assistant, one for charting, and one for medications.
   b. Clean surgical area including bedside, counters, and tables thoroughly with a hospital approved disinfectant solution prior to surgery. This may be done by housekeeping or the bedside nurses if pressed for time.
   c. Assure that infant is placed on a radiant warmer with adjustable height control. Maintain Cardio-pulmonary monitoring, NICU central monitor, pulse oximeter, and thermoregulation via skin probe with skin control. The ventilator should be positioned at head of the bed, and intravenous pumps on IV poles. Intravenous access for medication administration must be established with extension tubing attached to give anesthesiologist access to administer medications as needed. Set up bedside with a clean chux and alcohol wipes for anesthesiologist use.
   d. Place infant on clean linen or chux in the recommended position for procedure prior to surgery as infant condition allows.
   e. The surgical area of the infant's room with the door and the screened windows are closed
4. The OR team brings the necessary supplies/equipment for the surgical procedure. All equipment brought from surgery is wiped down with hospital approved disinfectant prior to entering the patient care area.
5. FIRE SAFETY related to surgery is managed and documented by the OR team.
   a. The NICU staff is aware of the location of the fire extinguishers on the unit and the Fire Alarm pull closest to their area.
6. All surgical staff entering the NICU, whether to deliver equipment or attend the surgical procedure, must perform a 90 second scrub prior to entering the infant care area.
7. Persons directly participating in the surgical procedure are to wear appropriate sterile attire per OR standards.
8. All NICU associates working or entering a room where a surgery is taking place must wear a cap and mask. Anyone within the boundaries of the surgical area cordoned off must be in surgical scrubs. Entry

into this area is kept at a minimum and should include the infant's bedside RN, RRT, and physician.

9. The OR team does a time out with NICU RN to make sure that the correct infant, correct site, and correct procedure is being performed. The OR team documents the “Time Out” and is responsible for all documentation of the infant during the surgical procedure.
10. The NICU RN assigned to the infant assigned to the infant has the same responsibilities as in the main OR.
11. An RRT trained in neonatal care is available to the OR team during the surgical procedure and must stay at the infant's bedside/ventilator until the procedure has been completed.
12. Normothermia is strictly maintained during the surgical procedure with documentation of skin temp every 15 minutes during the procedure.

PRE - OP DOCUMENTATION:

A. Pre-operative care is documented on appropriate forms in infant's record.
B. Record vital signs, blood glucose, accurate Intake and Output in the chart.
C. If applicable; time the infant is transferred to surgery, mode of transport, and who accompanies the infant is documented on infant's record.
D. To whom report was given and infant's clinical condition prior to transport is documented on infant's record.
E. For the NICU: Tolerance of transport is documented on the infant's record, pain assessment is included.
F. Pre-operative teaching/education to Parents (as appropriate) is documented on infant's record. Provide parents with written material with simple drawings prior to surgery

POLICY FOR POST OPERATIVE:

A. The infant's post-op care is performed by a registered nurse (RN)
B. The NICU infant going to the operating room (OR):
    1. An infant in the NICU is accompanied to and from the OR by a NICU RN. If the infant requires ventilator support a respiratory therapist (RT) accompanies the infant also.
    2. An Anesthesiologist accompanies the NICU infant back to the unit from OR. Care is transferred to the attending neonatologist upon return to NICU.
    3. Cardiopulmonary and pulse oximetry monitoring continues on the infant throughout transport to and from the OR.
    4. Staffing of the infant is according to identified acuity guidelines.
    5. The NICU infant is returned directly to the unit for recovery.
C. NICU Infant undergoing surgery on the unit:
    1. A NICU RN and RT are assigned to the infant (the NICU RN gives a verbal SBAR report to the OR nurse and completes the Transfer of Care in the electronic health care record if applicable--NICU RN and RT remain at the bedside throughout the procedure).
    2. The OR team (includes an anesthesiologist) takes over care of the infant for the surgical procedure.
    3. After the procedure the anesthesiologist transfers care to the Attending Neonatologist.
    4. The OR nurse gives a verbal SBAR report to the NICU RN and completes the transfer of care in the

electronic health care record, if applicable.

5. The NICU RN assigned to the infant provides the same post-op care as an infant having a surgical procedure in the OR.

D. Appropriate pain management is provided.

PROCEDURE FOR POST OPERATIVE;

A. NICU infant

1. Upon return from surgery or after the surgical procedure on the unit, the infant is placed or remains under a radiant warmer or pre-warmed isolette with skin probe to maintain thermoregulation (skin probe, if needed, in the isolette).
2. Monitor and document vital signs (including pain assessment) every 15 minutes times 4, 30 minutes times 2, then every one hour for 24 hours if stable.
3. A physical assessment is done with the first set of vital signs upon readmission to the NICU or after the surgical procedure.
    a. Axillary temperature is taken within 15 minutes of transfer of care of infnat back to NICU RN (temp should be maintained between 36.5 degrees to 37.5 degrees Celcius).
    b. Assist with Chest x-ray, labs, and other procedures as required.
    c. Assess the condition of the surgical dressing.
    d. Obtain orders/clarification from surgeon in regards to dressing change, suture removal, or any special post-up procedures.
    e. Change dressing as ordered or increased drainage noted, assess wound for color, type, amount and odor of drainage.
4. If infant returns from surgery extubated or is extubated after the surgical procedure on the unit, have emergency intubation set-up available at bedside.
5. If infant remains intubated, ventilator settings are maintained. Oxygen saturations and/or Transcutaneous carbon dioxide monitor are monitored, and ABG/CBG as ordered.
6. Check blood glucose via glucometer within one hour after surgery, notify physician if blood glucose less than 50 mg/dL, or greater than 180 mg/dL
7. If gastric decompression is needed after surgery, use replogle tube to low intermittent suction or as ordered per physician.
8. Pain is assumed for the first 24 hours post-op and analgesic administered every 2 to 4 hrs as ordered and/or via continuous drip.
9. Post-operative orders must be written and include the orders prior to surgery if those orders are to be maintained.
10. Dressings are changed and assessed after 24 hours unless the surgeon orders otherwise. Notify the physician if the dressings are saturated with blood/drainage prior to 24 hours.
11. Parents may visit when infant is stabilized.
12. Post-operative environment sanitation after surgical procedure when done in the NICU.
    a. All items which have come in contact with the infant and/or sterile field are considered contaminated and disposed of in the appropriate manner by a member of the surgical team.

DOCUMENTATION POST OPERATIVE:

- Document in (EHR) the condition of the infant when readmitted to unit or condition after the surgical procedure if done on the unit, include: Vital signs (include pain assessment), tolerance of surgery and transport, and fluid totals given during surgery.
- Document any special post-op orders or procedures (dressing change, suture removal, etc).
- Intake and output, vital signs, Laboratory work document in the (EHR).
- Procedures and infant tolerance, nursing interventions document in EHR.
- Medications, IV fluids: time, route in the EHR.
- Parent teaching and follow up care. Contact information about available resources to parents such as visiting nurses and parent support groups are provided to parents prior to discharge.

~~REFERENCES:~~REFERENCES:

~~AWHONN: NOEP, 3rd edition, 2015~~

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All revision dates: 1/13/2026, 12/14/2022, 7/1/2015, 2/1/2010, 2/1/2002

Attachments

No Attachments

Approval Signatures

Step Description	Approver	Date
Medical Executive Committee	Stephanie Denson: Manager, Medical Staff Office	pending
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Nursing Administration	Sherri Block: Associate Chief Nursing Executive, VCMC & SPH	1/20/2026
NICU	Robert Posen: NICU Medical Director	1/20/2026
NICU	Kristina Swaim: Nurse Director, Maternal Child Health	1/13/2026

VENTURA COUNTY HEALTH CARE AGENCY

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Owner:	*Kristina Swaim: Nurse Director, Maternal Child Health*
Policy Area:	*NICU*
References:	

N.62 Neonatal Injection Administration

POLICY:

To describe appropriate technique for administration of injectable medication in neonates and infants.

PROCEDURE:

A. Standard precautions. Follow the seven Rights of Medication administration.

1. **Subcutaneous (SQ) site selection:**
    a. Adequate amounts of subcutaneous fat that can be separated from muscle:
        i. Low birth weight babies:
            1. The back between the shoulder blades.
            2. The back of the upper arm.
        ii. Infants:
            1. The upper arm.
            2. The thigh.
2. **Intramuscular (IM):**
    a. The patient should be evaluated for adequacy of muscle mass and developmental needs before choosing an injection site. Approved injection sites for intramuscular injections in infants are the vastus lateralis or the rectus femoris muscles in the thigh.

EQUIPMENT

A. 1ml syringe

B. Needle Size Recommendations:

1. Subcutaneous administration of medicines: use 3/8 inch, 27 gauge needle.
2. IM injection for pre term infants less than 1.5kg: use 1/2 inch needle (25 - 27g).
3. IM injection for pre term – newborn: use 5/8 inch long needle (25 - 27g).
4. IM injection for infants > 2 months: use 1 inch (25 - 27g) needle.

C. Medication

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D. Alcohol prep pad.

GUIDELINES

A. Double check dose with second registered nurse (RN) or licensed vocational nurse (LVN).

B. Identify site which should be located a minimum of 2 cm from previous injection. See attached diagrams and photographs.

C. Prep site with alcohol.

1. **SQ** – Lift skin fold with finger and thumb. Insert needle at 30° angle into skin fold. Release skin fold. Inject contents without aspiration. Wait 5 seconds after completion of injection to withdraw needle.
2. **IM** – Grasp muscle between thumb and forefinger while stabilizing extremity. Inject at 45-90° angle. Aspirate slightly, if blood appears, withdraw needle and restart procedure. Maximum volume is 1 ml for >1500 grams and 0.5 ml for < 1500 grams. Simultaneous injection by two nurses may be used for volumes greater than 1 ml.

D. Use gauze if needed to stop bleeding.

E. If bandaid applied, remove bandaid at 12 hours or sooner.

F. DOCUMENTATION

1. Medication Administration Record – Medication, dose, time, and site.
2. Nursing Notes – Patient complications.

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Medical Executive Committee	Stephanie Denson: Manager, Medical Staff Office	pending
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Nursing Administration	Sherri Block: Associate Chief Nursing Executive, VCMC & SPH	3/6/2026
Nursing Administration	Danielle Gabele: Chief Nursing Executive, VCMC & SPH	3/6/2026

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Step Description	Approver	Date
NICU	Kristina Swaim: Nurse Director, Maternal Child Health	3/6/2026
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References:	

N.64 Standardized Procedure for Peripherally Inserted Central Catheters (PICC) Neonatal Intensive Care Unit

Purpose:

To provide nursing guidelines regarding Peripherally Inserted Central Catheters (PICC) in the Neonatal Intensive Care Unit (NICU) at Ventura County Medical Center (VCMC).

Policy

To provide a Registered Nurse (RN) standardized procedure for Peripherally Inserted Central Catheter (PICC) insertion in the Neonatal Intensive Care Unit. It is the policy of Ventura County Medical Center and Santa Paula Hospital that all standardized procedures are developed collaboratively and approved by the Interprofessional Practice Committee (IPC), whose membership consists of Physicians, Registered Nurses (RN), Pharmacists, Advanced Practice Nurses, and Administrators. Standardized procedures are reviewed every three years. To outline and define responsibility in performing interventions requiring a physician order in accordance with the California Board of Registered Nursing and the Nursing Practice Act, all approved standardized procedures will be kept in Policy Stat. The Registered Nurse, as outlined in the Nurse Practice Act, Business and Professions Code Section 2725, is authorized to implement appropriate standardized procedures or changes in treatment regimen after observing signs and symptoms of illness, reactions to treatment, general behavior, or general physical condition, and determining that these exhibit abnormal characteristics.

Scope

This applies to Registered Nurses (RNs) who have successfully completed population- appropriate training and demonstrated competency in vascular access device insertion, care and maintenance, and patient/ caregiver education across the care continuum.

Definition

Peripherally Inserted Central Catheter (PICC): a central vascular access device (CVAD) inserted into a peripheral vein and threaded into the central venous circulation. The tip of the PICC should reside in lower 1/3 of the superior vena cava (cavoatrial junction) for upper-body insertions.

Roles and Responsibilities

PICC placement will be completed by the trained RN. RNs will review and implement these functions whenever this task is performed.

A. Scope of supervision is required
   1. The RN is responsible and accountable to the Nurse Executives
   2. Provider consultation is to be obtained under the following circumstances
      a. Emergency conditions requiring prompt medical intervention
      b. Upon the request of the patient, RN, or physician
      c. Anytime any deviation from this protocol is necessary

B. Requirements for the RN
   1. Active California RN license
   2. Basic Life Support (BLS) and Neonatal Resuscitation Provider(NRP)
   3. Special training: formal orientation to specific procedure referenced in this policy with demonstrated competency validation

C. A list of RNs who demonstrate competency to perform this procedure is held by the Nursing Administration Nurse Manager

Provisions

A. Selection of the appropriate vascular access device shall accommodate:
   1. Patient's vascular needs
   2. Diagnosis
   3. Type and length of prescribed treatment regimen
   4. Duration of dwell
   5. Condition of the vasculature

Considerations for Vascular Access Device Placement

Competency/Experience/Training/Education

A. A qualified Registered Nurse with a minimum five years of experience level II or Level III; in the Neonatal Intensive Care Unit and (valid State of California Registered Nurse License) will have completed initial orientation (education/training/demonstration of competency) to the Neonatal Intensive Care Unit.

B. Completion of an approved PICC Certification Course.

C. Initial competency assessment:
   1. A minimum of three complete PICC insertions while being proctored by a qualified Neonatal PICC Nurse, Clinical Nurse Specialist, and/or Medical provider who is competent in PICC insertions to assess and verify clinical competency followed by a minimum of three successful independent PICC insertions directly supervised by a qualified Neonatal PICC Nurse, Clinical Nurse Specialist and/or Medical provider. The competency and proctoring will be documented on the Neonatal Intensive

Care Unit Registered Nurse orientation competency sheet and kept in the employee file.

D. **Annual Competency Assessment:** Minimum four hours of Continuing Education Units (CEUs) related to Vascular Access

1. A minimum of 2 successful PICC insertions per year.
2. Re-validation for those who do not meet minimum annual requirements will be 1 PICC observed by a qualified NICU PICC Nurse, Clinical Nurse Specialist, and/or Medical provider for a skills check-off. If this check- off is not passed, all initial competency requirements must be repeated.
3. The Annual Competency Summary Sheet is kept in the employee file.

Indications for Neonates: PICC is needed under any of the following conditions:

1. When central venous catheter (CVC) is needed and there is no access to umbilical venous catheter (UVC), or by the discretion of the clinician.
2. Intravenous antibiotics or fluids required for ~~more than~~a minimum 7 days.
3. When dextrose concentrations greater than 12.5% are needed.
4. Continuous vasopressors or continuous analgesia sedation.
5. Difficulty obtaining vascular access.

EQUIPMENT

Insertion for PICC:

A. General Equipment and Supplies:

1. Sterile gloves (two pairs): Efforts should be made to provide latex-free and di-(2-ethylhexyl) phthalate (DEHP)-free products
2. Sterile gown
3. Surgical hat
4. Face mask
5. Protective ~~eyewear~~eye wear
6. Restraints or swaddling device
7. Imaging device such as transilluminator, or ultrasound (if available) and sterile sleeve or glove

B. Catheter Equipment and Supplies:

1. Manufacturer's procedural kit, which contains:
   i. Single and double lumen ~~silicone~~Polyurethane catheter (1.9 French) and 1.4 French single lumen Polyurethane catheter
   ii. Introducer needle
   iii. Transparent dressing
   iv. Tape measure

v. Sterile tourniquet
vi. Povidone-iodine swab sticks
vii. Alcohol swab sticks
viii. Gauze sponges
ix. Surgical drape
x. Scissors
xi. Syringe with 18-gauge needle

~~T-connector extension set with luer-lock~~

2. Blue port closed-end adapter (needleless connector)
3. Sterile towels
4. Flush solution with heparin (1/2 normal saline with heparin), ordered by medical provider and supplied by Pharmacy
5. Sterile water, warmed
6. Needles or needleless dispenser for drawing flush
7. 5 mL and 10 mL syringes x2
8. Sterile hemostat clamps x~~3-4~~3
9. Chlorhexidine gluconate for > 2 months old
10. Extra introducer needles x2
11. Steri-strips

~~Isovue contrast agent~~

~~Sweet-ease~~

12. Sweet-ease ordered by Medical provider and supplied by Pharmacy
13. Sedation/Pain Medication as ordered by Medical provider

C. Dressing Change:

~~Alcohol swabs for babies <2 months of age~~

1. ~~Povidone-iodine~~Alcohol swabs for babies <2 months of age and sterile normal saline
2. ~~Chlorhexadine~~Chlorhexidine gluconate for children >2 months of age
3. Two pairs Sterile gloves, hat, mask and sterile gown
4. Sterile Transparent dressing
5. Sterile Steri-strips
6. Sterile gauze

~~Optional: catheter/t-connector stabilization supplies (arm board, Posey, etc.)~~

D. Central Line Maintenance, Tubing and Bag Change:

1. Fluid/Parenteral Nutrition Solution as ordered by physician~~/neonatal nurse practitioner (NNP)~~.
2. Sterile gloves

3. Alcohol swabs and ~~Betadine swabs~~sterile normal saline
4. Sterile gauze
5. Blue port closed-end adapter (needleless connector)
6. Intravenous (IV) Tubing~~/Burette set/~~ 0.2-micron filter
7. Labels: tubing/bag

E. Blood Samples

1. Syringes (sample is obtained using a 5ml or greater syringe)
2. Alcohol swabs
3. Sterile gloves
4. 4x4 gauze
5. Heparinized flush solution per physician~~/NNP~~ orders
6. Laboratory tubes

PROCEDURE

- ~~A PICC qualified registered nurse (RN), NNP, or physician may insert a PICC in the NICU.~~A qualified Neonatal PICC Nurse, Clinical Nurse Specialist, and/or Medical provider may insert a PICC in the NICU.
- The RN will care for the PICC including fluids, medications, blood draws, dressing, and tubing changes.
- Strict aseptic technique must always be followed. A three-minute scrub and complete surgical attire is required for insertion.
- Ensure that a signed, witnessed consent has been obtained.
- Daily heparin flush is not required for continuous infusing central lines.

GUIDELINES

A. **Insertion of PICC**

1. Verify ~~physician/NNP~~licensed medical provider order.
2. Confirm informed consent with parents/guardians completed by the licensed medical provider.
3. Verify the identity of the infant with at least two patient identifiers.
4. Perform time out at bedside.
5. Perform hand hygiene before touching the infant, before setting up the sterile field, and at the conclusion of the procedure.
6. Assess the infant and select the vein for insertion. Choose accessible vein least likely to interfere with developmental needs of the patient.
7. Measure the length of the catheter to be inserted.
    A. Arm Insertion: Measure from the site of the venipuncture along the route of the vein, under the clavicle to the clavicular head, and to the right of the sternum to the third intercostal space. **OR** Measure from the insertion site along the course of the vein, to the right of sternal border, to the third intercostal space.
    B. Scalp/Neck Insertion: Measure from the site of the venipuncture along the route of the vein to the right of sternum and to the third intercostal space.

C. Leg Insertion: Measure from the venipuncture site along the route of the vein to the femoral pulse, then veer to the right of the umbilicus to the xiphoid process. **OR** measure from the insertion site along the course of the vein, to the right of the umbilicus and up to the xiphoid process.

8. Measure insertion site to mid-sternum to guide placement length.
9. Provide neutral-thermal environment and provide appropriate monitoring as appropriate (e.g., cardio-respiratory monitor, pulse oximetry, etc.).
10. Provide developmentally supportive care, swaddling, pacifiers and/or pharmacological support.
11. Restrain and give medication as ordered for pain/sedation.
12. Position the infant appropriately. For arm insertion, turn the head toward the arm being accessed to reduce the likelihood of the catheter entering the jugular vein.
13. A second licensed staff member is required to assist and monitor infant's tolerance to procedure.
14. Don mask, hat, sterile gown, and gloves.
15. Open insertion kit, set up according to manufacturers' directions, including trimming, flushing, and checking guide wire.
16. Prepare the catheter by trimming to the length needed for the procedure, per manufacturer's recommendations.
17. Attach a luer-locking extension set to catheter and flush both catheter and extension set to ensure patency and air removal.
18. Prep the insertion site and surrounding skin with povidone-iodine per protocol and allow to dry (chlorhexidine gluconate if greater than ~~2~~two months old).
19. Place a sterile drape under the insertion area and drape patient and bed to provide sterile field.
20. Apply the tourniquet (for extremity insertion) as desired.
21. Insert the introducer slowly into the vein while observing for blood return. After blood return is evident, pull back the needle stylet and gently advance cannula.
22. At this time, blood return is easily noticed out of cannula.
23. Remove the tourniquet, if used.
24. Using the non-toothed forceps, thread the catheter through the introducer in 0.5-1cm increments to the pre-measured length.
25. Difficulty threading the catheter may be encountered at various times during insertion and may be alleviated by flushing, repositioning the infant, retracting and re-inserting the catheter, or massaging over the vein. Common causes of threading difficulty are vein specific, but may include:
    A. Blockage by the venous valve
    B. Difficulty traversing the junction of two veins
    C. Anatomic variability
26. Apply pressure to the indwelling portion of the catheter above the introducer and carefully remove the introducer. Apply pressure to the site until bleeding ceases.
27. Release the breakaway needle or peel-away-cannula per the manufacturer's recommendations.
28. Reposition the catheter if necessary to ensure it is at the pre-measured length.

29. If a stylet is present, remove it slowly while monitoring the catheter for bunching, which may indicate too-rapid removal.
30. Aspirate for a blood return and flush the catheter.
31. Temporarily stabilize catheter with steri-strips while awaiting x-ray confirmation. (Position patient to include entire length of the catheter on the X-ray film).
32. Maintain catheter patency by flushing intermittently with 0.5mL flush solution in a 5-10mL syringe.
33. Radiographically verify the location of the catheter tip and reposition the catheter if necessary. An anteroposterior view is usually adequate, but a lateral view can reveal catheter malposition. Position the infant in a neutral or commonly assumed position for x-ray confirmation. For upper extremity PICCs, position arm straight down beside body.
    - Catheter may be viewed without injecting contrast. However, water-soluble contrast agents may be instilled to slightly overfill the catheter to help visualize the catheter tip by altering the radiologic image on the viewer. Aspirate contrast agent from the catheter after radiologic verification, taking care to clear blood from the catheter once the contrast media is removed.
    - For catheters inserted via upper extremity or scalp veins, in neonates, the optimal location for the tip of the catheter is thoracic vertebrae T3-T5 level.
    - PICC entering from the lower extremity, the optimal position is with the catheter tip to be in thoracic Vena Cava at T8-T10 level.
34. Remove the skin antiseptic agent with tepid warm sterile water or saline.
35. Loop catheter and secure the PICC using transparent dressing over looped area. Ensure that the catheter is positioned in a single layer and that there are no kinks or sharp angles in the catheter. (Strips of tape or wound closure strips should not be placed on catheter tubing because of risk for catheter damage, but they may be used on the catheter securement hub).

    ~~Date, time and initial on or near dressing.~~
36. Connect to IV fluids ~~or~~and apply needle-less heparin cap as ordered. A filter (0.2 micron or less) is used with all filterable fluids.
37. Return infant to age-appropriate bed with appropriate monitoring as needed.
38. Date and time documented in Cerner (EMR).

B. **Dressing Change**

1. Dressing changes are done as needed, if soiled, or becomes non-occlusive (loosened).
2. Position infant on back. Restrain with soft restraints or obtain assistance in holding extremities to prevent contamination of area, if necessary.
3. Wash hands, and don mask, and hat with sterile gown.
4. Open supplies on to sterile field, using sterile technique.
5. Secure catheter extension and IV tubing using assistant as necessary to prevent catheter from becoming dislodged when the dressing is removed
6. Don sterile exam gloves and remove old dressing (begin at hub end and working up toward insertion site) being careful not to dislodge catheter.
7. Observe site carefully for signs of infiltration, infection, leakage, dislodgement, and erosion of catheter at insertion site and report any of above to physician~~/NNP~~.

8. ~~Wash hands and don sterile~~Remove first pair of gloves. Wash hands and don sterile gloves.
    - **For infants < 2 months:**
        - Cleanse the site, catheter, and surrounding skin three (3) times with alcohol swabs ~~or povidone-iodine swabs~~to an area as big as the transparent dressing. Begin at the catheter exit site and work outward in a circular motion covering a 2" area swabbing the catheter with alcohol swabs to clean it also. Total scrub time is 2-3 minutes).
        - Remove any crust or debris from the exit site, skin, and catheter.
        - Allow site to dry completely.
        - Remove dried antiseptic with sterile normal saline solution or sterile water after the antiseptic solution has dried completely.
        - Loop catheter and place transparent dressing over looped area. Ensure that the catheter is positioned in a single layer and that there are no kinks or sharp angles in the catheter.
        - ~~Date, time and initial on or near dressing.~~Document date, time dressing change was done in Cerner (EMR) under lines and drainage. Document in progress note of Cerner (EMR) width of external length of the catheter from insertion site, appearance of the catheter exit site surrounding skin, type of dressing used and infant's response to procedure.
        - Report any signs of infiltration, infection, leakage, or dislodgement to physician~~/NNP~~.
    - **For infants >2 months:**
        - Open chlorhexidine swab, pinch the wings on the applicator to release the antiseptic into the sponge. Do not touch the sponge.
        - Wet the sponge by repeatedly pressing and releasing the sponge against the PICC site area until liquid is visible on skin.
        - Cleanse the site in circular motions working outward for 30 seconds, removing any crust or debris from exit site, skin, or catheter~~—~~ completely wetting the site/area. Cleans high risk areas (i.e., femoral/groin sites with a 2-minute scrub).
        - Let air dry for 30 seconds.
        - Loop catheter and apply transparent dressing. (2x2 sterile gauze may be placed over insertion site prior to application of transparent dressing if drainage is present). Ensure that the catheter is positioned in a single layer and that there are no kinks or sharp angles in the catheter.
        - Secure to prevent pulling on catheter exit site.

CENTRAL LINE MAINTENANCE, TUBING AND BAG CHANGE

A. Change IV fluids/Parenteral Nutrition fluids every 24 hours.

B. If a PICC line with Intravenous fluids is infusing at 1 ml/hr or 0.5 ml/hr; heparin should be increased from 1 unit/ml to 2 units/ml for infant's gestational age >35 weeks; if infant's gestational age is less than 35 weeks; heparin should remain at 1 unit/ml if intravenous fluids are infusing at 1 ml/hr or 0.5 ml/hr.

C. Change tubing/~~burette/~~micron filter/blue port (needleless connector) every ~~96~~24 hours including intralipid and medication tubing.

D. Tubing and bag change preparation:

1. Check parenteral nutrition label against physician~~/NNP~~ order and patient identification band and verify such with another licensed staff.
2. Assemble equipment on a clean surface at patient's bedside.
3. Wash hands.
4. Insert administration set spike into solution bag, connect tubing, ~~burette,~~ micron filter, etc. Flush air from tubing. Protect end of tubing from contamination.

E. Tubing change:

1. Don sterile gloves.
2. Using alcohol swabs or pads, clean catheter/tubing junction. Swab outward from the connection one inch x 3.
3. Hold connection for 1-2 minutes, allowing the alcohol to dry. Place sterile 4x4 under catheter hub.
4. Clamp off catheter with attached clamp.
5. Quickly disconnect old tubing and fill central line hub with 1-2 drops IV solution to expel air bubbles. Replace with new tubing/set-up.
6. ~~Unclamp~~Un-clamp catheter and start infusion at ordered rate.
7. All extension tubing (e.g., that used with ~~intralipids~~intralipid and medications) ~~is to~~will be changed every 24 hours.
8. Observe for catheter and dressing stability to prevent migration or breakage.
9. Label bag and tubing with date, time, and initials.

F. Blood Samples

1. NICU ~~PICCs~~PICC's are only accessed by physician~~/NNP~~ order for blood sample. Frequent blood sampling may necessitate the use of a ~~three~~blue port closed ~~way stopcock~~end adapter (needleless connector).
2. Aseptic technique to be followed:
    1. Turn off IV fluids and clamp tubing with in-line clamp. Multi-lumen catheters must have unused ports clamped.
    2. Don sterile gloves.
    3. Cleanse hub of PICC vigorously x3 with alcohol pads (1-2 minutes in length). Allow to dry.
    4. Using a 5-10ml syringe, withdraw 1-1.5mL blood sample waste, depending on size of patient.
        i. ~~Return of aspirated blood is not recommended. If patient cannot tolerate blood loss per physician/NNP, it may be returned per physician order. (BLOOD MUST NOT CONTAIN A VASOACTIVE DRUG.)~~Return of aspirated blood is not recommended.
        ii. Maintain sterility of syringe if blood is to be returned to patient.
    5. Blood collected for sampling must be aspirated with a 5-10ml syringe. Blood may be aspirated directly from hub after inserting empty syringe into injection port--ensuring that tubing or connector are changed or remain sterile.
    6. ~~Unclamp~~Un-clamp catheter and flush with normal saline or heparin flush (per physician~~/NNP~~

order) after the sample is obtained and blood to be returned (if any) has been replaced. Use a 5mL or greater syringe to flush catheter and maintain positive pressure as flush is withdrawn from heparin lock.

G. Removal of PICC

1. Check for PICC insertion length.
2. Remove dressing carefully. Remove PICC slowly and in small segments to prevent breakage.
3. If resistance is felt, stop withdrawing and notify physician~~/NNP~~. Warm extremity and retry when infant is relaxed.
4. When completely withdrawn, measure to ensure catheter is original length. Notify physician~~/NNP~~ if catheter is not intact.

H. Key Points

1. Pain Statement: All infants should be screened for presence of pain as part of each assessment using an age-appropriate scale. For moderate to severe pain, further assessment should be obtained and physician~~/NNP~~ notified for intervention.
2. Always verify patient identity prior to procedure per hospital policy.
3. Standard Precautions: All health care workers should routinely use appropriate barrier precautions to prevent skin and mucous membrane exposure when contact with blood or other body fluids of any patient is anticipated. Gloves should be worn for touching blood and body fluids, mucous membranes, or non-intact skin of all patients and for handling items or surfaces soiled with blood or body fluids, and for performing venipuncture and other vascular access procedures. Gloves should be changed after contact with each patient. Masks and protective ~~eyewear~~eye wear or face shields should be worn during procedures that are likely to generate droplets of blood or other body fluids to prevent exposure of mucous membranes of mouth, nose, and eyes.

DOCUMENTATION

A. Progress Note: procedure description, type of dressing ~~change~~, ~~patient~~infant tolerance, type, size and length of inserted catheter with lot # for catheter inserted. The appearance/condition of site, length of removed catheter, and lab specimens obtained.

B. Confirmation of catheter tip placement per X-ray

C. Informed Consent: date, time, parent/guardian signature, benefits/risk of procedure

D. Time Out form

E. CLIP form

F. Medication Administration Record: fluids and medications

G. IV Bag/Tubing: ~~label~~ with date~~,~~ and time~~, and initials~~ in Cerner (EMR)

H. Dressing change: ~~label with~~Record date~~,~~ and time~~, and initials~~ in Cerner (EMR).

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Medical Executive Committee	Stephanie Denson: Manager, Medical Staff Office	pending
Pediatrics Committee	Stephanie Denson: Manager, Medical Staff Office	4/3/2026
Nursing Administration	Sherri Block: Associate Chief Nursing Executive, VCMC & SPH	3/6/2026
Nursing Administration	Danielle Gabele: Chief Nursing Executive, VCMC & SPH	3/6/2026
NICU	Kristina Swaim: Nurse Director, Maternal Child Health	3/6/2026
NICU	Robert Posen: NICU Medical Director	1/20/2026

VENTURA COUNTY HEALTH CARE AGENCY

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Next Review:	*3 years after approval*
Owner:	*Pearl Dahm: Clinical Nurse Specialist*
Policy Area:	*NICU*
References:	

N.71 Clinical Humidification in the NICU

PURPOSE:

To provide a method to decrease evaporative heat loss due to trans-epidermal water loss (TEWL) during postnatal maturation of the epidermal barrier in premature infants. Humidification has the following advantages: increased ability to maintain the infant's temperature; improved maintenance of fluid and electrolyte balance; improved energy balance--fewer calories expended in temperature maintenance and improved skin integrity.

POLICY:

1. The Giraffe Omni-bed (GE Healthcare) shall be used to provide humidity infants.
2. Humidity shall be provided for all premature infants from birth up to 30 weeks gestation. See attached Humidification protocol and weaning.
   - ~~A. 23 to 28 weeks gestation: 80% for one week. Then 50% until 30 weeks gestation.~~
   - ~~B. Greater than 28 weeks gestation: 70% for one week. Then 50% until 30 weeks gestation. Then ambient humidity.~~
3. Humidity shall be instituted within the first 6 hours of life.
4. Special attention should be paid to the assessment of the infant's body temperature with increases or decreases in humidity levels.
   - A. If the neonate becomes hypothermic, discontinue weaning and return relative humidity to last setting where the neonate's temperature was stable.
   - B. If the neonate becomes hyperthermic, decrease the humidity by 5% decrements to a minimum of 50%.
   - C. If condensation occurs along any surface of the incubator to the point where visual contact with the neonate is obscured, decrease humidity by 5% decrements and wipe down condensation.

DEFINITION(S):

Neonatal skin is more fragile than adult skin because fewer fibers connect the epidermis to the dermis. Increased skin permeability in premature infants increases the loss of fluids and electrolytes. Infants born at 23-25 weeks have very delicate skin that is not keratinized and will have transepidermal water losses (TEWL) up to ten times higher than a term infant. They are high risk for severe dehydration via fluid losses from the

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skin if proper humidification is not maintained and water intake is not increased to replace the inordinate Insensible water loss. The skin is not mature until 30-32 weeks post conceptual age.

PROCEDURE(S):

1. Keep direct contact with infant to a minimum.
2. Monitor infant's temperature with skin temperature probe.
3. Use portholes to access infant.
4. While infant is receiving humidity therapy, keep the Giraffe Omni-bed in incubator mode and only raise the canopy as needed.
5. Remove all stuffed animals from the incubator for the duration of the humidity use.
6. Change all linens, including Snuggle-Ups and Bendy bumper covers as needed.
7. Document in the EMR humidity use every shift; including when humidity is implemented, percentage being delivered and setting changes.

IMPLEMENTING HUMIDITY:

1. Remove reservoir from bed and fill to maximum line with sterile distilled water.
   A. Use a fresh unopened bottle for every refill.
   B. Bottles must not be shared.
   C. Any fluid not used from the bottle needs to be discarded.
2. Enter option screen to adjust humidifier per physician order.
3. Reservoir will be cleaned when humidity is discontinued per Giraffe Manual protocol.
   A. Cavicide can be used for cleaning reservoir and will need to rinse after.

REFERENCE(S):

Gardner, S.; Carter, B. S., Enzman-Hines, M., Niermeyer, S. (2021) Merenstein & Gardner's Handbook of Neonatal Intensive Care: An Interprofessional Approach. 9th ed. Elsevier, Inc

Kenner, C., Altimier, L., & Boykova, M. (2020). Comprehensive Neonatal Nursing Care. 6th ed. New York, Springer Publishing.

The Association of Women's Health, Obstetric and Neonatal Nurses. (2018) Neonatal Skin Care: Evidenced Based Clinical Practice Guideline. Washington DC: The Association. 4th Ed

All revision dates: 7/14/2025, 6/11/2024

Attachments

Humidification protocol.png

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Approval Signatures

Step Description	Approver	Date
Medical Executive Committee	Stephanie Denson: Manager, Medical Staff Office	pending
Pediatrics Committee	Stephanie Denson: Manager, Medical Staff Office	4/3/2026
Nursing Administration	Sherri Block: Associate Chief Nursing Executive, VCMC & SPH	3/6/2026
Nursing Administration	Danielle Gabele: Chief Nursing Executive, VCMC & SPH	3/6/2026
NICU	Kristina Swaim: Nurse Director, Maternal Child Health	3/6/2026
NICU	Robert Posen: NICU Medical Director	9/3/2025
NICU	Pearl Dahm: Clinical Nurse Specialist	8/5/2025

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Owner:	*Kristina Swaim: Nurse Director, Maternal Child Health*
Policy Area:	*OB Nursing*
References:	

OB.69 Administration of Rho Immune Globulin for Prophylaxis

POLICY:

To reduce the incidence of D alloimmunization. Since the introduction of human Rho Immune Globulin in 1968, the incidence of D alloimmunization has had a marked decline. See also policy *MST.18 Blood and Blood Component Administration*.

PROCEDURE:

Candidates for Rho Immune Globulin (Rhophylac, RhoGAM) administration are Rh negative women, with negative antibody screens who have:

A. delivered Rh positive babies
B. had ectopic pregnancies
C. had spontaneous or induced abortions
D. undergone chronic villus sampling (CVS)
E. undergone amniocentesis
F. undergone fetal manipulation such as external cephalic version (ECV) or an attempted ECV
G. undergone ~~cordcentesis~~cord0centesis
H. experienced an antepartum hemorrhage
I. suffered antepartum trauma or fetal death
J. undergone any event which could have resulted in fetal-maternal hemorrhage.

DETERMINATION OF THE Rh

On the initial prenatal visit all patients should be tested for ABO-Rh type and have an antibody screening performed. If the patient is determined to be Rh negative, and the anti-body screen is negative, another type and screen should be performed at 28 weeks gestational age to identify patients who may have already have become alloimmunized. Rho Immune Globulin may be administered before the results of this test is known in order to ensure optimal timing prophylaxis. If the antibody screen subsequently returns positive for anti-D antibody, the patient should be referred to a maternal fetal medicine specialist. If there has been no prenatal care, the ABO-Rh and antibody testing should be done~~. If the patient is determined to be Rh negative and the~~

~~antibody screen is negative, she should be retested at 28 weeks and if the screen remains negative will be given a prenatal dose of Rho Immune Globulin. If there has been no prenatal care, the ABO-Rh and antibody testing should be done~~ on admission to obstetrics.

If the antibody screen on any OB patient is positive, an antibody identification must be done immediately and the attending physician notified STAT. Maternal antibodies can and do cross the placenta and can cause grave problems for the fetus.

At the time of delivery, cord blood will be obtained in the delivery room and sent to the Blood Bank for an HDN (Hemolytic Disease of the Newborn) work-up. The HDN work-up includes an ABO-Rh typing and a Direct Coombs test. If the test shows the baby is Rh positive, the mother is a candidate for the administration of another dose of Rh Immune Globulin. If the baby is Rh negative Rho Immune Globulin administration to the mother is unnecessary. (AABB Technical Manual, 2008)

GUIDELINES:

After a determination has been made that the baby is Rh positive, the mother will be asked to sign an Informed Consent to Receive Rho Immune Globulin Form (Attachment A). After the Consent is signed, the mother's blood will be drawn for a Rho Immune Globulin work-up (a physician's order for the Lab work and the Rho Immune Globulin injection must be written in the chart by the patient's physician, then ordered in the computer). The Rho Immune Globulin work-up, in addition to an ABO-Rh type (to ensure that the mother is indeed Rh negative) and screen involves an initial qualitative screening test for D positive fetal red blood cells. If this test is positive then a Kleihauer-Betke test will be run to determine how many additional doses of Rho Immune Globulin are needed. **Rho Immune Globulin must be administered within 72 hours of delivery.**

A. Administration of Rho Immune Globulin:

1. The Rho Immune Globulin will be picked up from the Laboratory by a nursing staff member or Medical Staff member who will verify, along with a Clinical Laboratory Scientist, the name of the patient, the patient chart number, the Rho Immune Globulin lot number and the expiration date.
2. Two licensed nurses (one must be an RN) will again verify this information at the patient's bedside as well as the signed patient consent form and the attending physician's order. All of the checks will be documented on the Unit Issue Form (UIF), which accompanies the Rho Immune Globulin.
3. Observe Standard Precautions when administering the Rho Immune Globulin.
4. The Rho Immune Globulin is administered by ***intramuscular*** injection.
5. The yellow copy of UIF is placed in the patient's chart and the pink copy of the UIF is returned to the Blood Bank.
6. ***Do not*** administer Rho Immune Globulin intravenously.
7. ***Do not administer Rho Immune Globulin to the baby.***
8. Give the patient the Rho Immune Globulin card on which you have entered our hospital name and date of injection.

DOCUMENTATION

Document injection time, site and lot number on MAR. Records patient's response in Nurses Notes, as appropriate.

All revision dates: 1/7/2026, 10/14/2020, 8/1/2010, 5/1/2004

Attachments

A: Consent to Receive Rho Immune Globulin Form

Approval Signatures

Step Description	Approver	Date
Medical Executive Committee	Stephanie Denson: Manager, Medical Staff Office	pending
Medical Staff Committees: Family Medicine & OB	Stephanie Denson: Manager, Medical Staff Office	3/8/2026
Pharmacy & Therapeutics Committee	Sul Jung: Associate Director of Pharmacy Services	2/11/2026
Nursing Administration	Sherri Block: Associate Chief Nursing Executive, VCMC & SPH	1/7/2026
Nursing Administration	Danielle Gabele: Chief Nursing Executive, VCMC & SPH	1/7/2026
Policy Owner	Kristina Swaim: Nurse Director, Maternal Child Health	1/7/2026

VENTURA COUNTY HEALTH CARE AGENCY

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Owner:	*Sara Pendleton: Medication Safety Officer*
Policy Area:	*Pharmacy Services*
References:	

PH.042 Adverse Drug Reaction Reporting System

POLICY:

Ventura County Medical Center (VCMC) ~~and~~, Santa Paula Hospital (SPH), and Ambulatory Care (AMB) responds to actual or adverse events and significant adverse drug reactions (ADR). The ADR reporting system raises awareness of the risks associated with adverse drug reactions, identify ADRs that have occurred, and reduce their risk of associated harm.

Background:

A robust ADR reporting system involves different types of surveillance to identify ADRs.[1]

A. Prospective surveillance system for high-risk medications and/or patients at high risk for ADRs.

B. Ongoing and concurrent surveillance based on reporting suspected ADRs by ~~Pharmacists~~pharmacists, Licensed Practitioners (LP), nurses, other caregivers, and patients.

C. Retrospective surveillance that includes identifying orders for the use of trigger medications that are used to treat common ADRs (e.g., NOW orders for anti-histamines, epinephrine, etc.).

The ultimate goals of a robust ADR reporting system[1] are to

A. Improve patient care and decrease length of stay by ensuring safer use of drugs and appropriate follow-up.

B. ~~Educating~~Educate health care professionals and patients about drug effects and increasing their level of awareness regarding ADRs.

C. ~~Providing~~Provide an indirect measure of the quality of drug therapy through identification of potential ADRs and anticipatory surveillance for high-risk drugs or high-risk patients.

D. Assess the safety of drug therapies.

E. ~~Providing~~Enable quality-assurance screening to identify opportunities for medication-use evaluation or other performance improvement initiatives.

F. Characterize ADR incidence.

Definition:

A. **Adverse Drug Event (ADE)[1-2]:** Harm resulting from medical intervention involving a drug. Adverse drug events may be preventable (i.e, medication errors) or non-preventable (i.e., adverse drug reactions). All

ADEs are associated with harm.

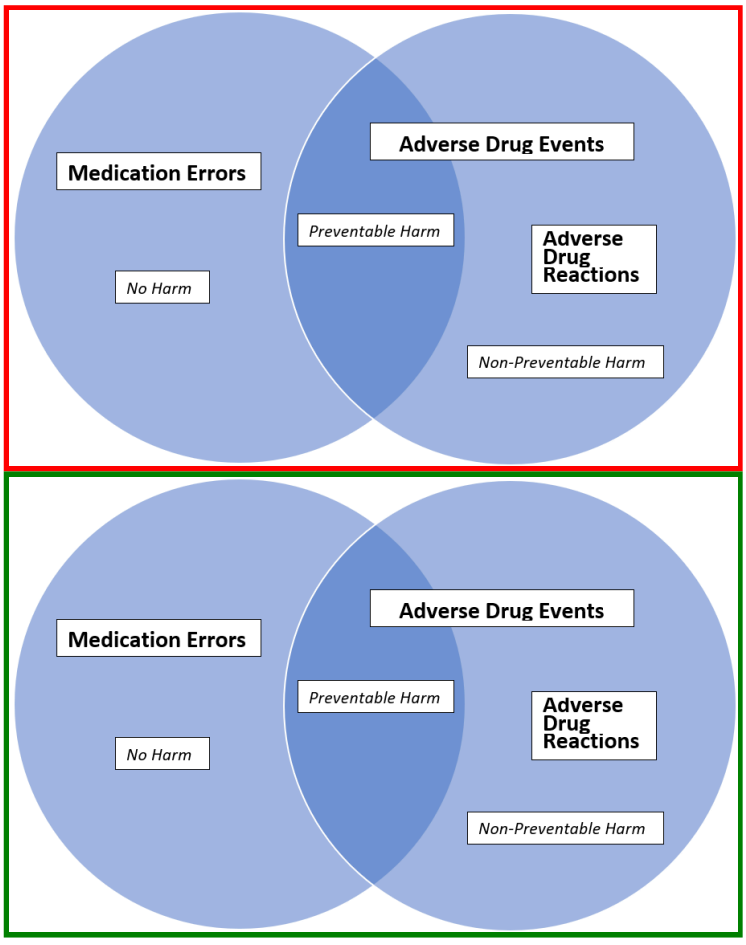
B. **Adverse Drug Reaction (ADR)[2]:** Any response to a drug which is noxious and unintended which occurs at doses normally used in man for prophylaxis, diagnosis, or therapy of disease, or for the modifications of physiological function.

   1. Side effect is a a popular term typically used to describe ADRs that are known to occur with a medication with varying degrees of associated harm.
   2. Drug withdrawal, drug-abuse syndromes, accidental poisoning, and drug-overdose complications should not be defined as ADRs.

C. **Harm[3]:** Impairment of the physical, emotional, or psychological function or structure of the body and pain or injury resulting therefrom.

D. **Medication Error[3]:** A medication error is any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. For more information on medication errors, see policy PH.48 Medication Error Reduction Plan (MERP)

Relationship between medication errors and adverse drug events and adverse drug reactions.[3-4]



Procedure:

Adverse Drug Reaction Reporting

A. ADRs should be reported electronically through the electronic notification system. Access to the notification system is available on all healthcare agency desktops. For more information on safety events, assistance, and escalation, see policy 107.082 Just Culture - Response to Safety Events

B. If an ADR is identified during ongoing/concurrent drug therapy, the Licensed ~~Independent~~ Practitioner (~~LIP~~LP) shall be notified immediately.

C. If an ADR is determined to have caused preventable harm (e.g., a medication error), both a medication error notification and an adverse drug reaction report should be completed.

D. Records of the adverse drug reaction review shall be retained by the Medication Safety Officer (MSO) for at least three (3) years from the date the event occurred.

E. The following information is important for initiating an ADR assessment (minimal information in **bold**):

1. **Patient information (i.e., two patient identifiers)**
2. **Date/time of onset**
3. **Description of suspected ADR including the suspected drug(s).** *See Table 1 for affected body system.*
4. Reaction Type. *See Table 2 for classification of adverse drug reactions.*
5. Management and Treatment
    a. No action taken
    b. Supportive treatment
    c. Drug(s) discontinued
    d. Antidote/antagonist used
    e. Drug dose decreased
    f. Other
6. Outcome
    a. No harm/discharged home
    b. Required intervention to prevent ~~permenant~~permanent impairment/damage
    c. Hospitalization
    d. Life threatening
    e. Disability/permanent damage
    f. Death
7. Severity
    a. Severe: Caused death or was life threatening
    b. Significant: Caused or contributed to hospitalization, or prolonged length of stay (LOS) by 1 day or more
    c. Moderate: Did not prolong LOS, but required antidote/antagonist and/or discontinuation of

suspected drug(s)

d. Mild: Required no antidote/~~antagonisht~~antagonist or drug discontinuation. Drug dosage may have been reduced.

8. Probability. *See Table 3 for Naranjo Adverse Drug Reaction Probability Scale.*

Adverse Drug Reaction Analysis

Once the adverse drug reaction notification is filed, the notification shall be routed to the Medication Safety Officer (MSO) or designee who shall review and investigate as soon as reasonably possible. The ADR may be forwarded to the appropriate department for further review and analysis, including Event Analysis (EA), Root Cause Analysis (RCA) and/or peer review referral if indicated.

The MSO or designee shall initially assign ADR metrics (e.g., severity and probability) with Medical Staff consultation if warranted. Pharmacy and Therapeutics Committee shall review and evaluate ADRs and ADR metrics quarterly. The Pharmacy and Therapeutics (P&T) committee members/attendees can request re-assessment and/or change in severity assignment. Likewise, for any ADRs that are reviewed during EA and RCAs.

Findings from ADR interdisciplinary discussion may be incorporated into ongoing quality improvement activities. This may include preventative and corrective interventions, monitoring for future ADRs, education, and promoting the awareness of the consequences of ADRs.

Medication Safety generated summaries, data, and action plans shall be reported to the following committees:

A. Patient Safety Committee

B. Pharmacy and Therapeutics Committee

C. Medical Executive Committee

External Reporting

Voluntary reporting to external reporting systems helps identify unknown risks and trends. Serious or unexpected ADRs should be reported to the medication manufacturer and/or the Food and Drug Administration (FDA).

A. FDA Medwatch for observed or suspected adverse events for human medicinal products (e.g., medications, equipment, and ancillary supplies). Reporting can be made online by visiting The FDA Safety Information and Adverse Event Reporting Program | FDA

B. Vaccine Adverse Events (see Attachment B - VAERS and VERP)

1. VAERs (Vaccine Adverse Event Reporting System) for vaccines causing adverse reactions.
    a. Report all COVID-19 vaccine administration errors to VAERs regardless of whether an adverse event occurred.
    b. Reporting can be made on line by visiting https://vaers.hhs.gov/reportevent.html.
2. VERP (Vaccine Error Report ~~Progam~~Program) for preventable vaccine administration errors. Reporting can be made on-line by visiting ~~ismp.org/form/verp-form~~https://www.ismp.org/form/verp-form
3. CAIR (California Immunization Registry) documentation should be corrected if indicated.

~~myCAvax for reporting COVID vaccine shipment incidents (e.g., damaged/missing shippers or~~

~~packages, missing or surplus vaccine, missing kit supplies, and temperature excursions in transit).~~

~~California Department of Public Health (CDPH) should be contacted to report any deficiencies or defects related to the ancillary supply kits . Reporting can be made online by visting myCAvax under Vaccine Inventory.~~

Analysis Tools

Table 1 Affected Body System(s)		
Cardiovascular	Gastrointestinal	Neurological
Dermatological	Generalized	Renal
Electrolyte homeostasis	Hematological	Respiratory
Endocrine/metabolic	Hepatic	
ENT/oral	Musculoskeletal	

Table 1 Affected Body System(s)		
Cardiovascular	Gastrointestinal	Neurological
Dermatological	Generalized	Renal
Electrolyte homeostasis	Hematological	Respiratory
Endocrine/metabolic	Hepatic	
ENT/oral	Musculoskeletal	

Table 2 Classification of Adverse Drug Reactions[5]			
Type of Reaction (mnemonic)	**Features**	**Examples**	**Management**
A: Dose related (augmented)	- Common - Related to the pharmacologic actin of the drug – exaggerated pharmacologic response - Predictable - Low mortality	- Dry mouth with tricyclic anti-depressants - Respiratory depression with opioids - Bleeding from warfarin - Serotonin syndrome with SSRIs - Digoxin toxicity	- Reduce dose or withhold drug - Consider effects of concomitant therapy
B: Non-dose related (bizarre)	- Uncommon - Not related to the pharmacologic action of the drug - Unpredictable - High mortality	- Immunologic reactions: anaphylaxis to penicillin - Idiosyncratic reactions: malignant hyperthermia with general anesthetics	- Withhold and avoid in the future
C: Dose related and time related (chronic)	- Uncommon - Related to the cumulative dose	- Hypothalamic pituitary adrenal axis suppression on corticosteroids - Osteonecrosis of the jaw with bisphosphonates	- Reduce dose or withhold - Withdrawal may have to be prolonged
D: Time related (delayed)	- Uncommon - Usually, dose related - Occurs or becomes apparent sometime after use of the drug	- Carcinogenesis - Tardive dyskinesia - Teratogenesis - Leucopenia with lomustine	- Often intractable
E: Withdrawal (end of use)	- Uncommon - Occurs soon after withdrawal of the drug	- Withdrawal symptoms with opiates or benzodiazepines (e.g., insomnia, anxiety)	- Re-introduce drug and withdraw slowly
F: Unexpected failure of therapy (failure)	- Common - Dose related - Often caused by drug interactions	- Inadequate dosage of an oral contraceptive when used with an enzyme inducer - Resistance to antimicrobial agents	- Increase dosage - Consider effects of concomitant therapy

Table 2 Classification of Adverse Drug Reactions[5]			
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Table 3 Naranjo ADR Probability Scale[6]				
Question	**Yes**	**No**	**UNK**	**Score**
1. Are there previous conclusive reports on this reaction?	+1	0	0	
2. Did the adverse event appear after the suspected drug was administered?	+2	-1	0	
3. Did the adverse reaction improve when the drug was discontinued, or a specific antagonist was administered?	+1	0	0	
4. Did the adverse event appear when the drug was readministered?	+2	-1	0	
5. Are there alternative causes (other than the drug) that, on their own, could have caused the reaction?	-1	+2	0	
6. Did the reaction reappear when a placebo was given?	-1	+1	0	
7. Was the drug detected in the blood (or other fluids) in concentration known to be toxic?	+1	0	0	
8. Was the reaction more severe when the dose was increased or less severe when the dose was decreased?	+1	0	0	
9. Did the patient have a similar reaction to the same or similar drugs in any previous exposure?	+1	0	0	
10. Was the adverse event confirmed by any objective evidence?	+1	0	0	
Total Score: 9=high probable; 5-8=probable; 1-4=possible; 0=Doubtful				UNK=unknown

References

1. ASHP Guidelines on Adverse Drug Reaction Monitoring and Reporting. AM J HEALTH-SYST PHARM.

2021.

2. Safety Monitoring of Medicinal Products. Guidelines for setting up and running a Pharmacovigilance Centre. Uppsala Monitoring Cen tre - WHO Collaborating Centre for International Drug Monitoring, EQUUS, London, 2000.
3. National Coordinating Council for Medication Error Reporting and Prevention. Contemporary review of medication-related harm. A new paradigm. Accessed March, 21, 2022. https://www.nccmerp.org/sites/default/files/nccmerp_fact_sheet_2015-02-v91.pdf
4. Morimoto T, Gandhi TK, Seger AC, et al. Adverse drug events and medication errors: detection and classification methods. Qual Safe Health Care 2004; 13:306-314.
5. Edwards IR, Aronson JK. Adverse drug reactions: definitions, diagnosis, and management. Lancet. 2000; 356: 1255-9.
6. Naranjo CA, Busto U, Sellers EM, et al. A method for estimating the probability of adverse drug reactions. Clin Pharmacol Ther. 1981; 30:239-245.

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Attachments

- Attachment A - Adverse Drug Reaction Report Form (VCHCA-345-008).pdf
- Attachment B - VAERs and VERP.pdf

Approval Signatures

Step Description	Approver	Date
Medical Executive Committee	Stephanie Denson: Manager, Medical Staff Office	pending
Pharmacy & Therapeutics Committee	Sul Jung: Associate Director of Pharmacy Services	3/20/2026
Pharmacy Services	Sul Jung: Associate Director of Pharmacy Services	3/10/2026
Pharmacy Services	Sara Pendleton: Medication Safety Officer	2/25/2026

VENTURA COUNTY HEALTH CARE AGENCY

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Owner:	*Sul Jung: Associate Director of Pharmacy Services*
Policy Area:	*Administrative - Patient Care*
References:	

PH.061 Automatic Stop Orders

POLICY:

Medication orders shall have defined automatic stops, which may vary in duration depending on the medication.

DEFINITIONS: Definitions of automatic stop types for medication orders:

A. Hard stop: A type of automatic stop where the order will automatically discontinue after the order has expired. Hard stop order types are not renewable.

B. Physician stop: A type of hard stop where the duration of therapy is defined by the provider. The order will automatically discontinue after the order has expired.

C. Soft stop: A type of automatic stop where the order will persist on the medication administration record (MAR) after the order has expired. Soft stop types are renewable, and shall be renewed or discontinued upon expiration of the order.

PROCEDURE:

A. Automatic hard stop orders:
   1. One day (24 hours) expiration:
      a. Sodium polystyrene sulfonate (Kayexalate) oral solution
      b. Sodium zirconium cyclosilicate (Lokelma) powder for suspension
         i. This restriction only applies for treatment of emergent hyperkalemia.
   2. Three-day (72 hours) expiration:
      a. Methocarbamol injection
   3. Five-day (120 hours) expiration:
      a. Ketorolac injection

B. Automatic soft stop orders:
   1. One day (24 hours) expiration
      a. Amiodarone drip
   2. Three day expiration:

a. Baclofen (oral), methocarbamol (oral), cyclobenzaprine (oral)

3. Fourteen day expiration:
    a. Antibiotics, oral and injectables
4. Twenty-one day expiration:
    a. Antifungals and antivirals, oral and injectables
5. Ninety-day (90 day) expiration:
    a. All other medications not listed in this policy

C. Start and Stop dates are noted in the order details and MAR in the electronic health record (EHR).
    1. Renewal notice icons will automatically populate the order details and MAR for soft stop orders 48 hours prior to expiration of the order. The renewal icon will persist until the order is renewed or discontinued.

D. Renewal of Medication Orders:
    1. Medication orders can be renewed by a provider by selecting the renew function for the order in the EHR.

E. Discontinuation of Medications:
    1. Hard stop orders will automatically discontinue upon expiration of the order. This includes physician stop orders.
    2. Soft stop orders will not automatically discontinue upon expiration of the order. The provider has the option to discontinue or renew the order.

All revision dates:	4/12/2023, 10/11/2022, 11/10/2021, 1/13/2021, 3/17/2020, 2/15/2018, 3/1/2015, 12/1/2013, 2/1/2011, 8/1/2008, 6/1/2006, 9/1/2002, 6/1/2000, 11/1/1998, 8/1/1994, 3/1/1991

Attachments

No Attachments

Approval Signatures

Step Description	Approver	Date
Medical Executive Committee	Stephanie Denson: Manager, Medical Staff Office	pending
Pharmacy & Therapeutics Committee	Sul Jung: Associate Director of Pharmacy Services	3/10/2026
Pharmacy Services	Sul Jung: Associate Director of Pharmacy Services	2/24/2026

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Next Review:	*2 years after approval*
Owner:	*Jessica Rodriguez: Manager, Cardiopulmonary Services*
Policy Area:	*Respiratory Care*
References:	

R.58 Respiratory Care Pulmonary Function Testing

POLICY:

To establish safe and effective guidelines and procedures for performing, documenting, and reporting Pulmonary Function Testing in the Respiratory Therapy Department's PFT Lab. These procedures will meet the standards set by the American Thoracic Society~~, AARC, JCAHO, OSHA, Title 22~~ and Ventura County Medical Center/Santa Paula Hospital policies and procedures.

PROCEDURE:

DEFINITIONS

PFT - Pulmonary Function Test
FVC - Forced Vital Capacity
FEV – Forced Expiratory Volume
FEF - Forced Expiratory Flow
PEF - Peak Expiratory Flow
DLCO- Diffusion Capacity of the Lung
COPD - Chronic Obstructive Pulmonary Disease
TLC - Total Lung Capacity
VC - Vital Capacity
RV - Residual Volume
FRC - Functional Residual Capacity
IC - Inspiratory Capacity
ERV - Expiratory Reserve Volume
MVV - Maximal Volume Ventilation
EHR - Electronic Health Record
O2 - Oxygen
RA - Room Air

GUIDELINES

1. The Pulmonary Function Laboratory Services performs the following procedures for both inpatients and outpatients.

A. Screener
    1. Flow Volume Loop Spirometry
        a. Lung Volumes and flow rates including Inspiratory and Expiratory
        b. FVC
        c. FEV1
        d. FEF 25-75%
        e. FEF 75-85%
        f. FEV1/FVC %
        g. PEF
    2. Indications
        a. Persistent shortness of breath
        b. Persistent cough
        c. Preop evaluation
        d. Tobacco Abuse
        e. Asthma
        f. COPD

B. Limited
    1. Flow Volume Loop Spirometry
        a. Spirometry testing is reference on A. 1 a-g
    2. Pre and post bronchodilator
        a. Albuterol 2 puffs will be administered with spacer
        b. Post administration a minimum of 10 minutes before repeating spirometry
    3. Indications
        a. Items listed in A, 2, a-f
        b. Testing responsiveness to Bronchodilator

C. DLCO may be added to the Screener or Limited testing
    1. Indications
        a. Patients needing baseline and follow up PFT's for chemotherapy or Amiodarone
        b. Restrictive diseases

D. Complete PFT
    1. Flow Volume Loop Spirometry
        a. Spirometry testing is reference on A. 1-8
    2. Pre and post bronchodilator
    3. Diffusion
        a. DLCO

b. Patient must be off oxygen for 30 minutes in order to complete DLCO testing

4. Plethysmography and/or lung volumes
    a. TLC
    b. VC
    c. RV
    d. RV/TLC %
    e. FRC Pl
    f. IC
    g. ERV
5. If patient is unable to perform plethysmography, nitrogen (N2) washout is utilized
    a. TLC
    b. VC
    c. RV
    d. RV/TLC %
    e. FRL N2
    f. IC
    g. ERV
6. MIP/MEP
7. MVV
8. Indications
    a. Indication listed in B, 3, a-b
    b. Distinguish restrictive from obstructive lung disease
    c. Pulmonary Fibrosis
    d. Restrictive diseases: Rheumatoid Arthritis, Lupus, Scleroderma, Pulmonary Fibrosis,
    e. Neuromuscular disease

E. Blood Gas Analysis
    1. Preformed Pre-Testing
    2. Physician must specify on RA or liter flow of O2
F. Pulse Oximetry
    1. Performed Pre-Testing
    2. Physician must specify on RA or liter flow of O2
G. The Pulmonary Function Lab exclusions
    1. Testing on patients less than four (4) years of age
    2. Methacholine (Provocholine) challenge testing
    3. Isolation patients

4. Trached patients

H. PFT requisitions for entities not utilizing the electronic health record (EHR):

1. Requirement
    a. Patient name
    b. Date of birth
    c. Test requested
    d. Prescribing practitioner and clinic location
    e. Diagnosis
    f. Language translation requirements other than Spanish (to allow for provision of translation on a timely basis)

I. PFT results will be for review in

1. EHR, interpretation only
2. PACS system, test results and interpretation

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Attachments

No Attachments

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Medical Executive Committee	Stephanie Denson: Manager, Medical Staff Office	pending
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Respiratory Care	Jessica Rodriguez: Manager, Cardiopulmonary Services	1/26/2026

VENTURA COUNTY HEALTH CARE AGENCY

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Owner:	*Jessica Rodriguez: Manager, Cardiopulmonary Services*
Policy Area:	*Respiratory Care*
References:	

R.94 Automatic Spacer Protocol

POLICY:

At Ventura County Medical Center (VCMC) and Santa Paula Hospital (SPH), all metered dose inhalers (MDI) shall be administered to patients with an appropriate spacer device.

PROCEDURE:

A. A Licensed Practitioner (LP) places an order for an MDI in the electronic health record (EHR). Example MDI treatments include but are not limited to the following formulary medications:
   1. Albuterol (Ventolin HFA)
   2. Ipratropium (Atrovent HFA)
   3. Albuterol-Ipratropium (Combivent Respimat)
   4. Budesonide/formoterol (Symbicort)
   5. Fluticasone (Flovent HFA)

B. An order for an appropriately sized spacer (with or without mask) shall be automatically entered to accompany the MDI order as a “protocol/standardized procedure – cosign.”

C. The appropriate size is auto-selected based on the patient’s age.
   1. Age <2 years old: Spacer with infant mask
   2. Age 2-6 years old: Spacer with pediatric mask
   3. Age >6 years old: Spacer
   4. Use of the spacer with adult mask will be determined on an individual basis.

D. To reduce duplicate orders, this automatic spacer order shall occur only once per patient encounter.

E. Pharmacy reviews the respiratory therapy order for appropriateness before verifying for distribution and administration (see policy *PH.55 Medication Order Management*).

F. Respiratory Therapists retrieves the appropriate sized spacer and places a patient label on the spacer for patient administration with the MDI.

G. If the spacer size is deemed inappropriate for the patient, the Respiratory Therapist may re-enter the spacer order for the corrected size as a “protocol/standardized procedure – cosign” communication order.

H. All MDI treatments shall be administered with the ordered spacer.

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Policy Area:	*Surgical Services*
References:	

S.80 Hybrid Surgery Suite

POLICY:

To define the use of the Hybrid Surgery Suite at Ventura County Medical Center to ensure consistent and proper use of this highly technical room.

The Hybrid Surgery Suite shall perform as a surgical operating suite with complicated operative procedures that include, but are not limited to, complex trauma cases, vascular and advanced abdominal cases necessitating inter-operative radiologic diagnostic testing, advanced neurological cases requiring diagnostic vascular techniques and imaging, advanced cardio thoracic surgery with the high probability of necessitating cardiopulmonary bypass capability and cardiac angiography that has a high potential for converting to an open cardiothoracic case. All Surgery Department policies shall be adhered to in this specialty suite.

PROCEDURE:

A. Egress, Access and Traffic Patterns

1. Access into and out of the Hybrid Surgery Suite which shall be designated as a "restricted" area.
2. All staff must wear surgical attire, masks and hair coverings at all times. Glasses, goggles, shields or masks with shields shall be worn for all cases to protect staff from splatters and exposure to blood and bodily fluids. (See Surgery policy S.73, *Standard (Universal) Safeguards in The Operating Room*). All staff entering the restricted area of the Hybrid Surgery Suite are to wear closed-toe shoes. Shoe covers shall be worn for cases in which splattering is possible.
3. Only designated staff with documented Hybrid Surgery Suite competency may access the room and the associated control room.
4. Traffic patterns for entering and exiting the Hybrid Surgery Suite will be restricted and directed by the circulating Registered Nurse and/or the Surgeon during each surgical case.
5. For emergent and trauma cases, patient entry into the Hybrid Surgery Suite may occur through the outermost hallway entrance to facilitate rapid access and life-saving intervention. In these situations, traffic flow will be controlled by the circulating Registered Nurse to maintain patient safety while minimizing unnecessary personnel movement and preserving the sterile environment to the extent possible during emergent conditions
6. Once the patient is stabilized, standard restricted traffic patterns and sterile field practices will be re-established.
7. Vendors shall be vetted and approved for entry into the Hybrid Surgery Suite by the ~~Clinical Nurse~~

~~Manager~~Director of Perioperative Services or designee. Vendors may not enter the Hybrid Surgery Suite unescorted. All appropriate immunization and Health Insurance Portability and Accountability Act (HIPAA) compliance documents will be on file in hard copy or electronically. Vendors must wear appropriate surgical attire provided by the hospital.

B. Movable Equipment and Carts

1. At least one case cart is to be utilized for each case and will be brought to the Hybrid Surgery Suite via the sterile core.
2. Sterile supplies will enter the Hybrid Surgery Suite via the sterile core. Dirty instruments will exit the room via the semi- restricted corridors and returned back to the Sterile Processing Department (SPD) for decontamination.
3. Traffic patterns to and from the Hybrid Surgery Suite will isolate the clean and soiled case carts.
4. All specialty or case specific equipment such as a cell saver or microscope shall be stored in the equipment room and shall be delivered to the Hybrid Surgery Suite via the semi-restricted corridor prior to the start of the case.
5. Equipment shall be cleaned prior to each case and during the room's terminal clean procedure using manufacturer's instructions and returned to the equipment storage room after use.

C. Cleaning of the Hybrid Surgery Suite will be completed by the turnover team and Housekeeping.

1. The circulating nurse will initiate room turnover.
2. Housekeeping staff and turnover team staff will clean the room using the current Association of periOperative Registered Nurses (AORN) Standards outlined in the current cleaning Environmental Services (EVS) policies and protocols.
3. Trash will be transported out of the room via the semi-restricted corridor and delivered to the trash holding bin area.
4. Soiled linen will be bagged and removed via the semi-restricted corridor and placed in the dirty utility room soiled linen storage bin for pick up via laundry services.
5. Clean linen will be brought to the Hybrid Surgery Suite via the semi-restricted corridor.

D. Radiation Safety

1. All staff will adhere to radiation safety procedures.
2. Staff must wear radiation protective gear and follow radiation safety precautions.
3. Clean portable lead shields will be available in the room and used when appropriate.
4. All staff will wear radiation detection devices that are measured and changed monthly.

E. Room Capacity

1. Only staff assigned to the case or vendors authorized to be in the Hybrid Surgery Suite during a specific case will be in the room.
2. There shall be no more than 20 individuals in the room at one time to ensure that all radiation safety processes can be maintained and monitored by the circulating RN.
3. The circulating RN in charge of the case and the surgeon will determine who may be in the room

~~Resource:~~

~~Guideline for environmental cleaning. In: *Guidelines for Perioperative Practice*. Denver, CO: AORN, Inc; 2019.~~

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Attachments

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Surgery Committee	Stephanie Denson: Manager, Medical Staff Office	pending
Nursing Administration	Danielle Gabele: Chief Nursing Executive, VCMC & SPH	3/23/2026
Nursing Administration	Sherri Block: Associate Chief Nursing Executive, VCMC & SPH	3/23/2026
Surgical Services	Gwendolyn Vontoure: Director Perioperative Services	3/23/2026

VENTURA COUNTY
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References:	

Z.20 Court Procedures in the In-Patient Psychiatric Unit (IPU)

POLICY:

~~To assist patients, the Public Defender and the Patient's Rights Advocates in the exercise of due process of law regarding detention for involuntary treatment. Accuracy in the preparation of reports to the court and timely handling of the legal documents and attention to the necessary procedures of the court are given our highest priority. TERMS: Welfare and Institution Code sections are referred to by the section number only. For example, W&I Code Section 5150 will be referred to as 5150 legal status.~~

The In-Patient Psychiatric Unit (IPU) shall support patients, the Public Defender, and Patient Rights Advocates in the exercise of due process related to involuntary detention and treatment in accordance with applicable Welfare and Institutions Code provisions. Accuracy, timeliness, confidentiality, and proper handling of legal documents are required to ensure protection of patient rights and compliance with legal standards.

TERMS

Welfare and Institutions Code sections are referred to by section number only. For example, W&I Code Section 5150 will be referred to as “5150 legal status.” Legal status references correspond to applicable provisions governing involuntary detention and treatment.

PROCEDURE:

COURT INTERPRETER

1. ~~A Certified Court Interpreter is required for any court procedure requiring patient translation services. The existing list of Certified Court Interpreters is accessed through notification to Mental Health Court (MHC) of the impending court procedure along with the request for specific translation services. See Translator/ Interpreter Services Policy and Procedure for specific instructions on ordering a Court Interpreter.~~

   ~~ACUTE CARE PSYCHIATRIST:~~

2. ~~Determine the need for or change of involuntary legal status.~~
3. ~~Complete the documentation as required by the court~~
   a. ~~5250~~

b. 5260

c. 5270

d. 5300

e. 5353

f. Capacity for Medication Consent (Riese)

SHIFT SUPERVISOR/CHARGE NURSE (SS/CN)

4. Stay abreast of the changes in legal status anticipated on each shift and ensure nursing staff follows through.
5. Oversee the nursing and clerical staff for accuracy and timeliness in completion of the court documents. Group all document copies for one patient together. The court clerks will distribute them after stamped.
6. Review Court Cases from email sent from Courts.
7. Clerk faxes documents to the appropriate court for processing. Documents must be delivered at 1500 hours by the day prior to the court hearing. Conservator papers may be entered prior to 1700.
8. Charge Nurse Completes Notification Form for any errors resulting in lapse in legal status.
9. On the day of court in the IPU:
    a. Assign a trained staff as bailiff. Regular court days are Monday, Tuesday, Thursday and Friday.
    b. Arrange for back-up coverage for the bailiff during the time special court duties are carried out.
    c. Prepare court office for on-line Court Hearing during Covid. Ensure availability of Conference room post pandemic. Find out the name of the patient and the type of hearing scheduled.
    d. As early as possible in the shift, confirm the court calendar and:
        1. Notify the team psychiatrist and tell them the time the documentation is due to the nursing clerk/bailiff. Psychiatric evaluations for 5250 hearings are required to be done on the day of the hearing. Conservatorships (5353, 5358) may be done earlier.
        2. Notify the staff designated as bailiff.
        3. Arrange for notification of the team RN.
    e. Requests for additional cases to be placed on the calendar may be made, such as a capacity hearing. The judge makes the decision when to calendar the item.

Charge RN

10. Assign appropriate staff to prepare the patient as appropriate for the event. Whenever possible, the patient should wear his/her own clothing rather than hospital clothing.

BAILIFF

11. Prior to court session:
    a. Gather charts and reports and remind psychiatrists whose reports are late.
    b. Make copies as needed.
    c. Assist the Public Defender to find and interview patients on the calendar.
    d. Assist in notifying the psychiatrist to appear when needed.

e. ~~Distribute authenticated copies of 5250/5260 RIESE. Documentation of 5353/5358 is via Court Clerk list placed in court notebook, until formal letters arrive within three (3) business days.~~

~~SHIFT SUPERVISOR/CHARGE NURSE~~

12. ~~Obtain from the court, the Public Defender, a Patient's Rights Advocate, or the Public Conservator, the disposition for every case heard by the court. Input from the bailiff may also be useful, but may not be considered official communication of the results of the hearing. May call Court Clerk for verification.~~

    a. ~~Place in "Court" book the original listing of hearings and their disposition.~~

~~TEAM RN/designated LNS:~~

13. ~~Give patient appropriate copy.~~
14. ~~File the Medical Record copy in the legal section of the chart.~~
15. ~~Complete the Firearms Prohibition when necessary. See Firearms Prohibition Policy and Procedure.~~

A. A Certified Court Interpreter is required for any court procedure requiring patient translation services. Certified Court Interpreters shall be requested through notification to Mental Health Court (MHC) of the impending court procedure along with the request for specific translation services. See Translator/ Interpreter Services Policy and Procedure for instructions on ordering a Court Interpreter.

PSYCHIATRIST:

B. Determine the need for or change of involuntary legal status.
C. Complete the documentation as required by the court
    a. 5250
    b. 5260
    c. 5270
    d. 5300
    e. 5353
    f. Capacity for Medication Consent (Riese)

Nursing Shift Manager/Charge Nurse (CN)

- Maintain awareness of anticipated legal status changes each shift and ensure appropriate follow-through by nursing staff.
- Oversee nursing and clerical staff for accuracy and timeliness of court documentation preparation.
- Review court case notifications received from the court.
- Ensure documents are transmitted to the appropriate court within court-required timelines, typically by 1500 hours on the day prior to the hearing unless otherwise directed by the court. Conservatorship papers may be submitted prior to 1700 hours when applicable.
- Complete Notification Form for any errors resulting in lapse in legal status.
- Assign staff to prepare the patient for court participation. Whenever possible, patients should wear personal clothing rather than hospital attire.
- Obtain from the court, the Public Defender, a Patient's Rights Advocate, or the Public Conservator, the disposition for every case heard by the court.May call Court Clerk for verification.

- Place in "Court" book the original listing of hearings and their disposition.
- Complete the Firearms Prohibition when necessary. See Firearms Prohibition Policy and Procedure.

- **COURT DAY PROCEDURES** On the day of court in the IPU Confirm the Court Calendar

A. Assign trained staff to serve as court coordinator. Regular court days are Monday, Tuesday, Thursday, and Friday, except court holidays or as otherwise scheduled by the court.b. Arrange back-up coverage during court duties.c. Prepare court space for virtual or in-person hearings as scheduled.

1. Notify the team psychiatrist of documentation deadlines. Psychiatric evaluations for 5250 hearings shall be completed on the day of the hearing. Conservatorship evaluations may be completed earlier.
2. Notify assigned court coordinator.
3. Notify assigned nursing staff.

B. Requests for additional cases to be placed on the calendar may be made, such as a capacity hearing. The judge makes the decision when to calendar the item.

A. **Court Coordinator**

B. The assigned staff member serves a coordination role supporting court operations and does not perform law enforcement functions.

a. Make copies of court calendar as needed.

b. Assist the Public Defender to find and interview patients on the calendar.

c. Assist in notifying the psychiatrist to appear when needed.

All revision dates: 2/26/2026, 4/12/2023, 2/18/2020, 3/1/2009, 9/1/2008, 8/1/2008, 2/1/2007, 10/1/2006, 7/1/2004, 7/1/2002, 2/1/2000

Attachments

No Attachments

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Medical Executive Committee	Stephanie Denson: Manager, Medical Staff Office	pending
Psychiatry Committee	Stephanie Denson: Manager, Medical Staff Office	4/3/2026
Nursing Administration	Danielle Gabele: Chief Nursing Executive, VCMC & SPH	2/26/2026
Nursing Administration	Sherri Block: Associate Chief Nursing Executive, VCMC & SPH	2/26/2026

Step Description	Approver	Date
Inpatient Psychatric Unit & Crisis Stabilization Unit	Erin Olivera: Clinical Nurse Manager, IPU/CSU	2/26/2026

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References:	

Z.79 CSU Patient Assessment Referrals from Outside Facilities

POLICY:

Ventura County Medical Center's Psychiatric Crisis Stabilization Unit (CSU) shall accept ~~all referrals~~referral inquiries for review when capacity permits. Referrals shall be accepted based on clinical appropriateness and bed availability. Patients shall be accepted if they are determined to be medically ~~screened (or medically cleared when clinically indicated)~~stable for psychiatric crisis stabilization services, stable for transport, ~~alert~~ and able to participate in the assessment process to the extent clinically feasible. Language is not considered a barrier for assessment. Patients shall be evaluated on an individual basis. The appropriate and least restrictive level of care shall be determined in accordance with current W & I ~~code~~Code. The CSU physician retains final authority to determine medical appropriateness for admission.

PROCEDURE:

1. ~~Staff in the CSU shall take calls from outside facilities referring patients for assessment. Staff shall complete an initial review to determine clinical appropriateness for CSU services.~~
2. ~~Medical screening shall be completed prior to acceptance to the CSU.The CSU physician, on call physician, or medical director shall review the case to determine if medical screening is complete and medical clearance is not indicated. If medical clearance indicated (as determined by referring entity or requested by our medical staff), the medical clearance evaluation will be reviewed by the CSU physician, on call physician, or medical director.~~
3. ~~CSU staff shall advise all callers that patients being referred for assessment must be ambulatory or able to safely transfer self from wheelchair to toilet/bed and back.~~
4. ~~The CSU is not equipped to provide oxygen or IV administration.~~
5. ~~The following information may be requested from the referring facility:~~
    a. ~~Demographics – Must be received and reviewed prior to acceptance of the patient for assessment.~~
    b. ~~Lab values, including Blood Alcohol Level (BAL) drug screen including, if applicable:~~
        - ~~Acetaminophen level – Two levels~~
        - ~~Tricyclic level – Two levels~~
        - ~~Other relevant level(s)~~

c. ~~Current pregnancy tests on patients of child-bearing age.~~

d. ~~Studies/imaging studies which may include EKG, X-rays, CT Scan, MRI results or other clinically relevant tests.~~

e. ~~Treatment, vital signs, and physician's statement of medical clearance from the referring facility.~~

f. ~~Current and complete legal status (i.e., 5150, LPS conservatorship, etc.).~~

6. ~~Once medical screening (or clearance) has been established, CSU staff shall notify the referring facility that the patient has been accepted for further evaluation and assessment.~~

7. ~~It is the responsibility of the sending hospital to arrange transport for the patient to the CSU.~~

A. The Intake Department will take calls from outside facilities referring patients for possible admission. Intake staff shall complete an initial review to determine clinical appropriateness for CSU services.

B. Medical screening documentation shall be completed prior to acceptance to the CSU. The CSU physician, on-call physician, or medical director shall review the case to determine whether the available documentation demonstrates medical stability appropriate for CSU services. If medical clearance is indicated (as determined by the referring entity or requested by CSU medical staff), the medical clearance evaluation shall be reviewed by the CSU physician, on-call physician, or medical director prior to acceptance.

C. Intake staff shall advise all callers that patients referred to the CSU must be able to safely mobilize or transfer with assistance consistent with CSU staffing capabilities.

D. The CSU is not equipped to provide continuous oxygen therapy or intravenous (IV) medication or fluid administration. Patients whose medical needs require ongoing oxygen therapy or IV treatment exceeding CSU clinical capabilities are not appropriate for CSU level of care.

E. If a patient is identified prior to or after arrival as requiring services beyond CSU capability, the patient shall be transferred to the Emergency Department for medical evaluation and management.

F. **The following information may be requested from the referring facility:**

1. Demographics – Must be received and reviewed prior to acceptance of the patient for assessment.
2. Laboratory values, which may include Blood Alcohol Level (BAL), toxicology screening, or other clinically relevant studies, including, if applicable:
    - Acetaminophen level – Two levels
    - Tricyclic level – Two levels
    - Other relevant level(s)
3. Current pregnancy tests on patients of child-bearing age.
4. Studies or imaging which may include EKG, X-rays, CT scan, MRI results, or other clinically relevant tests.
5. Treatment provided, vital signs, and physician documentation of medical stability or clearance from the referring facility.
6. Current and complete legal status (i.e., 5150, LPS conservatorship, etc.).

G. Once medical stability documentation has been established, Intake staff shall notify the referring facility that the patient has been provisionally accepted. Final admission determination is confirmed upon arrival

assessment by CSU clinical staff.

H. It is the responsibility of the sending hospital to arrange transport for the patient to the CSU.

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Medical Executive Committee	Stephanie Denson: Manager, Medical Staff Office	pending
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Nursing Administration	Danielle Gabele: Chief Nursing Executive, VCMC & SPH	2/26/2026
Nursing Administration	Sherri Block: Associate Chief Nursing Executive, VCMC & SPH	2/26/2026
Inpatient Psychatric Unit & Crisis Stabilization Unit	Erin Olivera: Clinical Nurse Manager, IPU/CSU	2/26/2026

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Policy Area:	*Crisis Stabilization Unit (CSU)*
References:	

Z.81 Psychiatric Assessment in the Crisis Stabilization Unit (CSU)

POLICY:

All patients presenting to the Ventura County Medical Center Crisis Stabilization Unit (CSU) shall ~~be assessed~~receive an assessment by a licensed mental health professional as clinically indicated and consistent with CSU services.

PROCEDURE:

- After it is determined that a patient is appropriate for CSU physician-level services, the information shall be presented to the on-duty psychiatrist.
- ~~The CSU psychiatrist shall provide psychiatric assessments and is available Monday through Sunday, 07:00 am to 7:00 pm. An after hours on-call psychiatrist is available from 7:00 pm to 7:00 am.~~

  The CSU psychiatrist provides on-site psychiatric assessment services Monday through Sunday from 07:00 am to 7:00 pm. Psychiatric coverage is available after hours via an on-call psychiatrist from 7:00 pm to 7:00 am.

  ~~After it is determined a patient meets the criteria for physician-level CSU services, the information shall be presented to the on duty psychiatrist.~~
- ~~The psychiatrist shall complete orders in the electronic health record (EHR) when indicated. This may include orders for medications for medical conditions and psychiatric medications.~~

  The psychiatrist shall complete orders in the electronic health record (EHR) when indicated. This may include orders for psychiatric medications and medications for medical conditions.
- ~~All patients shall be seen and assessed within 24 hours of arrival and daily while in the CSU. Physician assessments shall be documented in the EHR on a daily basis.~~

  All patients shall receive a psychiatric assessment within 24 hours of arrival, or sooner as clinically indicated, and shall be reassessed daily while receiving CSU services. Physician assessments shall be documented in the EHR on a daily basis.
- ~~After hours, the on-call psychiatrist shall be responsible for completing patient orders. The on-call psychiatrist may use a three-way call with the patient and the nurse to obtain medication consent for psychiatric medications. Orders for medications for patient medical problems may also be ordered at this~~

~~time.~~

After hours, the on-call psychiatrist shall be responsible for completing patient orders. The on-call psychiatrist may use a three-way call with the patient and the nurse to obtain medication consent for psychiatric medications. Orders addressing patient medical conditions may also be issued at this time.

- ~~The CSU psychiatrist may elect to evaluate psychiatric patients in the VCMC Emergency Department (ED) under certain circumstances, such as when the CSU is at capacity or on diversion.~~

  The CSU psychiatrist may elect to evaluate psychiatric patients in the Ventura County Medical Center Emergency Department (ED) under certain circumstances, such as when the CSU is at capacity or on diversion.

- The CSU psychiatrist may elect to evaluate psychiatric patients in the Ventura County Medical Center Emergency Department (ED) under certain circumstances, such as when the CSU is at capacity or on diversion.

- ~~Generally, patients requiring seclusion or restraints are directly admitted into the Inpatient Psychiatric Unit (IPU) under a psychiatrist's orders.~~

  Patients requiring seclusion or restraints beyond CSU capability shall be transferred or admitted to the Inpatient Psychiatric Unit (IPU) under psychiatrist orders.

- ~~Patients requiring immediate medical attention shall be seen by a physician in the ED.~~

  Patients requiring medical evaluation or treatment beyond CSU capability shall be transferred to the Emergency Department (ED) for evaluation by an ED physician.

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Nursing Administration	Sherri Block: Associate Chief Nursing Executive, VCMC & SPH	2/26/2026
Nursing Administration	Danielle Gabele: Chief Nursing Executive, VCMC & SPH	2/26/2026
Inpatient Psychatric Unit & Crisis Stabilization Unit	Erin Olivera: Clinical Nurse Manager, IPU/CSU	2/26/2026

VENTURA COUNTY HEALTH CARE AGENCY

Origination:	*12/12/2019*
Effective:	*Upon Approval*
Last Approved:	*N/A*
Last Revised:	*4/3/2026*
Next Review:	*3 years after approval*
Owner:	*Erin Olivera: Clinical Nurse Manager, IPU/CSU*
Policy Area:	*Crisis Stabilization Unit (CSU)*
References:	

Z.82 Alcohol Detoxification--Clinical Institute Withdrawal Alcohol (CIWA)

POLICY:

Ventura County Medical Center (VCMC) and Santa Paula Hospital (SPH) are dedicated to the delivery of safe, quality patient care. Patient alcohol withdrawal may be treated in the Emergency Department (ED), hospital inpatient units, Crisis Stabilization Unit (CSU), Inpatient Psychiatric Unit (IPU) using the Clinical Institute Withdrawal Alcohol (CIWA) protocol.

PROCEDURE:

HOSPITAL refers to Ventura County Medical Center (VCMC), including the Inpatient Psychiatric Unit (IPU), Crisis Stabilization Unit (CSU), and Santa Paula Hospital (SPH). ~~***See Section I below.***~~ ***See Section I below.***

SECTION I – HOSPITAL

All locations/departments:

Licensed nursing staff shall:

- Assess the patient as soon as possible using the CIWA scale, once ordered.
- Document the assessment on the CIWA scale.
- Medicate the patient based on the CIWA alcohol detoxification orders and the findings of the CIWA scale.
- Document in the electronic health record (EHR).

Emergency Department (ED):

Staff shall:

- Identify the patient as at risk for alcohol withdrawal.
- Assess for coexisting mental illness
- Notify the provider on duty regarding the patient's condition.

Crisis Stabilization Unit (CSU):

Staff shall:

- Identify the patient as at risk for alcohol withdrawal.
- Assess for coexisting mental illness.

- Notify the psychiatrist on duty regarding patient's condition.

The CSU psychiatrist shall:

- Evaluate the patient for appropriateness of management in the CSU.
- If indicated, order CIWA protocol.

Licensed nursing staff shall:

- Assess the patient as soon as possible using the CIWA scale, once ordered.
- Document the assessment on the CIWA scale.
- Medicate the patient based on the CIWA alcohol detoxification orders and the findings of the CIWA scale.
- Document in the electronic health record (EHR).

Inpatient Psychiatric Unit (IPU):

The IPU psychiatrist shall:

- Evaluate the patient for appropriateness of management in the IPU.
- If indicated, order CIWA or a benzodiazepine sparing protocol in the EHR.

Staff shall:

- Identify the patient as at risk for alcohol withdrawal.
- Assess for coexisting mental illness.
- Notify the psychiatrist on duty regarding patient's condition.

Licensed nursing staff shall:

- Assess the patient as soon as possible using the CIWA scale, once ordered.
- Document the assessment on the CIWA scale.
- Medicate the patient based on the CIWA alcohol detoxification orders and the findings of the CIWA scale.
- Document in the electronic health record (EHR).

All revision dates: 4/3/2026, 12/12/2019

Attachments

No Attachments

Approval Signatures

Step Description	Approver	Date
Medical Executive Committee	Stephanie Denson: Manager, Medical Staff Office	pending
Psychiatry Committee	Stephanie Denson: Manager, Medical Staff Office	4/3/2026
Nursing Administration	Sherri Block: Associate Chief Nursing Executive, VCMC & SPH	2/26/2026
Nursing Administration	Danielle Gabele: Chief Nursing Executive, VCMC & SPH	2/26/2026
Inpatient Psychatric Unit & Crisis Stabilization Unit	Erin Olivera: Clinical Nurse Manager, IPU/CSU	2/26/2026

Step Description	Approver	Date

VENTURA COUNTY
HEALTH CARE AGENCY

Origination:	*N/A*
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Owner:	*Danielle Gabele: Chief Nursing Executive, VCMC & SPH*
Policy Area:	*Nursing Practice Protocols*
References:	

NPP.10 Case Management Orders by Protocol to Facilitate Discharge

Policy:

The purpose of this policy is to improve efficiency in care delivery, eliminate unnecessary discharge delays, and facilitate hospital throughput.

It is the policy of Ventura County Medical Center (VCMC) and Santa Paula Hospital (SPH) that all standardized procedures are developed collaboratively and approved by the Interprofessional Practice Committee (IPC), whose membership consists of Physicians, Registered Nurses (RN), Pharmacists, Advanced Practice Nurses and Administrators. Standardized procedures are reviewed every three years.

To outline and define responsibility in performing interventions requiring a physician order in accordance with the California Board of Registered Nursing and the Nursing Practice Act, all approved standardized procedures will be kept in Policy Stat. The Registered Nurse, as outlined in the Nurse Practice Act, Business and Professions Code Section 2725, is authorized to implement appropriate standardized procedures or changes in treatment regimen after observing signs and symptoms of illness, reactions to treatment, general behavior, or general physical condition, and determining that these exhibit abnormal characteristics.

Function to Be Performed:

Registered Nurse Case Managers will utilize this protocol for initiating three types of orders to facilitate discharges and transfers. These orders are for COVID -19 testing, arranging discharge transportation, and for Home Health Agency (HHA) services.

Applicable Departments:

Case Management and Social Services (heretofore called Case Management). Case Management RNs are the only nurses who may use this policy.

Roles and Responsibilities

Protocol ordering for this procedure will be completed by the Case Management RN. Case Management RNs will review and implement these functions whenever this task is performed.

A. Scope of supervision required

1. The RN is responsible and accountable to the Director of Case Management.
2. Overlapping functions are to be performed in areas which allow for a consulting provider to be available to the RN by phone or in person.
3. ~~Provider~~Licensed practitioner (LP) consultation is to be obtained under the following circumstances:
    a. Emergency conditions requiring prompt medical intervention
    b. Upon the request of the patient, RN or ~~physician~~LP
    c. Anytime any deviation from this protocol is necessary
4. Limitations on Settings - This policy applies to patients treated at VCMC and SPH.

B. Requirements for the RN
1. Active California RN license
2. Special training: formal orientation to care coordination and discharge planning

C. Evaluation of the RN competence
1. Initial upon hire to department: the Nurse director will onboard case management RNs to this protocol. Documentation of training will be held by the department director.

Procedures:

RN Case Managers ~~will~~may enter orders for the following using the communication type “Protocol/ Standardize Procedure – co-sign”:

A. **COVID-19 Testing:** Knowledge of Covid Status is often needed timely to facilitate timely transitions of care. At the request of a receiving facility such as an Acute Care Hospital, Acute Rehabilitation Facility, Skilled Nursing Facility, shelter, or other post-acute care provider, the RN Case Manager will enter an order for “SARS-CoV-2 (COVID-19) Ag POC” using the communicate type “Protocol/Standardize Procedure – Co-sign.”

B. **Transportation:** Upon learning of the need for transportation for discharge/transfer the RN Case Manager will confirm the appropriate level of transportation needed. Once determined, the RN Case Manager will enter an “Arrange Discharge Transportation” order using the communication type “Protocol/ Standardize Procedure – Co-sign” for ambulatory, wheelchair, gurney, or ambulance transport.

C. **Home Health:** Home Health Agencies require an order for home health services as part of the referral packet. Home Health orders fall into two categories, start of care and resumption of care, and need to specify the specific type of staff and services needed. Upon learning of the need for home health services the RN Case Manager will enter a “Referral to Home Health Nursing” or "Referral to Home Health Physical Therapy PT/Occupational Therapy OT~~"~~. “(Ensure orders reflect current weight bearing status and other restrictions per orthopedics and therapy services)” order using the communication type “Protocol/Standardize Procedure – co-sign.”

Upon entering any of these types of orders, the RN Case Manager will notify the ~~treating physician or licensed practitioner~~LP that an order(s) has been entered and requires a co-signature.

Documentation:

A. The RN will document the following in the electronic health record (EHR)
1. Orders entered for co-signature as outlined above

2. Any subsequent communications with care team members that relate to these orders

All revision dates:

Attachments

No Attachments

Approval Signatures

Step Description	Approver	Date
Medical Executive Committee	Stephanie Denson: Manager, Medical Staff Office	pending
Interdisciplinary Practices Committee	Stephanie Denson: Manager, Medical Staff Office	4/7/2026
Utilization Management Committee	Laura Zarate: Clinical Nurse Manager, Case Management	3/28/2026
Nursing Administration	Sherri Block: Associate Chief Nursing Executive, VCMC & SPH	3/12/2026
Nursing Administration	Danielle Gabele: Chief Nursing Executive, VCMC & SPH	3/12/2026
Protocol Author	Danielle Gabele: Chief Nursing Executive, VCMC & SPH	3/12/2026