MemorialCare™
Saddleback Medical Center

LABORATORY SERVICES

COMPENDIUM

2023 - 2025

MemorialCare Saddleback Medical Center

24451 Health Center Drive

Laguna Hills, CA 92653

(949) 452-3554

MemorialCare™
Saddleback Medical Center

LABORATORY SERVICES

ACCREDITATIONS

College of American Pathologists (CAP)	AU-ID# 1187862/AP# 2337601
Health Care Financing Administration (CLIA)	# 05D0578029
State of California Department of Health Services License	# CIF 539

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MEMORIALCARE SADDLEBACK MEDICAL CENTER

LABORATORY SERVICES

SMC MISSION:

To improve the health and well being of individuals, families and our communities through innovation and the pursuit of excellence.

SMC VISION:

To become Southern California's preferred, operationally excellent, fiscally sound provider of comprehensive, high-quality health services.

DESCRIPTION

At MemorialCare Saddleback Medical Center, we are dedicated to providing quality services to our patients with the most advanced laboratory testing and uncompromising customer service. We offer:

- Laboratory services 24 hours a day, 365 days a year
- State-of-the-art testing methodologies
- A wide range of in-house testing
- Quick and accurate STAT testing
- Reliable specimen handling and processing

DEDICATED & PROFESSIONAL STAFF

Our highly trained and dedicated staff is committed to providing you with the highest level of service:

- Courteous and knowledgeable staff
- Experienced phlebotomists (neonatal and pediatric proficient)
- Portocath nurse available at main laboratory location
- Back laboratory staffed with licensed Clinical Laboratory Scientists (CLS) and Medical Laboratory Technicians (MLT)
- Board-certified pathologists available for consultation 24 hours a day

For questions regarding test results, please call **(949) 452-3554**.

COMPREHENSIVE LAB TESING

Following is sampling of our comprehensive laboratory testing services:

- Blood Bank, Definitive
- Antibody Testing
- Bone Marrow Examinations
- Chemistry, Automated & Esoteric
- Coagulation Assays
- Consultative Pathology
- Endocrinology
- Fetal Lung Maturity Studies
- Hematopathology
- HIV Antibody Testing
- Microbiology
- Obstetrical/Prenatal Studies
- Therapeutic Drug Monitoring
- Urine Chemistry

PATHOLOGIST-SUPPORTED SPECIALTY TESTING AVAILABLE

Our pathologists are available to assist physicians with their decisions in a variety of medical specialties, including:

- Surgical and Cytopathology
- Fine Needle Aspiration
- Non-gynecological Cytology
- Clinical Pathology
- Breast Pathology
- Immunopathology
- Blood Bank and Transfusion Medicine
- Hematopathology
- Coagulation and Cellular Immunology
- Pediatric and Placental Pathology
- Bone Marrow Examination
- Cytochemical Stain

DIRECTORY

Laboratory: MEMORIALCARE SADDLEBACK MEDICAL CENTER

Locations: 24451 Health Center Drive
Laguna Hills, CA 92653

Phone/FAX:

Clinical Laboratory	(949) 452-3554
Clinical Laboratory (Fax)	(949) 452-3563
Anatomic Pathology	(949) 452-3562
Anatomic Pathology (Fax)	(949) 452-3066

Facility CEO	Marcia Manker	(949) 452-3622
Facility COO	Catherine Shitara	(949) 452-3853
Laboratory Medical Director	Vivian Mendoza, M.D.	(949) 452-3562
Transfusion Medicine Director	Thomas Hirose, M.D	(949) 587-3056

Laboratory Leadership:

Executive Director	Cheryl Dilbeck, CLS	(949) 452-3613
Technical Manager, Phlebotomy/Specimen Processing/Blood Donor Center/Point of Care	Usha Veeranna, CLS	(949) 452-3047
Technical Manager, Clinical Lab/Anatomic Pathology	Marose Ang, CLS	(949) 452-3055
Phlebotomy/Pathology Supervisor	Jessica Gray	(949) 452-3697
Blood Bank Supervisor	Cheryl Louie, CLS	(949) 452-3559

Technical Specialists/Coordinators:

Hematology Coordinator	John Turrin, CLS	(949) 452-3705
Microbiology/Chemistry Coordinator	Dolores Wertenberger, CLS	(949) 452-3560
Point of Care Technical Specialist	Gwen Uthus, CLS	(949) 452-3045
Quality Coordinator	Dharm Patel, CLS	(949) 452-3059
Anatomic Pathology	Amber Pham	(949) 452-3562

Laboratory Information Systems:

		(949) 452-3668

Blood Donor Center:

Blood Donor Center Coordinator	Gayle Harriman, RN	(949) 452-3161
Blood Donor Center Program Support Representative	Christine Draper	(949) 452-3159

TESTING GUIDELINES

ACCREDITATION/LICENSURE

MemorialCare Saddleback Medical Center (SMC) Laboratory maintains a current Clinical Laboratory Improvement Amendments (CLIA) number with the U.S. Department of Health and Human Services Health Care Financing Administration, is accredited by the College of American Pathologists (CAP), and holds all other necessary state licenses. For additional information or copies of our certificates, please call (949) 452-3532.

ALPHABETICAL TEST LIST

Information about specific tests can be found in the alphabetical test list section of this Compendium. This section contains test numbers, mnemonics, methodologies, performed/reported schedules, specimen requirements, CPT codes, and notes.

MEDICARE COVERAGE OF LABORATORY TESTING

When ordering laboratory tests that are billed to Medicare/Medicaid or other federally-funded programs, the following requirements may apply:

1. Only tests that are medically necessary for the diagnosis or treatment of the patient should be ordered. Medicare does not pay for screening tests, except for certain specifically approved procedures, and may not pay for non-FDA approved tests or those tests considered experimental.
2. If there is reason to believe that Medicare will not pay for a test, the patient must be informed. The patient must sign an Advance Beneficiary Notice (ABN) to indicate that he or she is responsible for the cost of the test if Medicare denies payment.
3. The ordering physician must provide an ICD-10 diagnosis code, not a narrative description, if required by the fiscal intermediary or carrier.
4. Organ or disease oriented panels should be billed only when all components of the panel are medically necessary.
5. Client customized panels should be billed to Medicare only when every component of the customized panel is medically necessary.
6. Medicare National Limitation Amounts for Current Procedural Terminology (CPT) codes are available through Health Care Finance Administration (HCFA) or its intermediaries. Medicaid reimbursement will be equal to or less than the amount of Medicare reimbursement.

Questions concerning utilization of CPT codes should be addressed with your local carrier, as local medical review policies may vary from one third-party payer to another. Call Admitting at (949) 452-3546 for more information.

MINIMUM ACCEPTABLE VOLUMES

This Compendium lists minimum acceptable volumes. If there is insufficient volume for testing, attempts will be made to locate any additional sample at SMC Laboratory which was collected at the same time. In this case, there may be delays.

This Compendium also lists pediatric minimum acceptable volumes. This volume is defined as the amount sufficient to perform one test, with no repeat or confirmatory testing.

PANELS

MemorialCare Saddleback Medical Center offers groups of standard HCFA Panels approved for Medicare patients; customized profiles require medical staff approval or physician signature at time of request. Individual components of Custom Panels may also be ordered individually, unless otherwise indicated.

REFLEX TESTING

Approved parameters for reflex testing and mandatory confirmation testing, which will occur when initial test result are positive or outside normal parameters and indicate that a second related test is medically indicated are defined in Table 1.

Table 1: REFLEX TESTS

Ordered Test	Result to Reflex	Mneumonic	Conditions	Department
ABO or RH	NA	**ABORH**	Per protocol	Blood Bank
Antibody Screens (ABSC)	Positive	**ABID**	Positive antibody screens require Antibody Identification.	Blood Bank
Bacterial Culture	Positive	Susceptibilities will be added when indicated.		Microbiology
CBC	If review criteria met, peripheral smear review or manual differential performed.	**PATH**	Review Criteria available upon request (LBD 500-4).	Hematology
Crossmatch	Incompatible	**ABID**	Incompatible crossmatch will be resolved by antibody identification.	Blood Bank
Fibrin Degradation Products	FDP not offered.	**D-Dimer**	Preferred methodology	Coagulation
FTI	FTI not offered.	**Free T4**	Free T4 measured instead of reporting calculated FTI.	Chemistry
GI PCR	CDiff Positive	**CDIFFTOX**	If GI PCR is positive, reflex to C Stool.	Microbiology
GI PC	PLSH or SALM or Yersi or VICH or SHIG or E0157 or E1 EC	**C Stool**		Microbiology

Table 1: REFLEX TESTS

Ordered Test	Result to Reflex	Mneumonic	Conditions	Department
Glucose	> 140 mg/dL	**HgbA1C**	If Glucose is greater than 140 mg/dL, reflex to HgbA1C for adult patients, excluding the Emergency Department with no previous HGbA1C in last 90 days.	Chemistry
HIV 1&2	Positive	**HIV SUP**	Positive screens reflex to HIV SUP. Differentiation, Supplemental. If HIV SUP is negative or indeterminate, reflex to HIV 1 by Quantitative NAAT ARUP.	Chemistry
LACTATE **POC LACTATE**	> 2.0 first occurrence	**D/C** **LACTATE (.LA)** Blood Cultures x 2	> 2.0 first occurrence, reflex to LACTATE 3 hours after initial LACTATE/POC LACTATE result. STAT Blood Cultures x 2 if not previously collected within 24 hours.	Chemistry POC
LIPID PANEL	TRIG > 400 < 1000 mg/dL	**LDL DIR**	TRIG > 400 < 1000 mg/dL, reflex to LDL Direct.	Chemistry
Ova & Parasite (O&P)	Parasite Panel performed unless conditions stated in order.	**PARASITE P:** Cryptosporidium Antigen and Giardia Antigen		Microbiology
Rh Immune Globulin Screen	Evidence of a large fetal-maternal hemorrhage (FMH)	**Kleihauer-Betke**	Kleihauer-Betke Stain will be done when there is evidence of a large fetal-maternal hemorrhage (FMH).	Blood Bank
Stool Culture		**Shigatoxin**	Regulatory	Microbiology
Syphilis	Reactive	**RPR**	**Reactive** samples will reflex a RPR confirmatory test that will be performed at LBMC. If the RPR results as Non-Reactive, the test Tpal AB-ARUP test will be ordered by a reflex rule. **Equivocal** samples will reflex to an RPR order and supplemental testing as indicated.	Chemistry

Table 1: REFLEX TESTS

Ordered Test	Result to Reflex	Mneumonic	Conditions	Department
Transfusion Reaction	Evidence of a transfusion reaction	**TRXN if DAT is positive.**	Notify pathologist and initiate extended investigation.	Blood Bank
UA	Positive Protein, positive nitrite, leukocyte esterase or blood	**UA MIC IND**	Microscopic added if nitrite, leukocyte esterase, blood or protein are positive.	Urinalysis
UAM	If WBC's are greater than 5 WBC/hpf and SQE ≤ 10.	**C UR**	Culture added if positive for leukocyte esterase or nitrite, or > 5 WBC/hpf and SQE ≤ 10.	Urinalysis
Urine Drug Screen	Positive drug screen from Hospital patients (women and children)	**- AMPS UR** **- BARBITURATES, URINE, QUANTITATIVE** **- BENZOD-ARUP** **- CDCO THC** **- COCAINE METABOLITE, URINE, QUANTITATIVE** **- CDCO METH** **- OPI UR QNT** **- PCP URINE** **- Fentanyl UR**	Drug level must be confirmed for all LDRP patients and children less than 12 years old.	Chemistry
Wet Mount	All wet mounts	**RAPID TRICHOMONAS**	All wet mounts Rapid Trichomonas	Microbiology

REFERRAL TESTING

One of SMC Laboratory's service goals is to support clients by providing comprehensive service for all reference laboratory testing. To accomplish this goal, SMC has enhanced its in-house test menu and test combinations by selecting primary vendors to perform additional tests not performed at SMC. Primary vendors are selected based upon aspects of service, quality, reliability, turnaround time, and price.

SMC's established referral test vendors fax or transmit test results expediently to SMC so that clients receive results by the fastest, most error-free method possible. If a client requests that a test performed by SMC, or by one of our primary vendors, be performed by another laboratory, SMC will honor that request if it is clearly indicated on the test request form submitted at the time the test is ordered. A handling fee will be added to reference testing.

SMC reserves the right to change vendors, test parameters, and costs for referral testing at any time. For questions, please contact staff at (949) 452-3554.

SPECIMEN CONTAINERS AND TUBES

- Saddleback Medical Center Laboratory requests that clients use the following guidelines to ensure safe handling procedures, non-compromised specimens, and fast and accurate test results.

ACCEPTABLE CONTAINERS

- Sterile specimen containers
- Swabs (sterile)
- Transport media

UNACCEPTABLE CONTAINERS/CONDITIONS

- Syringes with needles attached
- Specimens received in expired transport containers, media, or tubes
- Transfer tubes secured with parafilm
- Specimens that are mislabeled or unlabeled or don't have at least two (2) identifiers
- Specimens that are leaking from the container

SPECIMEN REJECTION/TEST CANCELLATION

All specimens must be collected, labeled, minimum last and first name with date of birth, transported, and processed according to procedure. Selecting the container type, volume, and special handling requirements needed for analysis before the specimen is collected is essential. If the criteria for these processes are not met, the specimen may be rejected or the test may be canceled. The following represent some reasons for specimen rejection or test cancellation:

- Inappropriate specimen type or difficulty in obtaining the specimen (e.g. hemolysis, clotted specimens)
- Insufficient volume for analysis
- Improperly labeled specimen
- Inappropriate specimen container
- Non-stable specimen container when culture is requested
- Improper specimen transport
- Specimen that has leaked in transit
- Specimen that has been sent in expired transport media
- Incomplete or incorrect test request form; for example, testing not marked
- Test request without a specimen
- Specimen without a test request
- Hemolyzed blood specimen where hemolysis affects results
- Clotted blood specimen for tests requiring whole blood

SPECIMEN STABILITY

Specimen stability for many tests is described in the alphabetical test list, for client convenience. Stability information may be useful in determining whether a previously processed patient sample is still appropriate for testing at SMC Laboratory. The temperatures and times listed under stability do not indicate preferred transport conditions or temperatures. If a particular specimen fits the stability criteria for an assay, please refer to the ***Transport*** section on how to send the specimen to SMC Laboratory.

STAT TESTING

Many procedures are offered by SMC Laboratory on a STAT (NOW) basis for emergency purposes 24 hours per day with an expected turn-around-time (TAT) of approximately one hour (unless otherwise indicated) from the time the

laboratory receives the specimen. ASAP orders are defined with an expected TAT of two to four hours from the time the laboratory receives the specimen.

Routine testing is generally completed within four hours.

All tests ordered on infants as STAT will be performed STAT.

The list of those tests which will be performed on a STAT basis for all other age populations are defined in laboratory procedure.

The following is a list of those tests that will be performed on a STAT basis for all other age populations:

Table 2: STAT Testing

Blood Bank		
1. Coombs, direct 2. Coombs, indirect 3. Cord blood studies 4. Rhogam work-up 5. Transfusion reaction work-up 6. Type & Crossmatch 7. Type & screen		
Chemistry		
1. Acetaminophen 2. Albumin 3. Alcohol 4. Alkaline Phosphatase 5. Ammonia 6. Amylase 7. Basic Metabolic Panel 8. Beta Hydroxybutyrate 9. B-Type Natriuretic Peptide (BNP) 10. Bilirubin, direct 11. Bilirubin, total 12. Calcium 13. Chloride 14. CKMB 15. Comprehensive Metabolic Panel 16. Cortisols 17. CPK	18. Creatinine 19. CRPHS (Cardiac) 20. CRP (non-cardiac) 21. CSF Protein/Glucose 22. Digoxin 23. Dilantin (Phenytoin) 24. Drug screen, rapid (coma urine) 25. Electrolytes 26. Gentamicin 27. Glucose 28. GGT (Gamma-glutamyl transferase) 29. HCG, quant 30. HIV – LDRP and Source Exposure Only 31. Lactate 32. LDH 33. Lipase 34. Lithuim	35. Mg 36. Myoglobin 37. Osmolality 38. Phosphorus 39. Potassium 40. Protein, total 41. Salicylate level 42. AST (SGOT) 43. ALT (SGPT) 44. Sodium 45. Tegretol (Carbamezapine) 46. Troponin 47. TSH – High Sensitive 48. Urea nitrogen 49. Valproic Acid 50. Vancomycin
Coagulation		
1. D-Dimer 2. Fibrinogen 3. Platelet Function Screen 4. Protime and INR 5. PTT 6. Plavix 7. Aspirin Resistance 8. Mixing Studies		
Hematology		
1. CBC 2. Hemoglobin 3. Hematocrit 4. Platelet count 5. Cell count and diff., CSF and Body Fluid 6. Sed Rate 7. ROM Plus		

Microbiology
1. Cryptococcal LFA – CSF (2 hours TAT) 2. Fetal Fibronectin 3. Gram stain (POS blood/CSF/Body Fluid gram stains (2 hours TAT) 4. Lactoferrin 5. ME PCR (CSF) – (2 hours TAT) 6. Mononucleosis 7. Occult Blood (FIT) – If ordered STAT 8. Strep A PCR 9. RP PCR (Respiratory Viral Panel) – (2 hours TAT) 10. Wet Mount/Rapid Trich 11. COVID-19 (Cepheid) 12. RSV/INFLU A+B/COVID (Cepheid) 13. Abbott BinaxNOW COVID-19 Antigen
Urinalysis
1. Pregnancy testing 2. Urinalysis

SPECIMEN COLLECTION

GENERAL INSTRUCTIONS FOR SPECIMEN COLLECTION

Collection instructions for individual tests appear in an alphabetical test list of this Compendium under Specimen Required. Please refer to this information to ensure that the appropriate sample has been collected for the test ordered.

I. ANTICOAGULATION LABORATORY MONITORING

Anticoagulation therapy is expanding with the addition of several new agents and newer medication on the near horizon. the following is a summary of laboratory monitory for these agents. When a laboratory assay is not used, weight adjusted administration provides the therapeutic dose. While factor Xa levels have been used in the past for the monitoring of the therapeutic effects of several anticoagulants, their utility has been limited and in many cases, does not correlate to the degree of therapeutic anticoagulation (e.g. LOVENOX). Currently, one of the only indications for Xa level monitoring is when a "lupus anticoagulant" (also known as anti-phospholipid antibody) is present which is interfering with the aPTT and/or Protime monitoring.

Anticoagulation should be used with caution for the following patients: obese, newborns, patients with renal failure (unless the medication is metabolized by the liver).

Recommendation for laboratory monitoring of patient anticoagulation:

Medication		Laboratory Monitoring	Metabolized
Coumadin		Protime	Liver
Unfractionated Heparin		aPTT	Liver
Low Molecular Weight Heparin	(Enoxaparin)	Weight and Creatinine adjusted, No laboratory monitoring	Kidney
	(Rivaroxaban)	Weight and Creatinine adjusted, No laboratory monitoring	Kidney
Direct Thrombin Inhibitors	(Argatroban)	aPTT	Liver
	(Dabigatran)	Weight and Creatinine adjusted, No laboratory monitoring	Kidney
Pentasaccharide Anticoagulants	(Fondaparidux)	Weight and Creatinine adjusted No laboratory monitoring	Kidney

Notes:

1. **Warfarin** is a Vitamin K inhibitor. Vitamin K is required for the terminal carboxylation of Factors II, VII, IX, X, and Protein C and Protein S. Coumadin is given as an oral medication. Initiation of therapy should not include "bolus" dosing. The average dose is approx. 4 mg to be taken orally daily. A therapeutic dose usually requires 4 - 6 days. The target INR for Coumadin in most cases is 2-3. Mechanical valves have a target INR of 2.5 - 3.5. Coumadin is contraindicated for the therapy of H.I.T. Type II until the platelet is above 150,000.

2. **Unfractionated Heparin** is monitored by aPTT. The target degree is based on Laboratory Heparin Therapeutic Range.

3. **Enoxaparin** prophylactic dose is 40 mg. daily administered subcutaneously. Full course anticoagulation is 1mg/kg twice daily or 1.5 mg/kg daily. Anti-Factor Xa Level Assays may be considered when an overdose of LMWH needs to be ruled out. Enoxaparin is only partially reversed by Protamine Sulfate (30%) and has no reversing agents. FFP may be considered for hemorrhagic complications but may have a paradoxical effect due to AT-III content of the plasma. This may be associated with increased bleeding.

4. **Ultra LMWH-Pentasaccharide Anti-coagulant** has no reversing agents. The prophylactic dose of Fondaparinux is 2.5 mg. subcutaneous daily. Full course anticoagulation is 7.5 mg. subcutaneous daily for patients < 100 kg. Studies have shown that there is no correlation with Anti-Factor Xa Level and should not be used for monitoring of the therapeutic effect. FFP may be considered for hemorrhagic complications. Fondaparinux may be considered for the treatment of H.I.T. Type II. Full course anticoagulation would be used.

5. **Argatroban and Lepirudin** is a direct thrombin anticoagulant used for the treatment of H.I.T. Type II. They are initially dosed at 0.5 ug/kg/minute as an intravenous infusion. The dose is adjusted until the aPTT is 1.5 to 2 times the mean of the normal aPTT. There is no reversing agent. FFP may be considered for hemorrhagic complications. They should not be used as an alternative for UFH while on cardio-pulmonary bypass machine as it can be associated with life threatening hemorrhagic complication in as many as 50% of cases.

6. **Dabigatran** is prophylactic treatment for non-valvular atrial fibrillation. The dose is 150 mg/12 hours.

7. **Rivaroxaban** is prophylactic treatment for non-valvular atrial fibrillation, DVT, PE, and for knee and hip replacement.

    - Knee replacement: 10 mg. PO qDay for 12 days; may take with or without food.
    - Hip Replacement: 10 mg. PO qDay for 35 days; may take with or without food.
    - DVT and PE: 15 mg PO BID for 21 days with food, THEN 20 mg. PO qDay for 6 months.
    - Nonvalvular Atrial Fibrillation: 20 mg./day PO with the evening meal.

II. HEMOSTASIS/THROMBOSIS SPECIMEN COLLECTION

To produce valid results for hemostasis/thrombosis tests and factor assays, specimen integrity is crucial and must be maintained. All specimens sent for testing must be collected and shipped in the following manner:

1. Obtain venous blood by clean venipuncture. Avoid slow flowing draws and/or traumatic venipunctures as either of these may result in an activated or clotted sample. Do not use needles smaller than 23 gauge.

2. Always draw a pilot tube (blue discard tube) before drawing coagulation specimens in light blue top tube.

   Note: Reference ranges have been established using 3.2% buffered sodium citrate.

3. Fill light blue top tubes as far as vacuum will allow, and mix by gentle inversion. Exact ratio of 9 parts blood to 1 part anticoagulant must be maintained. Underfilled specimens will be rejected. Send samples immediately after draw. Samples for APTT need to be run within 4 hours.

4. If transporting plasma or freezing coagulation specimens, the specimen must be processed as follows:

   a. Centrifuge the capped tube at 2500 xg for 10 minutes or at 5600 rpm for 5 minutes. Inspect for hemolysis or clot, which is not acceptable for coagulation testing and requires that specimen needs to be redrawn.

   b. Immediately remove the top two-thirds of the platelet-poor plasma from the specimen using a plastic transfer pipet (use of glass pipets can result in activation and/or coagulation of the plasma).

   c. Place the plasma in a properly labeled polypropylene tube. Seal the tube. Make sure to label that the specimen is PLASMA. (Glass vials will be rejected.)

   d. Freeze the specimen immediately at -20° Celsius; stability is 4 days. Specimens should not be frozen in an ordinary household or self defrosting freezer for storage.

   e. A separate tube must be submitted for each assay requested. (Those being sent for special studies such as Factor V, XII, etc.)

   f. Send specimen on dry ice – specimens must remain frozen during transport.

5. Some assays are performed on a priority basis if a medical emergency exists. Contact Client Services to make arrangements.

6. All requests for coagulation assays must include a brief patient history and other pertinent clinical information (e.g., medications, blood products, etc.).

Note: Samples containing heparin should not be used for coagulation studies. If possible, stop heparin therapy before the draw to avoid contamination. Heparin interferes with most clotting assays.

GENERAL INSTRUCTIONS

INFECTIOUS DISEASE SPECIMENS

I. SPECIMENS - GENERAL REQUIREMENTS

A. SPECIMEN CONTAINERS

1. SHIPPING CONTAINERS, STERILE SPECIMEN CONTAINERS, TRANSPORT MEDIA, AND SWABS ARE AVAILABLE FROM SMC.
2. REFER TO *INFECTIOUS DISEASES: COLLECTION AND TRANSPORT MEDIA* AT THE END OF THIS SECTION FOR GUIDELINES. SPECIMENS ARE ACCEPTABLE FOR PROCESSING ONLY WHEN COLLECTED AND SUBMITTED IN THE APPROPRIATE CONTAINER. SPECIMEN CONTAINERS MUST BE SECURELY TIGHTENED TO ELIMINATE ANY LEAKAGE. USE OF COLLECTION AND TRANSPORT CONTAINERS THAT ARE PAST THE EXPIRATION DATE IS UNACCEPTABLE.

B. RESULT REPORTING

1. PRELIMINARY RESULTS ARE ISSUED AS SOON AS ACCURATE DATA IS AVAILABLE. FINAL RESULTS ARE GENERATED AT THE COMPLETION OF THE CULTURE. IF REQUESTED, PRELIMINARY RESULTS WILL BE CALLED TO THE PHYSICIAN OR REQUESTING LAB ON ANY POSITIVE, SIGNIFICANT STAIN OR CULTURE (E.G. BLOOD, CSF (CEREBROSPINAL FLUID), STERILE BODY FLUID). THE REQUEST FOR PHONE NOTIFICATION SHOULD BE WRITTEN ON THE TEST REQUEST FORM. INFORMATION MUST INCLUDE THE NAME OF THE PERSON OR LAB TO CONTACT, AND THE TELEPHONE NUMBER. RESULTS OR INTERPRETATIONS OF RESULTS MAY BE OBTAINED BY CALLING THE LABORATORY DURING THE HOURS OF OPERATION OR BY CALLING (949) 452-3554.

C. REPORTABLE DISEASES

1. SADDLEBACK MEDICAL CENTER LABORATORY FOLLOWS APPLICABLE LOCAL AND STATE REQUIREMENTS FOR REPORTING.

II. SPECIMEN - SPECIFIC COLLECTION GUIDELINES

The proper collection of a specimen for culture is the most important step in the recovery of pathogenic organisms responsible for infectious disease. A poorly collected specimen may lead to failure in isolating the causative organism(s) and result in the recovery and subsequent treatment of contaminating organisms.

Basic Concepts for Collection

1. Collect the specimen from the actual site of infection, avoiding contamination from adjacent tissues or secretions.
2. Collect the specimen at optimal times (for example: early morning sputum for AFB (acid-fast bacillus) culture).
3. Collect a sufficient quantity of material.
4. Use appropriate collection devices: sterile, leak-proof specimen containers. Use appropriate transport media (Amies Gel Swab for bacterial culture, Cary-Blair for stool culture, Universal Transport Medium for viral and chlamydia cultures).
5. Whenever possible, collect specimens prior to administration of antibiotics or antivirals.
6. Properly label the specimen and complete the test request form. **The source of specimen, date and time of collection, and initials of collector is required.**
7. Minimize transport time. Maintain an appropriate environment between collection of specimens and delivery to the laboratory.
8. For Blood Cultures, decontaminate the skin surface. Use ChloraPrep™ to prepare the site. Allow a contact time of 30 seconds - 2 minutes to maximize the antiseptic effect for sweaty or clamy patients.

SPECIAL GUIDELINES FOR SPECIMEN COLLECTION AND TRANSPORT

I. Principle

All diagnostic information from the Microbiology Laboratory is contingent on the quality of the specimen received. Consequences of a poorly collected and/ or poorly transported specimen include failure to isolate the causative microorganism and recovery of contaminants or normal microbiota. This can lead to improper treatment of the patient. Often, direct specimen smears are utilized to determine the quality of the specimen, to provide rapid information for diagnosis and therapy, and to allow the physician to determine if additional, better quality specimens should be collected.

II. Specimen

A. General Considerations

This procedure addresses instructions that must be communicated to physicians, nurses, and phlebotomy teams.

1. Safety considerations
   a) Follow universal precaution guidelines. Treating all specimens as potentially hazardous eliminates the need for warning labels.
   b) Do not contaminate the external surface of the collection container and/or its accompanying paperwork.
   c) Minimize direct handling of specimens in transit from the patient to the laboratory. See Section B – Transport of Diagnostic Specimens.
2. General guidelines for proper specimen collection
   a) Collect specimen before administering antimicrobial agents when possible.
   b) Collect specimen with as little contamination from indigenous microbiata as possible to ensure that the sample will be respresentative of the infected site.
   c) Utilize appropriate collection devices. Use sterile equipment and aseptic technique to collect specimens to prevent introduction of microorganisms during invasive procedures.
   d) Clearly label the specimen container with the patient's full name and date of birth, and with the date and time of collection with initials or ID number of collector and RN initials.
   e) Collect an adequate amount of specimen. Inadequate amounts of specimen may yield false-negative results.
   f) Develop an understanding of the Microbiology Laboratory's source identification schemes. Know when to include "rule-out" requests. For example, the laboratory routinely screens for *Shigella, Salmonella, Plesiomona, Aeromonas, Vibrio*, and *Campylobacter* species in stool cultures but not for *Yersinia*.
   g) Identify the specimen source and/or specific site fully and correctly on the specimen so that proper culture media will be selected during processing in the laboratory. For example, use Abscess, right leg.
   h) If a specimen is to be collected through intact skin, cleanse the skin first. For example, use the ChloraPrep™ Clear 3 mL Applicator when collecting Blood Cultures for approximately 30 seconds for dry sites and 2 minutes for wet/moist/clammy sites. Allow the area to air dry for approximately 30 seconds. Do not blot or wipe away.
   i) Before collecting the specimen, consider the risk/benefit ratio of the collection procedure to the patient.

Collect specimens in sturdy, sterile, screw-cap, leakproof containers with lids that do not create an aerosol when opened.

3. General guidelines for proper specimen transport

    a) Transport all specimens to the laboratory promptly.
        i. To ensure the survival and isolation of fastidious organisms and to prevent overgrowth by more hardy bacteria.
        ii. To shorten the duration of specimen contact with some local anesthetics used in collection procedures that may have antibacterial activity.
        iii. To provide a more accurate diagnosis of the infectious disease process.

    b) Alternative to prompt delivery - refrigerate most specimens at 2° - 8° Celsius. The following are exceptions:

        i. Specimens that may harbor temperature-sensitive organisms such as *Neisseria* species should be left at room temperature.
        ii. For anaerobic specimens, use Amies Gel Swab. (See Table 3.)
        iii. Stool specimens
            (a) For bacterial culture: sterile specimen container
            (b) For parasitology examination: sterile specimen container
        iv. Hold cerebrospinal fluid (CSF) specimens at room temperature unless they are to be cultured for viruses.
        v. Wound and body fluid cultures should be left at room temperatures.

4. Use of specimen transport systems

    a) Aerobic transport methods are listed in Table 4. Certain types of swabs should be used for the collection and transport of certain cultures as described in Table 4.

    b) Specific transport containers for specimens are listed in Table 5.

Table 3: Transport Systems for <u>Anaerobic</u> Specimens

System & Supplier	Description
Syringe or needle aspirates	Express excess air from syringe, remove needle, and use syringe cover to cap syringe. If fairly large volume is collected (2 ml or more), transfer specimen to a sterile container. Anaerobic bacteria can survive for 24 hours at room temperature .
BD BD, Division of Becton Dickinson and Company, Rutherford, NJ	AMIES Gel without charcoal Soft Aluminum wire For male urethral sampling, as well as sinus and eye specimens
BD E Swab™ Collection and Transport System	E Swab™ Single swab For aerobic, anaerobic, and fastidious bacteria

Table 4 : Transport Systems for Aerobic Specimens

System & Supplier (references)	Comments
BD BD, Division of Becton Dickinson and Company, Rutherford, NJ	AMIES Gel without charcoal Single swab For throat, vaginal, skin, and abscess wound specimens (aerobic/anaerobic).
BD BD, Division of Becton Dickinson and Company, Rutherford, NJ	AMIES Gel without charcoal Soft Aluminum wire For male urethral sampling, as well as ear, nose, throat, and eye specimens.
Calcium alginate swabs	Can be toxic for some strains of *Neisseria gonorrhoeae,* HSV (herpes simplex virus), and *Ureaplasma urealyticum*, and may be toxic for some cell cultures. Useful for collection of *Chlamydia* cultures.
Cotton swabs	Residual fatty acids may inhibit some bacteria and *Chlamydia* species. If cotton is glued or spun to wooden applicator stick, wooden stick may inactivate HSV arid interfere with some *Ureaplasma* identification tests.
Dacron swabs	Useful in collection of viral and group A streptococcus specimens.
Nasopharyngeal swabs FLOQ Swabs	Universal Transport Medium (UTM) with flexible mini tip swabs especially for collection of nasopharyngeal specimens (UTM) of *Bordetella pertussis*.
Sterile screw-cap cups	Useful for collection of urine, sputum, stool, bronchoaveolar lavage, and biopsy specimens. Useful for hair or skin-scraping specimens. If biopsy specimen is small, add small amount of sterile nonbacteriostatic 0.85% NaCl to cup. **Never place biopsy specimen in formalin or wrap in gauze.**
Sterile tubes (screw-cap plastic tubes, tubes, sterile Vacutainer tubes without additives)	Useful for collection of sterile fluids, bronchoalveolar lavage, drainage or brush specimens.
BD Complete Urine Collection Kit	Useful for collection of urine for urinalysis and urine culture.

Table 5: Specimen Transport Guide

Source and Type of Specimen	Transport Method
Blood	Bactec bottles plus Aerobic/F and Lytic/10 Anaerobic/F or Peds Plus/F
Central Nervous System (CNS)	
CSF (cerebrospinal fluid)	Sterile screw-cap tube
Ommaya fluid	Sterile screw-cap tube
Brain abcess	Sterile screw-cap cup or tube
CNS biopsy	If specimen is small, send in sterile cup with small amount of sterile 0.85% NaCl**. (Never place in formalin for Microbiology.)**
Gastrointestinal System	
Feces	Sterile screw-cap cup
Rectal swab	Gel swab transport system (for pinworm, use pinworm collection kit)
Gastric lavage or washings	Sterile screw-cap or Lukens trap
Duodenal aspirate	Sterile screw-cap or Lukens trap
Rectal biopsy	Sterile screw-cap cup or tube. If specimen is small, send in sterile cup with small amount of sterile 0.85% NaCl**. (Never place in formalin for Microbiology.)**
Signoidoscopy specimen	Sterile screw-cap cup or tube. **(Never place in formalin for Microbiology.)**
Eye	
Conjunctival scrapings	Send prepared smears and directly inoculated media.
Corneal scrapings	Send prepared smears and directly inoculated media.
Intraocular fluid	Send prepared smears and directly inoculated media or Sterile screw-cap tube/cup, or capped syringe **without needle** with air expelled.
Genital tract, female	
Amniotic fluid	Sterile screw cap cup of 1 - 2 ml sample
Bartholin fluid	Sterile screw cap cup of 1 - 2 ml sample
Fallopian tube	Gel swab transport system 1- 2 ml of sample
Cervical	Gel Swab transport, viral or chlamydial transport, GeneXpert® swab (GC/Chlamydia)
Urethral	Gel Swab transport, viral or chlamydial transport, GeneXpert® swab
Vaginal/Rectal	Gel Swab transport, viral or chlamydial transport, GeneXpert® swab
Endometrial	Sterile screw-cap cup or tube
Vulva	Capped syringe **without needle**; swab transport, viral or chlamydial transport, GeneXpert® swab
Genital tract, male	
Anal swab	Gel swab transport, viral or chlamydial transport, GeneXpert® swab
Urethral	Gel Swab transport, viral or chlamydial transport, GeneXpert® swab
Epididymis	Gel swab transport system; sterile screw-cap cup, GeneXpert® swab
Prostatic massage	Sterile screw-cap cup, tube or swab transport system, GeneXpert® swab
Semen	Sterile screw-cap cup, tube or swab transport system, GeneXpert® swab
Penile lesion	Capped syringe **without needle**; Gel swab transport, viral or chlamydial transport system, GeneXpert® swab For GC/Chlamydia specimen from Male Urethral (penis), use Aptima Unisex swabs.
Skin Scraping	Glass slides in slide holder

Table 5: Specimen Transport Guide

Source and Type of Specimen	Transport Method
Specimens for *Neisseria gonorrhoeae* Anal, cervical, urethral, vaginal	Gel swab transport
Specimens for Candida auris screening	BD E Swab™ Collection and Transport System
Lower respiratory tract Lung biopsy Expectorated sputum Induced sputum Tracheal or endotracheal aspirate Bronchoalveolar lavage fluid Bronchial washings Transbronchial biopsy Bronchial brush Transtracheal aspirate Lung aspirate	 Sterile screw-cap cup; if specimen is small, place it in a small amount of sterile 0.85% NaCl **(Never place in formalin - for Microbiology)**. Sterile screw-cap cup Sterile screw-cap cup Lukens trap or sterile screw-cap cup or tube Lukens trap or sterile screw-cap cup or tube Lukens trap or sterile screw-cap cup or tube Sterile screw-cap tube with 1 - 2 ml of sterile 0.85% NaCl 1 - 2 unfixed slides labeled Sterile screw-cap cup or tube Sterile screw-cap cup or tube
Upper respiratory Throat swab Nasal swab Oral culture Nasopharyngeal swab Tympanocentesis fluid Sinus aspirate Nasopharyngeal suction/Nasal washings	 Gel swab transport or viral transport system or Eswab (PCR) Gel swab transport or viral transport system Gel swab transport or viral transport system Mini-tipped flocked swab in Universal Transport Medium (UTM) - OP and ANP Capped syringe **without needle or sterile screw-cap cup** Capped syringe **without needle or sterile screw-cap cup** Sterile screw-cap cup or viral transport system) - OP and ANP
Sterile body fluids (excluding cerebrospinal fluid, urine, blood) Pleural, peritoneal, ascites, joint, and synovial fluid	Sterile container, capped syringe **without needle**
Deep wounds, aspirates, tissues Site wound Deep wounds or abscesses Soft tissue aspirates Bone Punch skin biopsy	 Gel swab transport Sterile screw-cap container or gel swab transport system Sterile screw-cap cup; if specimen is small, place it in a small amount of sterile 0.85% NaCl to prevent drying. Sterile screw-cap cup; if specimen is small, place it in a small amount of sterile 0.85% NaCl to prevent drying.
Urine Clean catch Catheter (In/Out or Indwelling) Suprapubic aspirate Bladder washout Bilateral ureteral catheterization	 Urinalysis Preservative Plus conical tube, boric acid tube (gray top) for culture Urinalysis Preservative Plus conical tube, boric acid tube (gray top) for culture Sterile screw-cap cup or tube (be careful to label specimens with correct **times** and **sites**) Sterile screw-cap cup or tube (be careful to label specimens with correct **times** and **sites**)

Specimens obtained by a physician using needle aspiration should be transferred to a sterile tube or container prior to transport of the specimen to the laboratory. If there is little material in the syringe, the physician should draw a small amount of sterile I nonbacteriostatic 0.85% NaCl or sterile broth through the syringe and then transfer the specimen to a sterile tube. Alternatively, and only if the specimen will be compromised by transferring it from the syringe, a small amount of sterile 0.85% NaCl or broth may be drawn into the syringe prior to removal of the needle. The physician should use a protective device while removing the needle to avoid injury and should cap the syringe with a sterile cap prior to transporting it to the laboratory. **SYRINGES WITH NEEDLES WILL BE REJECTED.**

B. Transport of Diagnostic Specimens

1. MemorialCare Saddleback Medical Center Laboratory provides special transport bags to assist with handling of diagnostic specimens. All specimens must be in a leak-resistant primary container labeled "Biohazard" and must be placed in leak resistant secondary Biohazard plastic bags.

2. The requisition must be placed in the pouch on the back of the sample bag.

3. Couriers are not allowed to pick up specimens that are leaking and not in secondary containers such as the transport bag.

4. **Make sure specimens are sent at the appropriate temperature**. Most specimens should be sent at 2 - 8 degrees Celcius or refrigerated. Remember to NEVER FREEZE whole blood, except in very rare instances that instructions specify. Call SMC Laboratory staff at (949) 452-3554 if unsure about temperature requirements.

III. Collection Instructions for Different Anatomic Sites

Any collection method requiring an invasive technique should be performed by a physician. Some specimen collection techniques should be performed only by a physician specialist with advanced training and skills. The specimen collection guidelines in this section are brief summaries of the procedures used for specimen collection and are not intended to be used as a step-by-step guide for obtaining specimens.

A. General Venipuncture Procedure: refer to policies PL-415, ADULT VENIPUNCTURE AND CAPILLARY PUNCTURE and PL-416, INFANT CAPILLARY AND VENIPUNCTURE .

B. Glucose Tolerance Testing

1. When collecting specimens for glucose tolerance tests (GTT's), it is imperative that all specimens be collected at appropriately timed intervals.

   a) Patients referred for tests requiring a single timed collection, such as the 1-hour post 50 gm glucose load, should be in a fasting state.
   b) Please feel free to contact the laboratory at (949) 452-3554 with any questions.

2. **Glucose Tolerance Testing (3 Hour)**

   a) In an effort to standardize oral glucose tolerance testing, the Committee on Statistics of the American Diabetes Association (ADA) has recommended a set of conditions under which the test should be performed.

b) For three days prior to the GTT, a diet containing at least 300 grams per day of carbohydrate is required.
c) Two additional days of this diet are essential if the patient previously has not been on a diet sufficient in carbohydrates. The presence of anorexia or any other condition precluding adequate food intake automatically invalidates the test. Inactivity, such as bed rest, has been reported to reduce glucose tolerance; thus a GTT should not be performed in non-ambulatory patients.
d) During the 12 hours prior to a test, the patient must fast and avoid even black coffee. In addition, smoking and even mild exercise are not permitted.
e) The test should not be performed on those patients who have had an illness during the prior two weeks.
f) For non-pregnant or patient weighing 95 pounds or more, give 75 gm glucola.

3. **OB Glucose Tolerance Testing for gestational diabetes mellitus**

a) Screening 50-gram, 1-hour GTT at 24 - 28 weeks of gestation in women not previously diagnosed with diabetes (non-fasting) of glucose $\geq$ 140 mg/dL, proceed to GTT when fasting.

b) 2- or 3-hour OB-GTT at 24 - 48 weeks of gestation in women previously not diagnosed with diabetes (overnight fasting of at least 8 hours).

- 75-gram, 2-hr GTT
- 100-gram, 3-hr GTT

C. Blood Cultures Collections are defined in policy PL-417, BLOOD CULTURE COLLECTION PROCEDURE.

D. Central Nervous System (CNS) Specimens

1. CSF (cerebrospinal fluid)
Suggested volumes are 1 ml, 2 ml, and 3 ml for routine, fungal, and mycobacterial cultures, respectively.

a) Lumbar puncture
i. Clean the puncture site with antiseptic solution and alcohol before needle insertion to prevent introduction of infection.
ii. Insert a needle with stylet at the L3-L4, L4-L5, or L5-S1 interspace. When the subarachnoid space is reached, remove the stylet and spinal fluid will appear in the needle hub.
iii. Slowly drain the CSF into the sterile leakproof tubes. Three tubes are generally required for microbiology, hematology, and chemistry testing. The second tube drawn will generally go to microbiology, and the last tube drawn will generally go to hematology. (In traumatic taps, the CSF will often clear as the later tubes are collected.)
b) Ommaya reservoir fluid
i. Clean the Ommaya reservoir site with antiseptic solution and alcohol prior to removal of Ommaya fluid to prevent introduction of infection.
ii. Remove Ommaya fluid via the Ommaya reservoir unit, and place it in a sterile tube.

2. Other CNS specimens
a) Brain abscess
i. Ninety percent of brain abscesses will grow anaerobic bacteria. Transport the specimen without delay in a sterile screw-cap cup to the microbiology laboratory for **IMMEDIATE** processing.
ii. A physician aspirates material from a lesion and sends it to the microbiology laboratory in a sterile screw-cap cup or syringe. See Table 1 for transport of specimens in a syringe.

b) CNS biopsy samples
   i. Obtain a biopsy sample from the lesion at surgery and send it to the microbiology laboratory in a sterile screw-cap cup for immediate processing. ***DO NOT ADD FORMALIN.***

3. CNS specimen collection considerations are outlined in Table 6.

Table 6: Collection Considerations for CNS (Central Nervous System) Specimens

Culture	Vol (ml)[a]	Comments
Bacteria	1	Send cloudiest CSF (cerebrospinal fluid) specimen to microbiology laboratory immediately **(Tube # 2 is preferred)**.
Fungi	2	Rule out *Cryptococcus* species, *Coccidioides immitis* Mycobacteria: *Mycobacterium tuberculosis, Mycobacterium Avium, Mycobacterium intracellulare*
Meningitous/ Encephalitis PCR Panel	0.5 ml	Lumbar punctures (only) can be submitted for the Meningitous/Encephalitis PCR Panel.
Mycobacteria	2	Brain abscess or CNS biopsy specimens
Anaerobes	**NA**	Brain abscess or CNS biopsy specimens
Parasites	**NA**	Brain abscess or CNS biopsy specimens for *Entamoeba histolytica, Toxoplasma gondii, Naegleria* species[b], *Acanthamoeba* species[b]
Virus	1 - 2	Send to laboratory on ice.

[a] Amounts are guidelines applicable. Greater volumes increase the chance of organism recovery. NA, not applicable.
[b] CSF can be submitted.

E. Stool Specimens

1. GI PCR
   GI PCR will include bacteria, virus, and parasites. 5 ml of a diarrhea specimen is placed into a sterile container. Per Center for Disease Control guidelines, the specimen must take the shape of the container for it to be acceptable.

2. Stool cultures

   a) Fecal specimens for culture are submitted primarily for the detection of *Campylobacter*, *Shigella*, *Salmonella*, *Plesiomonas*, *E. coli-O157*, *Aeromonas* species, and *Vibrio*.

   b) General considerations
      i. Keep stool specimen cool (not frozen); do not incubate them.
      ii. The specimen should be placed in a sterile container.
      iii. Do not use toilet paper to collect stool. Toilet paper may be impregnated with barium salts which are inhibitory for some fecal pathogens.

   c) Have patient obtain stool specimen by one of the following methods:
      i. Pass stool directly into a sterile, wide-mouth container. Transfer a portion of the stool into the sterile container.
      ii. Pass stool into a clean, dry bedpan, and transfer portion of the stool into a sterile container.

3. Stool Specimens for Occult Blood (Fecal Immunoassay Test)

    a) Inpatient – 5 gm random stool (minimum 1 ml) in a sterile container

F. Gastrointestinal Tract Specimens

The gastrointestinal tract includes the esophagus, stomach, duodenum, small intestine, and colon.

1. Rectal swabs
    a) Submitted primarily for the detection of *Neisseria gonorrhoeae, Shigella* species, Herpes simplex virus (HSV), and anal carriage Vancomycin Resistant Enteroccoccus
    b) Pass the tip of a sterile swab approximately 1 inch beyond the anal sphincter. Carefully rotate the swab to sample the anal crypts, and withdraw the swab. Send the swab in a gel swab transport (Table 2).

2. Gastric aspirates
    a) The patient should fast prior to each of the following procedures.
        i. Gastric lavage
            (a) Submitted primarily for the detection of *Mycobacterium tuberculosis* in patients (most frequently children) unable to produce quality sputum. Should be performed after the patient wakes in the morning so that sputum swallowed during sleep is still in the stomach.
            (b) Pass a well-lubricated tube orally or nasally through to the stomach of the patient, and perform the lavage. Before removing the tube, release the suction and clamp to prevent mucosal trauma and/or aspiration.

        ii. Duodenal aspiration
            (a) Submitted primarily for the detection of *Giardia* species and larvae of *Strongyloides stercoralis* and *Ascaris lumbricoides.*
                (i) Pass a tube orally through to the duodenum of the patient.
                (ii) To aspirate a sample for giardiasis, the tube should be at least in the third portion of the duodenum.

3. Gastric biopsies and washings
    a) The patient should fast prior to each of the following procedures.

    b) Esophageal, stomach, or duodenum specimens
        i. Esophageal specimens are primarily used to detect Candida species, cytomegalovirus (CMV), and herpes simplex virus (HSV) infections. Stomach and duodenal specimens are primarily used for the detection of *Helicobacter pylori*.
        Duodenal specimens can also be used for the detection of Giardia species and the larvae of *Strongyloides stercoralis* and *Ascaris lumbricoides*.
            (a) Pass an endoscope orally.
            (b) Obtain specimens through a channel in the endoscope by using one of the following procedures.
                (i) Using biopsy forceps, obtain samples from the esophagus, stomach, or duodenum.
                (ii) Using a sheathed brush, brush suspicious areas several times to obtain adequate cellular material.
    c) Gastric Lavage
        i. Perform a wash by injecting approximately 25 to 30 ml of sterile nonbacteriostatic isotonic 0.85% NaCl through the biopsy channel onto the lesion.

ii. Collect the specimen by aspirating the fluid through the scope into a sterile trap, which is connected to the suction tubing. NOTE: If a gastric ulcer is seen, obtain biopsy samples from the base, the surrounding gastric mucosa, and each of the four quadrants of the margin.

d) Rectal biopsy
   i. Submitted primarily for the detection of *Entamoeba histolytica, Balantidium coli,* and HSV.
   ii. If lesions are not evident, biopsy the posterior rectal mucosa below the peritoneal reflection (within 7 to 10 cm of the anal verge).

e) Small bowel biopsy
   i. Submitted primarily for the detection of *Giardia, Cryptosporidium,* and *Microsporidium* species.
   ii. Biopsies of the small intestine provide the highest diagnostic yield for *Microsporidia* species. Biopsies from other gastrointestinal sites (stomach, colon, rectum) have a much lower yield in comparison. Obtain biopsy sample of lesion at surgery.

f) Sigmoidoscopy
   i. Useful in the detection of *Entamoeba histolytica* and *Mycobacterium* species and the diagnosis of pseudomembranous colitis associated with *Clostridium difficile* and possibly *Staphylococcus aureus.*
      (a) Perform flexible or rigid sigmoidoscopy.
      (b) Obtain endoscopic pinch biopsy samples of any lesions seen. Additionally, aspirate liquid from the inflammed bowel with a pipette passed through the sigmoidoscope. Transport specimens in a sterile screw-cap container. If biopsy samples are small, add a small amount of sterile nonbacteriostatic 0.85% NaCl to prevent the specimen from drying.

g) Gastrointestinal specimen collection considerations are summarized in Table 7.

Table 7: Collection Considerations for Gastrointestinal Tract Specimens

Culture	Comments
Bacteria	Stool: One stool specimen recommended. Gastric biopsy: Rule of *Helicobacter pylori.* Rectal swab: Rule out enteric pathogens (especially *Shigella* spp.) (*Neisseria gonorrhoeae or VRE).*
Fungi	Gastric aspirate, gastric biopsy, esophageal brush, esophageal biopsy.
GI PCR	GI PCR will include bacteria, virus, and parasites. 5 ml of a diarrhea specimen is placed into a sterile container. Per Center for Disease Control guidelines, the specimen must take the shape of the container for it to be acceptable.
Pinworm	For pinworm collection kit, contact the laboratory. Swab perianal area when patient gets up in the morning before patient bathes or defecates.
Mycobacteria	Gastric aspirate or gastric biopsy; feces.
Parasites	If transport to laboratory is delayed, place specimen in Para-Pak. Duodenal aspirates are useful for detecting *Giardia* species and larvae of *Strongyloides stercoralis* and *Ascaris lumbricoides*. Use rectal biopsy specimens for *Entamoeba histolytica* and *Balantidium coli*. Use small-bowel biopsy specimens for *Giardia, Cryptosporidium*, and *Microsporidium* species.
Virus	Use esophageal specimens for CMV (cytomegalovirus) and HSV (herpes simplex virus) and rectal biopsy specimens for HSV. Send to laboratory in Viral Transport Media. Do not freeze.

G. Genital Tract Specimens

1. **Female**

Genital tract specimens are submitted primarily for the detection of sexually transmitted pathogens (such as *Neisseria gonorrhoeae, Chlamydia trachomatis,* lumphogranuloma venereum, HSV (herpes simplex virus), human papillomavirus (HPV) with histological confirmation, trichomonads, group B streptococci, and *Candida* infections). See Table 5 (page 22) for transport systems.

a) Amniotic fluid
Aspirate fluid by catheter, at cesarean section, or at amniocentesis.

b) ROM Plus® Test Specimen Collection for Detection of Rupture of Membrane (ROM)

i. The test is for prescription use by health care professionals to aid in the detection of rupture of membranes (ROM) in pregnant women in conjunction with other signs and symptoms.

ii. The ROM Plus® fetal membrane rupture test is a rapid, non-instrumented, qualitative immunochromatographic test for the in-vitro detection of amniotic fluid in vaginal discharge of pregnant women with signs and symptoms of ROM. ROM Plus® detects AFP (Alpha-fetoprotein), IGFBP-1 (Insulin-like growth factor-binding protein-1 or PP12 (Placental protein 12)) from amniotic fluid in vaginal secretions.

iii. **EQUIPMENT**
   (a) ROM Plus® specimen collection kit which contains:
      (i) Directions for use on the outside of each pouch
      (ii) Using a sheathed brush, brush suspicious areas several times to obtain adequate cellular material. One sterile polyester vaginal swab
      (iii) One vial with buffer solution (phosphate buffered)
   (b) Biohazard bag
   (c) Gloves
   (d) Patient labels verified to match the patient's armband

Table 8: Procedure - ROM Plus® Test Specimen Collection for Detection of Rupture of Membrane (ROM)

STEP	PROCEDURE	KEY POINT
1	The ROM Plus® test requires a physician order in the EHR (electronic health record), STAT. Once the test has been ordered and acknowledged, the Registered Nurse must obtain the ROM Plus® collection kit.	
2	Remove the ROM Plus® contents from the packaging. Holding the buffer vial in an upright position, remove the shipping cap and set it aside.	
3	Verify that the patient label matches the patient's ID band.	Printed labels must be confirmed by holding them next to the armband to validate that the full name and Medical Record Numbers (Date of Birth and Contact Serial Number (CSN)) match prior to labeling a specimen at the bedside.
4	Explain test to the patient.	
5	Perform hand hygiene and don gloves.	
6	Remove the ROM Plus® contents from the packaging. Holding the buffer vial in an upright position, remove the shipping cap and set the vial aside.	Ensure that fluid is at the bottom of the vial.
7	Remove the sterile swab from its package to collect a sample from the vagina. The tip of the swab should not touch anything prior to its insertion. Insert the swab tip into the vagina 2 - 3 inches (5 - 7 cm) deep. Withdraw the swab after a minimum of 15 seconds.	
8	A. Place the swab into the vial and mix the swab in the buffer solution for at least 15 seconds. Break off the swab tip at the scored mark and leave the swab tip in the vial. B. Place the shipping cap back onto the vial and discard the remaining swab stick. C. Ensure that the lid of the vial is secure. D. Label the vial at the bedside in the presence of the patient, immediately after collection with the provided label, ensuring that the collection date, time, source, and initials of person collecting the specimen are placed on the label.	
	E. Document specimen as collected in the EHR.	The transmittal will print after the test is statused as collected.
	F. Place the labeled vial into a biohazard bag along with the specimen transmittal slip and tube the specimen **STAT** to the lab.	The test must be **performed by the lab personnel within 6 hours of placing the swab in the buffer for a valid result.**

iv. **STORAGE AND STABILITY**

(a) Store the ROM Plus® kit in a dry place at 4 - 37 degrees Centigrade (40 - 99 degrees Fahrenheit). Do not freeze.

(b) Use ROM Plus® within six (6) hours of collecting the vaginal swab sample and placing it into the buffer vial.

v. **PRECAUTIONS, LIMITS, AND WARNINGS**

(a) ROM diagnoses should not be based on any single test.
(b) ROM Plus ®is for in-vitro diagnostic use only.
(c) ROM Plus® is for healthcare professional use only.
(d) All instructions should be followed carefully for accurate results.
(e) The results are qualitative. No quantitative interpretations should be made.
(f) Rom Plus® test kits will function properly with trace amounts of blood in the sample. Significant amounts of blood discharge (> 10%) may cause the test to malfunction and is not recommended.
(g) Safety precautions should be observed when collecting, handling, and disposing of test samples. Used test kits are biohazardous.
(h) Elevated fetal serum, urine cord blood, and amniotic fluid as well as maternal serum levels of AFP have been reported in the literature in various developmental disorders such as neural-tube defects, hypothyroidism, autoimmune states, congenital heart defects, cystic fibrosis, etc. ROM Plus® has not been evaluated for potential interference in these conditions.
(i) **WARNING**: The test may report positive results in patients with intact membranes (see specificity in the performance section) and therefore decisions to induce labor should not be based solely on the ROM Plus® test results.

vi. **METHOD OR PERFORMANCE**

(a) ROM Plus® assay was validated for the parameters of linearity, limit of detection, accuracy/reproducibility, sensitivity, specificity, and cross-reactivity.
(b) High Concentration ("High Dose Hook" effect) – for the ROM Plus® upper-detection range, the IGFBP-1 and AFP were tests. Concentrations of IGFBP-1 were tests up to 400,000 ng/ml and AFP up to 200,000ng/ml with a positive visual rest. (Although lines may appear lighter in presence of very high AFP and IGFBP-1 concentrations, any line is considered positive.)

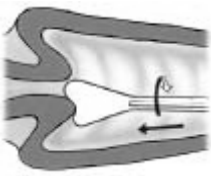
c) Bartholin gland
Decontaminate the skin with povidone-iodine, and aspirate material from the ducts.

d) Cervix
i. Do not use lubricant during procedure.
ii. Wipe the cervix clean of vaginal secretion and mucus.
iii. Rotate a sterile swab, and obtain exudate from the endocervical glands.
iv. If no exudate is seen, insert a sterile swab into the endocervical canal, and rotate the swab.
v. Do not use lubricant during procedure.

e) Cervix – Gynecological Specimen Collection – Thin Prep Pap Smear

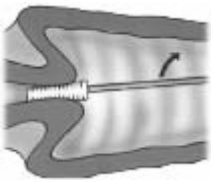
i. **Brush/Spatula Protocol**

ThinPrep® Pap Test Quick Reference Guide – Endocervical Brush/Spatula Protocol



Obtain...
...an adequate sampling from the ectocervix using a *plastic* spatula.

Rinse...
...the spatula as quickly as possible into the PreservCyt® Solution vial by swirling the spatula vigorously in the vial 10 times. Discard the spatula.



Obtain...
...an adequate sampling from the endocervix using an endocervical brush device. Insert the brush into the cervix until only the bottommost fibers are exposed. Slowly rotate 1/4 or 1/2 turn in one direction. DO NOT OVER-ROTATE.

Rinse...
...the brush as quickly as possible in the PreservCyt Solution by rotating the device in the solution 10 times while pushing against the PreservCyt vial wall. Swirl the brush vigorously to further release material. Discard the brush.

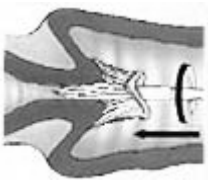
Tighten...
...the cap so that the torque line on the cap passes the torque line on the vial.

Record...
...the patient's Full name and Medical Record number on the vial, along with the source (cervix), Date collected, Time collected, and initials of person labeling vial. The above information along with the patient's medical history on the cytology requisition form.

Place...
...the vial and requisition in a specimen bag for transport to the laboratory.

ii. **Broom-Like Device Protocol**

ThinPrep® Pap Test Quick Reference Guide: Broom-Like Device Protocol



Obtain...
...an adequate sampling from the cervix using a broom-like device. Insert the central bristles of the broom into the endocervical canal deep enough to allow the shorter bristles to fully contact the ectocervix. Push gently, and rotate the broom in a clockwise direction five times.

Rinse...
...the broom as quickly as possible into the PreservCyt® Solution vial by pushing the broom into the bottom of the vial 10 times, forcing the bristles apart. As a final step, swirl the broom vigorously to further release material. Discard the collection device.

Tighten...
...the cap so that the torque line on the cap passes the torque line on the vial.

Record...
...the patient's Full name and Medical Record number on the vial, along with source (cervix), Date collected, Time collected, and initials of the person labeling the vial.
Also record above information with the patient information and medical history on the cytology requisition form.

Place...
...the vial and requisition in a specimen bag for transport to the laboratory.

f) Endometrium
Collect the endometrium specimens by transcervical aspiration through a telescoping catheter.

g) Fallopian tubes
Obtain aspirates (preferably) or swab specimens during surgery. Bronchoscopy cytology brushes may be used if exudate is not expressed.

h) Rectal swabs:
   i. Used primarily to detect *Neisseria gonorrhoeae,* HSV (herpes simplex virus), and anal carriage of VRE (Vancomycin-resistant Enterococci) .
   ii. Pass the tip of a sterile swab approximately 1 inch beyond the anal sphincter. Carefully rotate the swab to sample the anal crypts, and withdraw it. Send the swab in a swab transport, viral transport (for HSV (herpes simplex virus)), or *Neisseria gonorrhoeae* transport system (Table 3).

i) Urethra
   i. Collect specimens 1 hour or more after patient has urinated.
   ii. Stimulate discharge by gently massaging the urethra against the pubic symphysis through the vagina.
   iii. Collect the discharge with a sterile swab.
   iv. If discharge cannot be obtained, wash external urethra with betadine soap and rinse with water. Insert a urethrogenital swab 2 to 4 cm into the endourethra, gently rotate the swab, and leave it in place for 1 -2 seconds. Withdraw the swab, and submit it in the appropriate transport system for culture.

j) Vagina
   i. Use a speculum without lubricant. Collect secretions from the mucosa high in the vaginal canal with sterile pipette or swab.

k) Vulva
   i. Clean the surface of the lesion with 0.85% NaCl. If there is a crust on the lesion, remove it.
   ii. Scrape the lesion until serous fluid emerges.
   iii. Wipe away fluid and debris with sterile gauze. (Try to avoid bleeding.)
   iv. Press the base of lesion until clear fluid is expressed.
   v. Aspirate vesicular fluid with a 26 to 27-gauge needle.
   vi. Unroof the vesicle, and collect fluid with a sterile swab (for HSV detection) OR
   vii. Scrape the base of an open vesicle with a sterile scapel blade, and then rub the base vigorously with a sterile swab (for HSV (herpes simplex virus) and *Haemophilus ducreyi* detection).

l) Vaginal/pectal
   i. Screening for Group B Streptococcus at 35 - 37 weeks gestation.
   ii. Swab to lower vagina followed by the rectum using the same swab.
   iii. Submit swab to the laboratory.

2. **Male**

See Table 5 for *Neisseria gonorrhoeae* transport and swab transport systems.

a) Anal swab
   i. Submitted primarily for the detection of *N. gonorrhoeae*, HSV (herpes simplex virus), and anal carriage of *Streptococcus pyogenes*.
   Pass the tip of a sterile swab approximately 1 inch beyond the anal sphincter. Carefully rotate the swab to sample the anal crypts, and withdraw it. Send the swab in a swab transport, viral transport (for HSV), or *Neisseria gonorrhoeae* transport system (Table 5).

b) Epididymis
   i. Used primarily to diagnose nonspecific bacterial epididymitis and *Mycobacterium tuberculosis* infections generally occur after involvement of the prostate or seminal vesicles. Sexually transmitted epididymitis is most commonly due to *Chlamydia trachomatis* and *N. gonorrhoeae.*
   ii. Use a needle and syringe to aspirate material from the epididymis.

c) Penile lesion
   i. Used primarily to detect sexually transmitted pathogens such as *N. gonorrhoeae, C. trachomatis*, lymphogranuloma venereum, HSV, and *H. ducreyi*.
   ii. Clean the surface of the lesion with 0.85% NaCl. If there is a crust on the lesion, remove it.
   iii. Scrape the lesion until serous fluid emerges.
   iv. Wipe away fluid and debris with sterile gauze. (Try to avoid bleeding.)
   v. Press the base of the lesion until clear fluid is expressed.
   vi. Aspirate vesicular fluid with a 26 to 27-gauge needle. Refer to Table 3 for instructions on properly transporting specimens collected in a syringe.
   vii. Unroof the vesicle, and collect fluid with a sterile swab (for HSV detection) OR
   viii. Scrape the base of an open vesicle with a sterile scapel blade, and rub the base vigorously with a sterile swab (for HSV and *Haemophilus ducreyi* detection).

d) Prostatic massage
   i. Used primarily to diagnose acute or chronic prostatitis. For both diseases, gram-negative enteric organisms are the most frequently isolated pathogens. *Neisseria gonorrhoeae* is found infrequently, but is sometimes implicated in acute protatitis.
   ii. Perform a digital massage through the rectum.
   iii. Collect the specimen in a sterile tube or on a sterile swab.
e) Urethra
   i. Used primarily to detect *Neisseria gonorrhoeae* and *Chlamydia trachomatis.*
   ii. Collect specimens at least 2 hours after the patient has urinated.
   iii. Insert a thin urethrogenital swab 2 - 4 cm into the endourethra, gently rotate it, leave it in place for 1 - 2 seconds, and withdraw it.
f) Specimen collection considerations for genital tract specimens are summarized in Table 9.

Table 9: Collection Considerations for Genital Tract Specimens

Culture	Recommended specimens
Neisseria gonorrhoeae	Cervical, urethra, anal or vaginal swabs
Bacteria	Prostatic fluid, cervical, vaginal
Trichonomas vaginalis	Vaginal, prostatic fluid
Fungi	Anal, vaginal, or cervical
Anaerobes	Epididymis aspirate, amniotic fluid, abscess fluid
HSV (Herpes simplex virus)	Genital or perianal lesion
Chlamydia trachomatis	Urethral, vulval, cervical
Ureaplasma urealyticum	Urethral, epididymis or prostatic fluid
LGV (Lymphogranuloma venereum)	Rectal, cervical, urethral, bubo or ulcer material
Haemophilus ducreyi	Material from ulcers of genitalia and perianal areas, and from inguinal nodes

H. Ocular Specimens

1. General considerations
   a) Obtain viral and chlamydia samples before topical anesthetics are instilled.
   b) Obtain samples for chlamydial cultures with calcium alginate swabs and for viral cultures with Dacron swabs or cotton swabs with non-wood shafts (also refer to Table 2).
   c) Send prepared smears and inoculated media to the laboratory immediately.
   d) For appropriate media, call the Microbiology Department at (949) 452-3560.

2. Conjunctival scrapings
   a) One or two drops of topical anesthetic are generally instilled.
   b) Scrape the lower tarsal conjunctiva with a sterilized kimura spatula.
   c) Inoculate the appropriate media directly.
   d) Prepare smears by applying the scraping in a circular manner to a clean glass slide or by compressing material between two glass slides and pulling the slides apart.
   e) Alternatively, use a calcium alginate swab or a cotton-tipped applicator to swab the inferior tarsal conjunctiva (inside surface of eyelid) and the fornix of the eye. However, organisms are more readily detected in scrapings than from a swab.

3. Corneal scrapings
   a) Obtain conjunctival samples prior to corneal scrapings. Sometimes conjunctival cultures are helpful in assessing the possibility of contamination of corneal cultures.
   b) One or two drops of topical anesthetic are generally instilled.
   c) Using short, firm strokes in one direction, scrape multiple areas of ulceration and suppuration with a sterilized kimura spatula. (Keep the eyelid open, and be careful not to touch the eyelashes.)

d) Inoculate each scraping directly to appropriate media. (Multiple scrapings are recommended because the depth and extent of viable organisms may vary.)
e) Prepare smears by applying the scrapings in a gentle circular motion over a clean glass slide or by compressing material between two clean glass slides and pulling the slides apart.

4. Intraocular fluid
   a) Use a needle aspiration technique to collect intraocular fluid.
   b) Inoculate appropriate media directly, and/or immediately transport the samples to the laboratory in an aerobic transport system or a capped syringe with air bubbles expelled. Refer to Table 3 for instructions on properly transporting specimens collected in a syringe.
   c) Prepare smears by spreading a drop of material over the surface of a cleaned glass slide with a sterile kimura spatula or by compressing the material between two glass slides and pulling the slides apart.

5. Specimen collection considerations for ocular specimens are summarized in Table 10.

Table 10: Collection Considerations for Ocular Specimens

Culture	Comments
Bacteria	Inoculate media directly with ocular scrapings. (If *Neisseria gonorrhoeae* is suspected, inoculate a Thayer-Martin agar plate also.
Fungi	Inoculate media directly with ocular scrapings.
Anaerobes	Use anaerobic transport medium, or inoculate medium directly. If inflammation occurs after extracapsular cataract extraction, rule out *Propionibacterium* species.
Parasites	Use to detect *Acanthamoeba* species.
Chlamydia	Do not use cotton swabs for specimen collection.
Virus	Do not use calcium alginate swabs for specimen collection.
Mycobacteria	Ocular scrapings: use sterile screw-cap cup or tube. If specimen is small, add a small amount of non-bacteriostatic 0.85% NaCl.

I. Respiratory Specimens

1. General considerations
   a) Twenty-four-hour sputum collections are not acceptable for culture.
   b) If *Corynebacterium diphtheriae, Arcanobacterium haemolyticum, Bordetella pertussis, Neisseria gonorrhoeae,* legionellae, chlamydiae, or mycoplasmas are suspected, the physician should contact the clinical microbiology laboratory prior to specimen collection because special techniques and/or media are required for the isolation of these agents.

2. Lower respiratory tract
   a) Expectorated sputum
      i. If possible, have the patient rinse mouth and gargle with water prior to sputum collection.
      ii. Instruct the patient not to expectorate saliva or postnasal discharge into the container.
      iii. Collect specimen resulting from deep cough in sterile screw-cap cup or other suitable sterile collection assembly.
   b) Induced sputum
      i. Using a wet toothbrush, brush the buccal mucose, tongue, and gums prior to the procedure.
      ii. Rinse the patient's mouth thoroughly with water.
      iii. Using an ultrasonic nebulizer, have the patient inhale approximately 20 - 30 ml of 3 - 10% 0.85% NaCl.
      iv. Collect the induced sputum in a sterile screw-cap cup or other suitable sterile collection assembly.

c) Tracheostomy and endotracheal aspirations
   i. Tracheostomy is followed by colonization within 24 hours of insertion of the tube. Results must be correlated with clinical findings such as fever or infiltrate on chest X-ray. Aspirate the specimen into a sterile sputum trap.

d) Bronchoscopy specimens
   i. Bronchoscopy specimens include bronchoalveolar lavage, bronchial washing, bronchial brushing, and transbronchial biopsy specimens.
   ii. Pass the bronchoscope transnasally or transorally in non-intubated patients or via the endotrachael tube in intubated patients.
   iii. Wedge the tip of the bronchoscope in a segmental (for bronchial wash) or subsegmental (for bronchoalveolar lavage) bronchus.
   iv. To obtain specimens
      (a) Bronchial wash or bonchoalveolar lavage. Bronchial wash and bronchoalveolar lavage specimens are generally obtained before brushing or biopsy specimens to avoid excess blood in the recovered fluid, because blood may alter the concentration of cellular and noncellular components.

         (i) Inject sterile nonbacteriostatic 0.85% NaCl (generally 5 - 20 ml aliquots) from a syringe through a biopsy channel of the bronchoscope.
         (ii) Gently suction the 0.85% NaCl into a sterile container before administering the next aliquot. (In general, 50 - 75% of the 0.85% NaCl instilled is recovered in the lavage effluent.)
         (iii) Keep aliquots separate during collection. Combine aliquots from the same site for microbiology cultures and smears, but aliquots from separate sites (for example, right upper lobe and right lower lobe) should be combined only after consultation with the physician of record.

      (b) Bronchial brush specimens
         (i) Insert 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.

      (c) Transbronchial biopsies
         (i) Obtain the biopsy sample through the biopsy channel of the bronchoscope, and transport it in a sterile container with a small amount of nonbacteriostatic sterile 0.85% NaCl.

      (d) Lung aspirations
         (i) Use a computed tomography scan to obtain lung aspirates by inserting a needle through the chest wall into a pulmonary infiltrate. Aspirate material from the lesion. If the lesion is large or if there are multiple lesions, collect multiple specimens from representative sites. Refer to Table 1 for instructions on properly transporting specimens collected in a syringe.

      (e) Lung biopsies
         (i) Obtain a 1- 3 cm square piece of tissue is possible. If the lesion is large or if there are multiple lesions, collect multiple specimens from representative sites. Submit in a sterile container(s) without formalin.

3. Upper respiratory tract infections

   a) Throat (pharyngeal specimens)
      i. Submitted primarily for the detection of group A streptococci (can also be used to detect *Neisseria gonorrhoeae, Haemophilus influenzae* [for epiglottitis], **and used for COVID-19 testing**.
      ii. Do not obtain throat samples if epiglottis is inflamed, as sampling may cause serious respiratory obstruction.
      iii. Depress tongue gently with tongue depressor.
      iv. Extend sterile swab between the tonsillar pillars and behind the uvula (avoid touching the cheeks, tongue, uvula, or lips).
      v. Sweep the swab back and forth across the posterior pharynx, tonsillar areas, and any inflamed or ulcerated areas to obtain sample.

   b) Nasal swabs (Anterior nasal)
      i. Submitted primarily for the detection of MRSA (Methicillin-resistant Staphylococcus aureus) carriers or COVID testing.
      ii. Insert a sterile swab into the nose until resistance is met at the level of the turbinates (approximately 1 inch into the nose).
      iii. Rotate the swab against the nasal mucosa.
      iv. Repeat the process on the other side.

   c) ORO pharyngeal swab collection (in Universal Transport Medium) submitted for the Cepheid/COVID testing.

   d) ORO pharyngeal collection for Eswab – Strep A PCR

      ORO pharyngeal Swab Collection Process
      - Insert swab into posterior pharynx and tonsillar areas.
      - Rub swab over both tonsillar pillars and posterior oropharynx and avoid touching the tongue, teeth, and gums.
      - Place swab in media tube, and insure tip of swab is submerged at least ½ inch below media surface.
      - Break/cut protruding section of swab shaft, and reseal media tube **TIGHTLY**.

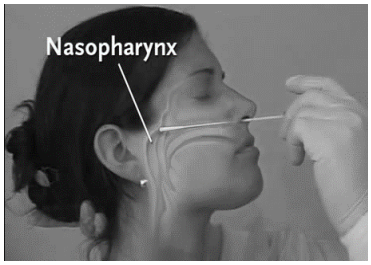
   e) Nasopharyngeal swabs (in Universal Transport Medium) submitted for the Respiratory Panel by PCR and Cepheid 4 in 1 respiratory panel.

      Collection Instructions to obtain a Nasopharyngeal Swab (NP) Specimen for Patients Requiring Respiratory Testing Including COVID-19 PCR

      Obtaining the Nasopharyngeal Swab Specimen
      - Verify orders for required testing have been placed in Epic.
      - Obtain a Respiratory Testing Kit from the laboratory (1 NP Swab and 3 mL UTM).
      - Collect 1 ***naso***pharyngeal specimen using the **mini tip** flocked swab, and place in UTM container. The swab has a break point and will break off easily into the UTM.
      - Label specimen with a patient label along with **NP** as the source, date/time, and collector's ID number.
      - Double bag the samples, ensuring the outermost bag is not contaminated.

TECHNIQUE FOR NASOPHARYNGEAL SAMPLE (NP) COLLECTION

1. If possible, have patient clear their airway, tilt head back, patient closes eyes.
2. Insert the swab until nasopharynx is felt.
3. Rotate the mini tip swab along the nasopharyngeal mucosa for 10 - 15 seconds.



f) Nasal washings
   i. Submitted primarily for Rapid Influenzae or Respiratory Panel by PCR.
   ii. Instruct the patient not to swallow during the procedure.
   iii. With the patient's head hyperextended (approximately 70° angle), instill approximately 3 - 7 ml of sterile 0.85% NaCl into each nostril.
   iv. To collect material, aspirate the fluid by inserting a rubber bulb syringe into each nostril.
   v. Place the saline wash in an equal volume of viral transport medium, or transport it in a sterile container.

f) Sinus aspirates
   i. Using a syringe aspiration technique, a specially trained physician or an otolaryngologist will obtain material from maxillary, frontal, or other sinuses.
   ii. Place the contents of the syringe into an anaerobic transport system, or send the specimen in the syringe.

g) Typanocentesis fluid
   i. Submitted primarily to diagnose middle ear infections only if previous therapy has failed.
   ii. Clean the external canal with mild detergent.
   iii. Using a syringe aspiration technique, the physician will obtain the fluid from the eardrum. Send the specimen in a sterile container, or send it in the syringe.
   iv. If the eardrum is ruptured, collect exudate by inserting a sterile swab through an auditory speculum.

h) Oral cultures
   i. Used to prepare smears for the detection of yeast or fusospirochetal disease.
   ii. Rinse mouth with sterile saline.
   iii. Wipe the lesion with dry sterile gauze.
   iv. Swab or scrape areas of exudation or ulceration.

4. Respiratory specimen collection considerations are summarized in Table 11.

Table 11: Collection Considerations for Respiratory Specimens

Culture	Vol (ml)[a]	Comments
Bacteria	NA	Contact laboratory if *Legionella* is suspected. Submit sputum only; **saliva is unacceptable.**
Fungi	3 - 5	Collect early morning fresh specimen resulting from deep cough or sputum induction on three consecutive days. Lung biopsy specimens or lung aspirates are also appropriate.

Table 11: Collection Considerations for Respiratory Specimens

Culture	Vol (ml)[a]	Comments
Anaerobes	1	Sinus aspirate, tympanocentesis fluid, transtracheal aspirate, and lung aspirates or biopsy specimens are appropriate.
Mycobacteria	5 - 10	Collect three early morning fresh specimens resulting from deep cough or sputum induction. Lung biopsy specimens or lung aspirates are also appropriate.
Pneumocystis spp.	2	Use induced sputum, bronchoalveolar lavage fluid, or lung biopsy specimen.
Pneumonia Panel by PCR	1	Bronchoalveolar lavage (BAL) specimen only
Parasites	3 - 5	Can be examined for amoebae, helminth eggs (*Paragonimus westermani*), hooklets of *Echinococcus* spp., larvae of hookworm, and *Ascaris* and *Strongyloides* spp.
Respiratory Panel by PCR	1	Nasopharyngeal swabs (in Universal Transport Medium) Carefully insert a flexible-wire calcium alginate-tipped swab through the nose into the posterior nasopharynx, and rotate the swab. (Keep the swab near the septum and floor of the nose.)

[a] Amount are guidelines. NA is not applicable.

5. Bordetella Pertussis (*B. pertussis*) infections

   a) Bordetella pertussis/parapertussis by PCR – Collect respiratory specimen: Aspirate, broncoalveolar (BAL), swab or sputum. Transfer to a sterile container. It is also acceptable to transfer to Associated Regional and University Pathologists, Inc. (ARUP) Laboratories Viral Transport Media.
   b) Bordetella pertussis/parapertussis is part of the Respiratory Panel by PCR. Collect using a nasopharyngeal swab and submit in Universal Transport Medium.

   For nursing, refer to collection procedure **PC 095 – Nasal Wash/Swab Procedure**.
   Repiratory Therapy is notified to collect outpatient nasopharyngeal washings in the laboratory (**Nasopharyngeal Washings RTD – 221**).

J. Sterile Body Fluids (excluding cerebrospinal fluid, urine, and blood)

1. Clean the needle puncture site with alcohol, and disinfect it with an iodine solution (1 - 2% tincture of iodine or a 10% solution of povidone-iodine [1% free iodine]) to prevent introduction of infection. (If tincture of iodine is used, remove with 70% ethanol after the procedure to avoid burn.)

2. The physician will aseptically perform percutaneous aspiration to obtain pleural, pericardial, peritoneal, or synovial fluids.

3. Expel any air bubbles from the syringe, and immediately inject the specimen into an anaerobic transport system or send the specimen in the syringe. Transp ort additional fluid or pus in a sterile screw-cap container.

4. Sterile body fluid collection considerations are summarized in Table 12.

Table 12: Collection Considerations for Sterile Body Fluids

Culture	Vol (ml)[a]	Comments
Bacteria	1 - 5	If gonococcal arthritis is suspected, notify Laboratory to add modified Thayer-Martin plate.
Fungi	> 10 In isolator tube only blood	Blood for *Histoplasma capsulatum* (AIDS), *Cryptococcus* species, *Candida albicans*[b], and *Candida tropicalis*[b].
Anaerobes	1 - 5	Use sterile screw-cap cup or tube.
Mycobacteria	> 10	Use sterile screw-cap cup or tube.

[a] Amount are guidelines. Greater volumes will increase the chance of organism recovery.

[b] Can also be recovered in most bacterial cultures.

K. Subcutaneous Tissue and Skin Specimens

1. Burn specimens
   The surfaces of burn wounds will become colonized by the patient's microbiota or by environmental organisms. When the organism load is large, infection of underlying tissue may occur, and bacteria may ensue. Cultures of the surface alone are misleading; therefore, biopsies of deeper tissue are often indicated. Additionally, organisms may not be distributed evenly in the burn wound, so sampling of different areas of the bum is recommended.

   a) Disinfect the surface of the burn with 70% alcohol and then with an iodine solution (1 - 2% tincture of iodine or a 10% solution of povidone-iodine [1% free iodine]). Allow the disinfectant to dry prior to collecting the specimen. *NOTE: Blood cultures should be used to monitor patient status*. If tincture of iodine is used, it must be removed with 70% alcohol after the procedure to prevent burns.
   b) Collect a punch biopsy sample (3 - 4 mm) for quantitative culture.

2. Superficial wound, bacterial

   a) Syringe aspiration is preferable to swab collection.
   b) Disinfect the surface of the wound with 70% alcohol and then with an iodine solution (1 - 2% tincture of iodine or a 10% solution of povidone-iodine [1% free iodine]). Allow the disinfectant to dry prior to collecting the specimen.
   c) Using a 3 -5 ml syringe with a 22 - 23 gauge needle, a physician will aspirate the deepest portion of the lesion. If a vesicle is present, collect both fluid and cells from the base of the lesion.
   d) If the initial aspiration fails to obtain material, inject sterile, nonbacteriostatic 0.85% NaCl subcutaneously.
   e) Repeat the aspiration attempt.
   f) If no material is obtained, rinse the needle and syringe with broth by drawing the culture medium through the needle into the syringe.

3. Superficial lesions, fungal

   a) Clean the surface with sterile water.
   b) Using a scalpel blade, scrape the periphery of the lesion border. Samples from scalp lesions should include hair that is selectively collected for examination. If there is nail involvement, obtain scrapings of debris or material beneath the nail plate. Transport in a sterile container or sterile petri dish.

4. Ulcers and nodules
    a) Clean the area with 70% alcohol and then with an iodine solution (1 - 2% tincture of iodine or a 10% solution of povidone-iodine [1% free iodine]). Tincture of iodine must be removed with alcohol after the procedure to prevent burns.
    b) Remove overlying debris.
    c) Curette the base of the ulcer or nodule.
    d) If exudate is present from ulcer or nodule, collect it with a syringe or sterile swab.

5. Subcutaneous tissue and skin specimen collection considerations are summarized in Table 13.

Table 13: Collection Considerations for Subcutaneous Tissue and Skin Specimens

Culture	Comments
Bacteria	Syringe aspirates or biopsy specimens are preferable to swab specimens.
Fungi	Useful in diagnosing dermatophytes, yeast, filamentous fungi, and dimorphic fungi.
Anaerobes	Uncommon in burn, ulcer, nodules, or superficial skin infections; useful following bites and trauma.
Virus[a]	Useful in diagnosing HSV (herpes simplex virus) and varicella-zoster virus.
Mycobacteria	Useful in diagnosing *Mycobacterium marinum, Mycobacterium fortuitum,* and *Mycobacterium chelonei.*

[a] Rate of recovery of HSV and varicella-zoster virus is highest from the youngest lestions (vesicles), then from pustules, ulcers, and crusted lesions, in that order.

L. Deep Wounds, Aspirates, and Tissue Specimens

1. Bite wounds
    a) Aspirate pus from the wound, or obtain it at the time of incision, drainage, or debridement of the infected wound. (Do not culture fresh bite wounds, as infectious agents will likely not be recovered.)

2. Bone
    a) Obtain bone specimen at surgery.
    b) Submit in sterile container without formalin. Specimen may be kept moist with sterile 0.85% NaCl.

3. Deep wounds or abscesses
    a) Disinfect the surface with 70% alcohol and then with an iodine solution (1 - 2% tincture of iodine or a 10% solution of povidone-iodine (1% free iodine). Tincture of iodine must be removed with 70% alcohol to prevent burns.
    b) Aspirate the deepest portion of the lesion, avoiding contamination by the wound surface. If collection is done at surgery, a portion of the abscess wall should also be sent for culture.

4. Punch skin biopsies
    a) Disinfect the skin surface with 70% alcohol and then with an iodine solution (1 - 2% tincture of iodine or a 10% solution of povidone-iodine (1% free iodine). Tincture of iodine must be removed at completion of procedure to prevent burns.
    b) Collect 3 - 4 mm sample with dermal punch.
    c) Submit for microbiological analysis in sterile container without formalin.

5. Soft tissue aspirate
   a) Disinfect the skin surface with 70% alcohol and then with an iodine solution (1 - 2% tincture of iodine or a 10% solution of povidone-iodine (1% free iodine). Remove tincture of iodine with alcohol after procedure to prevent burns.
   b) Aspirate the deepest portion of the lesion or sinus tract. Be careful to avoid contamination by the wound surface.

6. Deep wound, aspirate, and tissue specimen collection considerations are summarized in Table 14.

Table 14: Collection Considerations for Deep Wound, Aspirate, and Tissue Specimens

Culture	Comments
Bacteria	Biopsy specimens or aspirates are better than swab specimens.
Fungi	Useful in diagnosing *Pseudallescheria boydii, Bipolaris* species, *Exophiala* species, and *Fusarium* species.
Anaerobes	Useful in diagnosing actinomycosis; send in anaerobic transport system.
Mycobacteria	Useful in diagnosing *Mycobacterium tuberculosis, Mycobacterium bovis*, and *Mycobacterium kansasii.*

M. Urine Specimens: Refer to Nursing Elsevier Clinical Skills

1. General considerations
   a) **Never** collect urine from a bedpan or urinal.
   b) Thoroughly clean the urethral opening (and vaginal vestiblue in females) prior to collection procedures to ensure that the specimen obtained is not contaminated with colonizing microorganisms in this area.
   c) Soap rather than disinfectants is recommended for cleaning the urethral area. If disinfectants are introduced into the urine during collection, they may be inhibitory to the growth of microorganisms.
   d) Submit BD Collection container as follows using the BD Urine Collection Kit:
      i. C&S preservative tube (grey top) for C&S,
      ii. UA preservative tube (cherry red/yellow top) for UA,
      iii. For any additional urine chemistry testing, send urine in plain red top tube.
   e) If not collected using BD Urine Collection system, transport specimen to laboratory **WITHIN 2 HOURS** of collection. If it cannot be transported **within 2 hours** of collection, the urine specimen should be refrigerated. (Bacterial counts remain stable for at least 24 hours at 4° Celsius.) *Do not freeze.*
   f) Transport suprapubic bladder aspirate (SPA) specimens for anaerobic culture in a sterile screw-cap cup or tube.
   g) Any urine collection procedure involving catheterization must be done with scrupulous aseptic technique to avoid introducing microorganisms.
   h) Send the first morning voided urine. Three consecutive first morning urine specimens are recommended for mycobacterial culture.
   i) Do not submit 24 hour urine collections for culture.

2. Collection Techniques for random urine collection
   See Patient Instructions - Mid-Stream Clean Catch Instructions. For collection procedure using BD Urine Collection System, see below.

   HOSPITAL STAFF PROCEDURE
   a) RN/Patient Care Technician (PCT) will perform hand hygiene and don gloves.

b) After patient hands the urine to the RN/PCT, the urine must be transferred to the two (3 if chemistry tests are ordered) tubes. Gloves must be worn during transfer.

c) Compare the labels to the patient's armband and ensure they include patient's Full Name, Medical Record Number, Date and Time collected, initials, and source (UA Midstrea) recorded on the labels. (Urines are processed in Microbiology differently as to whether it is clean catch versus catheter specimen, so it is important to record UA – Mid.)

d) Label urine container and the 2 tubes (3 if chemistries are ordered) at the bedside with label(s) checked in c).

e) Peel back the sticker to expose the rubber covered cannula.

f) Push the grey stopper tube into the integrated transport port. Hold in position until flow stops. (Minimum required is 3 mL.)

g) Remove the tube and shake vigorously (inverting the tube at least 8 - 10 times).

h) Push the yellow/red tiger top UA Preservative Tube into the integrated transfer port.

i) Hold in position until flow stops. Minimum volume for tube is 7 mL.

j) Remove the tube. Invert UA Preservative tube 8 - 10 times to completely mix the sample.

k) If chemistry tests are ordered, push the sterile red stopper/clear cap tube into the integrated transfer port completely.

l) Hold in position until flow stops. Ideal volume is 5 - 6 mL.

m) Remove the tube.

n) Dispose the urine and cup per normal protocols, but insure that the blue lid with the integrated transfer port is placed in large sharps conteiners found in the dirty utilities or designated area(s).

o) If there is not enough urine to transfer to the tubes, take the labeled urine cup to the laboratory (**The blue top urine container can NOT be sent in the tube system.**). If you need to tube the urine to the laboratory, you must transfer the urine to a white top container, labeled appropriate as instructed in c).

p) If Point of Care (POC) testing is going to be done, it should be performed on the urine cup specimen to ensure that the tube stopper does not come off if tubed to the laboratory.

q) Place the tube(s) or the urine container into a biohazard bag.

r) Status the urine tests as collected in EPIC, print out the transmittals, and place them in the outside pocket of the biohazard bag.

s) Send the urine sample(s) with the transmittals to the lab.

3. Urine Collection (24 Hour) – see Patient Instructions.

MemorialCare
Saddleback Medical Center

Laboratory Services

Urinalysis Instructions for Patients

Mid-Stream Clean Catch Instructions

Female Cleansing Instructions

1. Stand in a squatting position over the toilet. Separate the folds of skin around the urinary opening.
2. Cleanse the area around the opening with the first castile soap towelette.
3. Repeat using a second clean towelette.
4. Urinate the first portion of urine in the toilet.
5. As you continue to urinate, bring the collection cup into the midstream to collect the urine sample. **DO NOT OPEN** the yellow label on the lid.
6. Do not touch the inside or lip of the cup.
7. Urinate remainder of urine into the toilet.
8. Replace the blue cap onto the BD Vacutainer® Urine Collection Cup.
9. Return the sample to the healthcare worker.

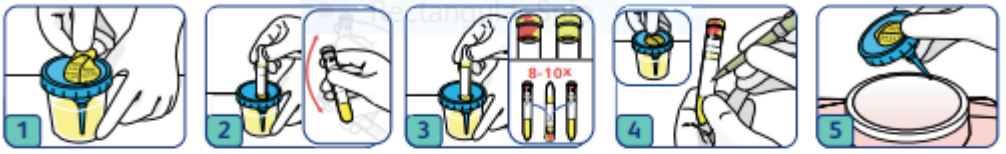
Male Cleansing Instructions

1. Cleanse the end of the penis with the first castile soap towelette beginning at the urethral opening and working away from it (the foreskin of an uncircumcised male must be retracted).
2. Repeat using a second clean towelette.
3. Urinate the first portion of urine in the toilet.
4. As you continue to urinate, bring the collection cup into the midstream to collect the urine sample. **DO NOT OPEN** the yellow label on the lid.
5. Do not touch the inside or lip of the cup.
6. Urinate remainder of urine into the toilet.
7. Replace the blue cap onto the BD Vacutainer® Urine Collection Cup.
8. Return the sample to the healthcare worker.

Processing urine samples with the BD Vacutainer® urine collection cup

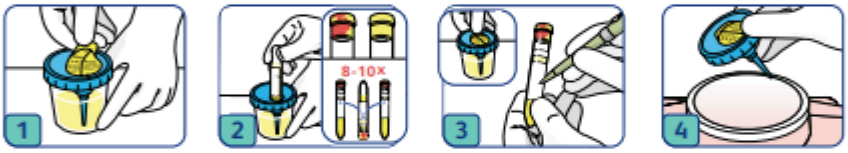
This document summarizes processing steps necessary for the BD Vacutainer® urine collection cup and the most common urine transport tubes: BD Vacutainer® Urinalysis (UA) Preservative tube, BD Vacutainer® Urinalysis (UA) plain tube, BD Vacutainer® Culture & Sensitivity (C&S) preservative tube.

UA Preservative or Plain UA Tube and C&S Preservative Tube



1. • Peel back protective sticker to expose rubber covered cannula.
2. • Push C&S Preservative Tube (gray top) into the integrated transfer port.
   • Hold in position until flow stops.
   • Remove tube and confirm minimum fill volume (3 mL).
   • Invert tube 8-10 times to mix the sample.
3. • Push UA Preservative Tube (cherry red/yellow top) or plain UA Tube (yellow top) into integrated transfer port.
   • Hold in position until flow stops.
   • Remove tube and confirm minimum fill volume (7 mL).
   • Invert UA Preservative Tube 8-10 times to mix the sample.
4. • Place protective sticker back over the integrated transfer port.
   • Label both filled tubes per your institution's requirements.
5. • Remove lid from cup and dispose in a sharps collector.
   • Dispose of urine according to your facility's policy
   • Dispose of collection cup as a biohazard.

UA Preservative or Plain UA Tube only



1. • Peel back protective sticker to expose rubber-covered cannula.
2. • Push UA Preservative Tube (cherry red/yellow top) or plain UA Tube (yellow top) into integrated transfer port.
   • Hold in position until flow stops.
   • Remove tube and confirm minimum fill volume (7 mL).
   • Invert UA Preservative Tube 8-10 times to mix the sample.
3. • Place protective sticker back over the integrated transfer port.
   • Label filled tube per your institution's requirements.
4. • Remove lid from cup and dispose in a sharps collector.
   • Dispose of urine according to your facility's policy.
   • Dispose of collection cup as a biohazard.

C&S Preservative Tube only

1. • Peel back protective sticker to expose rubber-covered cannula.
2. • Push C&S Preservative Tube (gray top) into the integrated transfer port.
   • Hold in position until flow stops.
   • Remove tube and confirm minimum fil volume (3 mL).
   • Invert tube 8-10 times to mix the sample.
3. • Place protective sticker back over the integrated transfer port.
   • Label filled tube per your institution's requirements.
4. • Remove lid from cup and dispose in a sharps collector.
   • Dispose of urine according to your facility's policy.
   • Dispose of collection cup as a biohazard.

BD Vacutainer® Technical Services: 1.800.631.0174
BD Vacutainer® Customer Services: 1.800.823.5433

Handle all biologic samples and medical "sharps" (lancets, needles and transfer straws) according to the policies and procedures of your facility. Obtain appropriate medical attention in the event of any exposure to biologic samples (for example, through a puncture injury) since they may transmit viral hepatitis, HIV (AIDS), or other infectious diseases. BD does not recommend reshielding used needles, but the policies and procedures of your facility may differ and must always be followed. Discard any medical "sharps" in biohazard containers approved for their disposal.

BD Life Sciences, 7 Loveton Circle, Sparks, MD 21152-0999 USA

bd.com

PATIENT INSTRUCTIONS FOR 24-HOUR URINE COLLECTION

1. Obtain a container for the specimen collection.
2. Check and make sure the container is labeled with identification (last and first name and date of birth).
3. Patient voids completely and discard the specimen. **Record this start time and date.**
4. For the next 24 hours, collect urine specimens in a separate container and pour them into the large collection container.
5. ***Keep refrigerated or on ice.***
6. At 24 hours, void and add this last specimen to the 24-hour collection container. **Record this end time and date.**
7. Record accurately on the container the time and the date the patient started collecting and the time and date of the the last collection specimen.
8. If you have any questions, please call the laboratory at (949) 452-3554.

NOTE: 24 HR CREATININE CLEARANCE TEST REQUIRES A BLOOD SPECIMEN UPON DELIVERY OF THE 24 HR URINE. BLOOD SPECIMEN MAY BE DRAWN 24 HOURS PRIOR TO OR AFTER THE 24 HR URINE COLLECTION.

4. Urine Collection - Other

   a) Ileal conduit urine
      i. Remove the external urinary appliance, and discard the urine within the appliance.
      ii. Gently swab and clean the stomal opening with a 70% alcohol pad and then with an iodine solution (1 - 2% tincture of iodine or a 10% solution of povidone-iodine (1% free iodine). Remove excess tincture of iodine with 70% alcohol after procedure to avoid burn.
      iii. Using sterile technique, insert a double catheter into the stoma. (A double catheter helps to minimize contamination of the specimen with skin flora.)
      iv. Catheterize the ileal conduit to a depth beyond the fascial level.
      v. Collect the urine drained into a sterile container.
   b) Straight catheter urine (in/out catheter urine specimens)
      i. In/out catheter urine specimens are useful when clean-catch urine cannot be obtained or when results from clean-catch urine specimens are equivocal and a diagnosis is critical.
      ii. Prior to catheterization, the patient should force fluids until the bladder is full. (Forcing fluids may reduce organism number.)
      iii. Clean the patient's urethral opening (and in females, the vaginal vestibule) with soap, and carefully rinse the area with water .
      iv. Using sterile technique, pass a catheter into the bladder.
      v. Collect the initial 15 - 30 ml of urine, and discard it from the mouth of the catheter .
      vi. Collect a sample from the mid or later flow of urine in a sterile container.
   c) Indwelling catheter urine -- Indwelling catheters are place in patients who are unable to pass urine.
      i. Clean the catheter collection port with a 70% alcohol wipe.
      ii. Using sterile technique, puncture the collection port with a needle attached to a syringe. ***(<u>NOTE</u>: Do not collect urine from collection bag.*)**
      iii. Aspirate the urine, and place it in a sterile container.
   d) Suprapubic skin aspiration (SPA) of the urinary bladder
      i. SPA is useful in determining urinary infection in adults in whom infection is suspected and for whom results from routine procedures have been equivocal and diagnosis is critical. SPA is also useful in pediatric patients when clean-catch urine specimens are difficult to obtain.
      ii. Before SPA, the patient should force fluids until the bladder is full. (Forcing fluids may reduce the organism number.)
      iii. Shave and disinfect the suprapubic skin overlying the urinary bladder.
      iv. The physician will make a small lance wound through the epidermis, just above the symphysis pubis.
      v. Aspirate urine from the bladder by using a needle aspiration technique.
   e) Bladder washout test (Fairly)
      i. The bladder washout test is useful in determining the site of infection in the urinary tract. Results are equivocal in about 10 - 20% of patients.
      ii. Prior to test, have the patient force liquids until the bladder is full. (Forcing liquids may reduce organism number.)
      iii. Clean the urethral area with soapy water, and rinse the area well with water.
      iv. Insert an indwelling catheter into the bladder through the urethra.
      v. Collect an initial urine specimen into a sterile container, and refrigerate it
      vi. Empty the bladder through the urethral catheter, and then irrigate it. (Use a sterile nonbacteriostatic 0.85% NaCl solution to irrigate the bladder.)
      vii. Collect three additional specimens (5 - 10 ml each) at 10-minute intervals into separately labeled containers after irrigation of the bladder is performed.
      viii. Submit the initial and timed collection samples to the clinical microbiology laboratory for culture. *(<u>NOTE</u>: It is imperative that each specimen container be clearly labeled with the time of specimen collection.)*

f) Cystoscopy: bilateral ureteral catheterization
   i. Bilateral ureteral catheterization is useful in determining the site of infection in the urinary tract.
   ii. Prior to cystoscopy, have the patient force liquids until the bladder is full. (Forcing liquids may reduce the organism number.)
   iii. Clean the urethral area (and vaginal vestibule in females) with soapy water, and rinse the area well with water. Insert a cystoscope (obturator in place) into the bladder.
   iv. With sterile technique, collect approximately 5 - 10 ml of urine from open stopcock into a sterile container.
   v. Label this sample CB, for catheterized bladder urine, and refrigerate it. Then irrigate the bladder. (Use sterile nonbacteriostatic 0.85% NaCI to irrigate the bladder.)
   vi. After irrigation of the bladder and insertion of the ureteral catheters, collect irrigating fluid passing from the bladder through the ureteral catheters by holding the ends of both catheters over an opened sterile container.
   vii. Label this sample WB, for washed bladder urine, and refrigerate it.
   viii. Pass the ureteral catheters to each midureter or renal pelvis without introducing additional irrigating fluid. Open both stopcocks of the cystoscope to empty the bladder.
   ix. Discard the first 5 - 10 ml of urine from each ureteral catheter.
   x. Collect four consecutive paired cultures (5 - 10 ml each) directly into opened sterile containers.
   xi. Label these specimens LK-1, RK-1, LK-2, and RK-2 (LK for left kidney and RK for right kidney). Submit all samples to the clinical microbiology laboratory for culture.

5. Urine specimen collection considerations are summarized in Table 15.

Table 15: Collection Considerations for Urine Specimens

Culture	Vol (ml)[a]	Comments
Bacteria	0.5 - 1.0	Do not collect 24-hour specimen. After proper cleansing of patient, use first morning midstream void.
Fungi	> 20	Do not collect 24-hour specimen. First morning void is recommended.
Mycobacteria	> 20	Do not collect 24-hour specimen. First morning three consecutive voided urine specimens are recommended.
Anaerobes	1	Use suprapubic aspirate. Send in sterile screw-cap cup or tube.
Virus	10 - 50	Do not collect 24-hour specimen. First morning void is recommended. Useful for adenovirus, mumps, and CMV (cytomegalovirus) detection. Send on ice, and transport to laboratory immediately.
Parasites	24-hour collection	Use for detecting *Shistosoma haematobium* eggs, *Trichomonas vaginalis* trophozoites in males, and *Onchocerca volvulus* microfilariae.

[a]Amount are guidelines. Greater volumes will increase the chance of organism recovery.

N. Collection of Cytology Specimens (Non-GYN)

1. For orders placed in the Electronic Medical Record (EMR), they must include all relevant clinical information. The EMR specimen transmittal will print automatically.

2. Specimen to be collected according to Table 16.

3. All cytology specimens from radiology are walked down by radiology technicians to pathology and the laboratory. The pathology specimen is placed in cytology basket and log is signed. After hours, pathology specimens are brought to main lab for Microbiology processing (after 4 pm). The laboratory specimen is given to the laboratory assistant in processing area of main lab.

4. All containers must be tightly sealed to prevent leakage and to prevent fresh specimens from drying out.

5. THE CONTAINER MUST BE LABELED WITH ADDRESSOGRAPH WHICH INCLUDES PATIENT'S NAME, MEDICAL RECORD #, DATE OF BIRTH, AND PHYSICIAN 'S NAME. HANDWRITTEN INFO ON THE LABELS MUST INCLUDE DATE, TIME, SOURCE AND INITIALS OF PERSON LABELING. SLIDES SENT DOWN MUST INCLUDE PATIENT NAME, MEDICAL RECORD #, AND SOURCE OF SPECIMEN.

6. For specimens sent from Surgical Center at Saddleback (SCS) Outpatient Surgery, the Pathology Request form (7060.04) must be filled out with all pertinent information including patient's name, age, sex, date, physician, source of specimen, and history.

7. The specimen and specimen transmittal/requisition must be transported to the Laboratory as soon as possible.

Table 16: SPECIMEN REQUIREMENTS FOR NON-GYN CYTOLOGY

SAMPLE SOURCE	SAMPLE REQUIREMENTS	STAT	EXPECTED TURNAROUND TIME	SPECIAL INSTRUCTIONS
BRONCHIAL WASHINGS	Send fresh specimen immediately. Obtained in suction/cup/lukens trap.	MD phone request only	24 - 48 hours	Do not add preservative/fixative. Refrigerate if delayed or delivered on weekend.
BRONCHIAL BRUSHINGS	Slides must be immersed in 95% Alcohol solution or sprayed with fixative immediately! Do not allow smears to air dry. NOTE: Slides that MD request to be air dried, do not fix. Allow air dry slides to dry.	MD phone request only	24 - 48 hours	Spread material over area about the size of a nickel. Immediately immerse slide in 95% Alcohol or spray with fixative. Do not allow smears to air dry.
CYST FLUIDS (Breast, renal, ovary)	Submit fresh, unfixed; do not add fixative.	Phone request only	24 - 48 hours	Refrigerate if delay anticipated or delivered on weekend.
FINE NEEDLE ASPIRATION BIOPSY - (FNAB)	Divide slides with ½ fixed in 95% Alcohol or spray fixed and other ½ air dried. Excess aspirate is to be put in a container with no fixative.	Phone request only	24 - 48 hours	Technical assistance available. 2 - 3 separate aspirates suggested. Excess aspirate should be refrigerated if delayed or delivered on weekend.
GASTRO-INTESTINAL BRUSHINGS (Esophagus, gastric, dudonel, colon)	Brushing slides are wet fixed in 95% Alcohol or spray fixed immediately.	Phone request only	24 - 48 hours	Spread cellular material over an area about the size of a nickel. Immerse in 95% Alcohol or spray before the slightest trace of drying ocurrs.
PARACENTESIS (Ascites, Cul De Sac, Peritoneal)	Submit fresh, do not add fixative or preservatives.	MD phone request only	24 - 48 hours	Refrigerate if delayed or delivered on weekend.
PELVIC WASHINGS	Submit fresh, unfixed; do not add fixative.	MD phone request only	24 - 48 hours	Refrigerate if delayed or delivered on weekend.
PERICARDIAL FLUID	Submit fresh, unfixed; do not add fixative.	MD phone request only	24 - 48 hours	Refrigerate if delayed or delivered on weekend.

Table 16: SPECIMEN REQUIREMENTS FOR NON-GYN CYTOLOGY (cont.)

SAMPLE SOURCE	SAMPLE REQUIREMENTS	STAT	EXPECTED TURNAROUN TIME	SPECIAL INSTRUCTIONS
CEREBROSPINAL FLUID (CSF, ventricular fluid)	Submit fresh, unfixed; do not add fixative.	MD phone request only	24 - 48 hours	Refrigerate if delayed or delivered on weekend.
SPUTUM	Early morning is the best sample. Prefer fresh specimen, but may be submitted in 70% Alcohol solution or equal Saccomanno fluid. Refrigerate if not processed immediately.	MD phone request only	24 - 48 hours	Separate specimen required for Microbiology. "Deep" cough sample necessary. Saliva/nasal secretions are unsatisfactory.
THORACENTESIS (Pleural Chest fluid)	Submit fresh; do not add fixative or preservatives.	MD phone request only	24 - 48 hours	Refrigerate if delayed or delivered on weekend.
URINARY TRACT (Voided, cath, bladder wash, renal pelvis wash)	No volume requirements. Submit fresh; do not add fixative or preservatives.	MD phone request only	24 - 48 hours	Refrigerate if delayed or delivered on weekend.
VIRAL SMEAR – Tzanck Preparation	Smears MUST be spray or 95% Alcohol fixed.	MD phone request only	24 - 48 hours	Scrape vesicle or lesion vigorously and spread material on the slide over an area about the size of a nickel. Fix the smear(s) immediately before the slightest trace of drying occurs.

Reference:
1. Cibas, E. and Ducatmen, B. Cytology; Diagnostic Principles and Clinical Correlates; 2008

O. Surgical Pathology Guidelines: Refer to policy PL-435 Surgical Pathology Guidelines.

P. Tzanck Test (Herpes Smear)

The Tzanck Test is done to detect the Herpes virus. Smears are made from a vesicle suspected to be the result of Herpes viral infection. The smears are stained and read by a Pathologist.

1. An intact vesicle suspected to be the result of a Herpes infection must be chosen rather than a crusted vesicle.
2. Clean the vesicle with alcohol.
3. Unroof the vesicle and use a swab at the base of the vesicle.
4. Use the swab and apply to two microscopic slides.
5. Spray fix the two slides.
6. The slides must be labeled with the patient's name and source.
7. The slide holder must be labeled with the patient's name, Medical Record number, date/time, initials of the collector, and source of specimen.
8. For areas using EHR (electronic health record), the Tzanck Test should be ordered and sent to the Laboratory with a transmittal. Alternatively, a pathology requisition should be sent with the specimen.

9. The slides must be submitted to the Pathology Department along with the specimen transmittal/requisition.
10. Slides are given a cytology assession number, processed, and stained by the pathology technician.
11. The Pathologist reads the slides and a pathology report is initiated in HER.

SPECIMEN LABELING

Specimen Labeling - Outpatient

To assure positive identification and optimum integrity of patient specimens from the time of collection until testing is completed and results reported, the staff must label all specimens submitted to MemorialCare Saddleback Medical Center for testing with the patient's first and last name, correctly spelled, and date of birth (D.O.B.). Samples should be labeled with the date and time of collection and the collector's initials. Samples are to be labeled in the presence of the patient.

Test request forms for outpatient can be requested by calling Saddleback Medical Center Laboratory at **(949) 452-3554**.

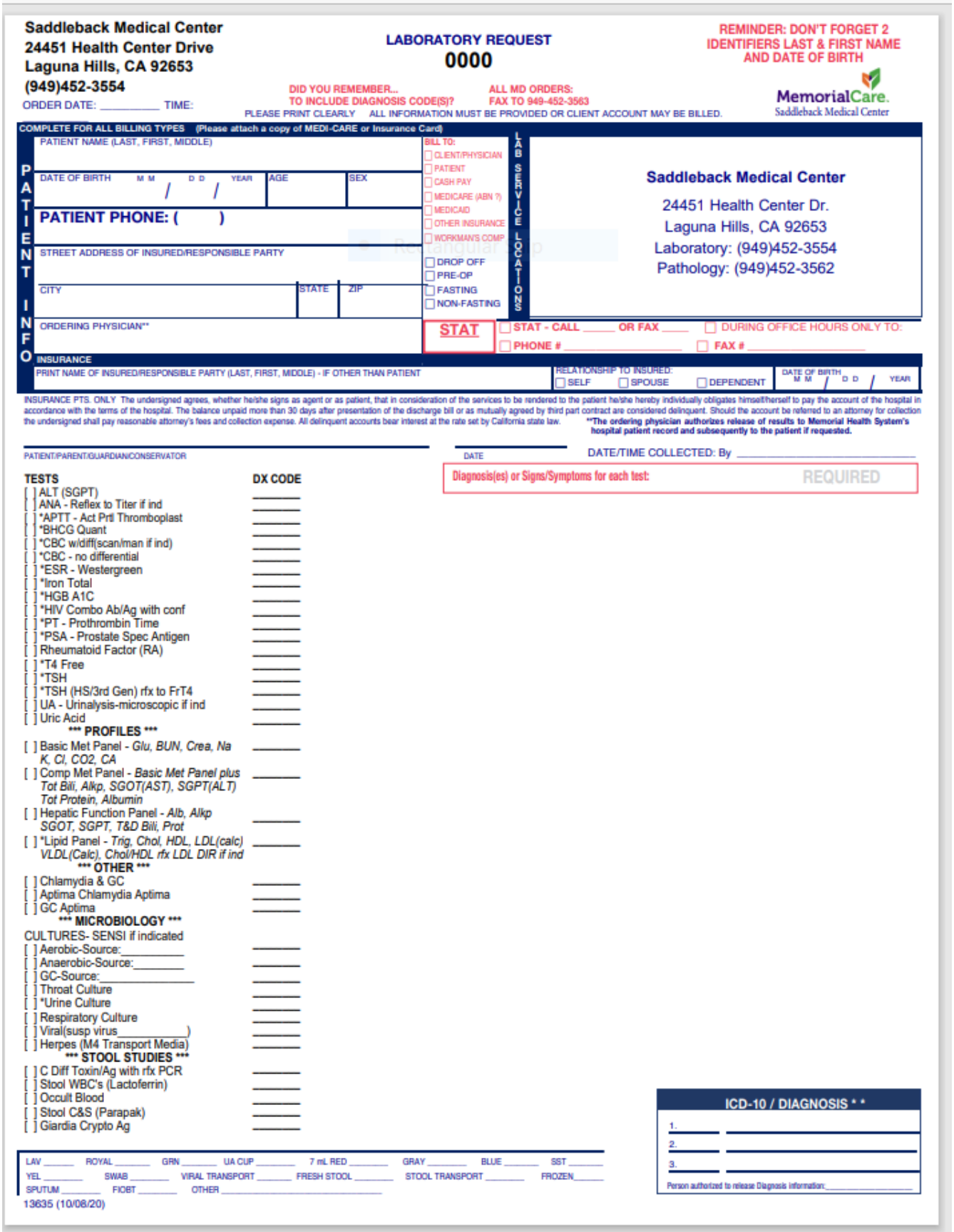
REQUISITION REQUIREMENTS:

1. Complete a separate test request form for each patient, as outlined here.
2. Be sure to record the following: **PLEASE <u>PRINT</u> LEGIBLY.**
   - Patient name, birth date, sex, address, phone number
   - **COLLECTION TIME AND DATE**
   - Order date
   - Physician
   - Type of specimen submitted
   - Source of specimen for infectious disease test(s) and other comments in the "Comments" box
   - Special instructions to the Laboratory (if any)
3 If STAT, be sure to mark the STAT box and enter the FAX and phone numbers of the physician.
4. Mark the box(es) [x] indicating the test(s) requested. **<u>ICD-10 Diagnosis Code MUST be entered.</u>**
5. If there is no box for a test you are requesting, **print** the **test name** on the blank line.
6. For an example of a requisition (front and back), see the following pages.

SPECIMEN LABELING:

1. **PRINT** patient's first and last name, **legibly and spelled correctly**, on the specimen container.
2. **PRINT** patient's date of birth (D.O.B.).
3. **PRINT** date and time collected.
4. For multiple tests, extra tubes or containers may be needed. Call Saddleback Medical Center Laboratory with any questions at (**949) 452-3554**.

LABORATORY TEST REQUEST FORM (FRONT)



Saddleback Medical Center
24451 Health Center Drive
Laguna Hills, CA 92653
(949)452-3554
ORDER DATE: _____ TIME:

LABORATORY REQUEST
0000

DID YOU REMEMBER... TO INCLUDE DIAGNOSIS CODE(S)?
ALL MD ORDERS: FAX TO 949-452-3563
PLEASE PRINT CLEARLY ALL INFORMATION MUST BE PROVIDED OR CLIENT ACCOUNT MAY BE BILLED.

REMINDER: DON'T FORGET 2 IDENTIFIERS LAST & FIRST NAME AND DATE OF BIRTH

MemorialCare. Saddleback Medical Center

COMPLETE FOR ALL BILLING TYPES (Please attach a copy of MEDI-CARE or Insurance Card)

PATIENT INFO
PATIENT NAME (LAST, FIRST, MIDDLE)
DATE OF BIRTH M M / D D / YEAR | AGE | SEX
PATIENT PHONE: ( )
STREET ADDRESS OF INSURED/RESPONSIBLE PARTY
CITY | STATE | ZIP
ORDERING PHYSICIAN**

BILL TO:
- CLIENT/PHYSICIAN
- PATIENT
- CASH PAY
- MEDICARE (ABN ?)
- MEDICAID
- OTHER INSURANCE
- WORKMAN'S COMP

LAB SERVICE LOCATIONS
- DROP OFF
- PRE-OP
- FASTING
- NON-FASTING

Saddleback Medical Center
24451 Health Center Dr.
Laguna Hills, CA 92653
Laboratory: (949)452-3554
Pathology: (949)452-3562

STAT
STAT - CALL _____ OR FAX _____ DURING OFFICE HOURS ONLY TO:
PHONE # _____ FAX # _____

INSURANCE
PRINT NAME OF INSURED/RESPONSIBLE PARTY (LAST, FIRST, MIDDLE) - IF OTHER THAN PATIENT
RELATIONSHIP TO INSURED: SELF SPOUSE DEPENDENT
DATE OF BIRTH M M / D D / YEAR

INSURANCE PTS. ONLY The undersigned agrees, whether he/she signs as agent or as patient, that in consideration of the services to be rendered to the patient he/she hereby individually obligates himself/herself to pay the account of the hospital in accordance with the terms of the hospital. The balance unpaid more than 30 days after presentation of the discharge bill or as mutually agreed by third part contract are considered delinquent. Should the account be referred to an attorney for collection the undersigned shall pay reasonable attorney's fees and collection expense. All delinquent accounts bear interest at the rate set by California state law.

**"The ordering physician authorizes release of results to Memorial Health System's hospital patient record and subsequently to the patient if requested.

PATIENT/PARENT/GUARDIAN/CONSERVATOR _____ DATE _____ DATE/TIME COLLECTED: By _____

Diagnosis(es) or Signs/Symptoms for each test: REQUIRED

TESTS	DX CODE
[ ] ALT (SGPT)	
[ ] ANA - Reflex to Titer if ind	
[ ] *APTT - Act Prtl Thromboplast	
[ ] *BHCG Quant	
[ ] *CBC w/diff(scan/man if ind)	
[ ] *CBC - no differential	
[ ] *ESR - Westergreen	
[ ] *Iron Total	
[ ] *HGB A1C	
[ ] *HIV Combo Ab/Ag with conf	
[ ] *PT - Prothrombin Time	
[ ] *PSA - Prostate Spec Antigen	
[ ] Rheumatoid Factor (RA)	
[ ] *T4 Free	
[ ] *TSH	
[ ] *TSH (HS/3rd Gen) rfx to FrT4	
[ ] UA - Urinalysis-microscopic if ind	
[ ] Uric Acid	
*** PROFILES ***	
[ ] Basic Met Panel - *Glu, BUN, Crea, Na K, Cl, CO2, CA*	
[ ] Comp Met Panel - *Basic Met Panel plus Tot Bili, Alkp, SGOT(AST), SGPT(ALT) Tot Protein, Albumin*	
[ ] Hepatic Function Panel - *Alb, Alkp SGOT, SGPT, T&D Bili, Prot*	
[ ] *Lipid Panel - *Trig, Chol, HDL, LDL(calc) VLDL(Calc), Chol/HDL rfx LDL DIR if ind*	
*** OTHER ***	
[ ] Chlamydia & GC	
[ ] Aptima Chlamydia Aptima	
[ ] GC Aptima	
*** MICROBIOLOGY ***	
CULTURES- SENSI if indicated	
[ ] Aerobic-Source:_____	
[ ] Anaerobic-Source:_____	
[ ] GC-Source:_____	
[ ] Throat Culture	
[ ] *Urine Culture	
[ ] Respiratory Culture	
[ ] Viral(susp virus_____)	
[ ] Herpes (M4 Transport Media)	
*** STOOL STUDIES ***	
[ ] C Diff Toxin/Ag with rfx PCR	
[ ] Stool WBC's (Lactoferrin)	
[ ] Occult Blood	
[ ] Stool C&S (Parapak)	
[ ] Giardia Crypto Ag	

LAV _____ ROYAL _____ GRN _____ UA CUP _____ 7 mL RED _____ GRAY _____ BLUE _____ SST _____
YEL _____ SWAB _____ VIRAL TRANSPORT _____ FRESH STOOL _____ STOOL TRANSPORT _____ FROZEN _____
SPUTUM _____ FIOBT _____ OTHER _____

13635 (10/08/20)

ICD-10 / DIAGNOSIS * *
1. _____
2. _____
3. _____
Person authorized to release Diagnosis information: _____

LABORATORY TEST REQUEST FORM (BACK)

Saddleback Medical Center
24451 Health Center Drive
Laguna Hills, CA 92653
Laboratory: (949)452-3554
Pathology: (949)452-3562

PATHOLOGISTS

Dr. Vivian Mendoza
Dr. Thomas Hirose
Dr. Michelle Fajardo
Dr. Nicolas Gallegos

Calif. License No. 206426
Medicare Provider No. M050603
Federal I.D. No. 95-2585792
CLIA No. 05D0578029

ADVANCE BENEFICIARY NOTICE

Medicare will only pay for services that it determines to be medically reasonable and necessary under section 1862(a)(1) of the Medicare Law. If Medicare determines that a particular test, although it would otherwise be covered, "is not reasonable and necessary", under the Medicare Program Standards, Medicare will deny payment.

Tests ordered by your physician which are likely to be denied for payment should be identified by the + symbol. By signing the separate acknowledgement form you are agreeing to be financially responsible for payment.