Specimen Collection and Test Catalog
Gainesville, Florida

Internal: https://bridge.ufhealth.org/shands-forms/specimen-collection-and-test-catalog/
External: https://professionals.ufhealth.org/labs/

Revised 10-2022
Introduction

The UF Health Medical Laboratories are privileged to serve you and your patients. Our team is composed of nationally recognized Pathologists in a wide variety of specialties and subspecialties along with laboratory staff licensed in the State of Florida. We strive to provide the highest quality patient care using state-of-the-art technology, with quick, accurate and professional attention to each patient case in the accredited laboratory environment. We are open 24 hours a day, seven days a week for routine and emergency laboratory testing.

UF Health Medical Laboratories are licensed and accredited by:
- The Centers for Medicare and Medicaid Services (CMS) under the Statutes of the Clinical Laboratory Improvement Amendments (CLIA). Our CLIA Numbers are:
  - 10D0665884 – UF Health Shands Hospital (Core Lab, Blood Gas Lab, Bone Marrow Transplant Lab, Microbiology, Blood Bank/Transfusion Services, Clinical Laboratory Support Center (CLSC), Cytology, and Surgical Pathology)
  - 10D0997531 – UF Health Medical Lab – Rocky Point (Transplant Histocompatibility, Hematopathology, Cytology, and Histology)
  - 10D0726675 – UF Health Medical Lab – Medical Plaza
  - 10D0726677 – UF Health Shands Hospital – Point of Care (POC)
  - 10D2059622 – UF Health Shands Emergency Center Laboratory – Springhill
  - 10D2116368 – UF Health Shands Emergency Center Laboratory – Kanapaha

- The College of American Pathologists’ Commission on Laboratory Accreditation. Our CAP laboratory accreditation numbers are:
  - 1482301 – UF Health Medical Lab – Shands Hospital
  - 1482314 – UF Health Medical Lab – Medical Plaza
  - 7178590 – UF Health Medical Lab – Rocky Point
  - 8743573 – UF Health Shands Emergency Center Laboratory – Springhill
  - 9472595 – UF Health Shands Emergency Center Laboratory – Kanapaha
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Contact Information and Maps

We are open 24 hours a day, seven days a week for routine and emergency laboratory testing. Contact Customer Service at 352-265-0522 with questions.

Current maps and directions for UF Health Shands Hospital Draw Stations can be located at:

UF Health Medical Lab – Shands Hospital
https://ufhealth.org/uf-health-medical-lab-shands-hospital/maps

UF Health Medical Lab – Medical Plaza (Cancer Center Lab)
https://ufhealth.org/uf-health-medical-lab-medical-plaza/maps

UF Health Medical Lab – Heart & Vascular and Neuromedicine (HVN) Hospitals
https://ufhealth.org/uf-health-medical-lab-hvn/maps

UF Health Medical Lab – Rocky Point
https://ufhealth.org/uf-health-medical-lab-rocky-point/maps
Notice to Physicians

To: Physicians and Clinical Staff, Clinics, and Community Physician Offices

From: Jesse Kresak, MD, Laboratory CLIA Medical Director
      Neil Harris, MD, Emergency Center Laboratories CLIA Medical Director
      Mary Reeves, MBA, Administrative Director of Clinical Laboratories and Operations

Date: July 26, 2022

UF Health Medical Laboratories are committed to providing excellent laboratory services to you and your patients. In an effort to comply with federal laws and regulations, our laboratories adopted a Clinical Laboratory Compliance Program as recommended by the Office of Inspector General (OIG). The OIG further recommends that clinical laboratories send an annual notice to physicians and other providers advising them of the compliance program. This letter serves as the annual notice and provides helpful information regarding the ordering and processing of tests.

LABORATORY ORDER FORMS

In order to provide excellent patient care, we must receive a complete laboratory order. Written laboratory orders must be legible as laboratory clerks transcribe them. The order, whether written or electronic via EPIC system, must contain the following information or the laboratory may be unable to process the specimen properly and in a timely manner. We request your help in providing compliant orders that contain these critical items:

1. Test or evaluation being ordered/requested.
2. Legible Signature of ordering Physician, PA, Resident, or APRN as outlined in CP02.058. All order forms requesting laboratory tests must be authenticated by the author. The method used can either be hand written or an electronic signature. The illegible signature must have a legible printed identity of the signature. Stamp signatures are NOT acceptable. If the signature requirements are not met, the medical necessity for the service requested and billed cannot be substantiated.
3. The Attending name, ID number, and address. PAs, APRNs, and Residents can order without an Attending signature, however the Attending Physician’s name and number are required for billing purposes and must be legible.
4. ICD-10 codes, vital signs, symptoms, or diagnoses that relate directly to the reason the test(s) are being ordered.
5. Patient Medical Record number, if patient has a record in the UF Health system.
6. Patient demographics; patient’s full name, home address, phone number, and date of birth (DOB).
7. Insurance and/or Medicare Information.
8. If the sample was drawn by someone other than Lab staff, the specimen collection information, date and time must be indicated.

For your convenience, for Non-UF Health providers, UF Health Medical Laboratories provides laboratory requisitions pre-printed with your clinic or office information that contain ample space for all patient demographics. These can be requested from Laboratory Administration. If you use any other form to submit laboratory orders, all of the necessary information listed above must be included. Please be advised that if ordering parties do not provide all required diagnosis codes or patient information, your patient’s care may be delayed.

MEDICAL NECESSITY FOR OUTPATIENT TESTING

Medicare will only pay for tests that meet the Medicare coverage criteria and are reasonable and necessary to treat or diagnose an individual patient. The physician is responsible for ordering medically appropriate tests with the corresponding supporting diagnostic or medical necessity information. Please ensure that the test(s) you order meet medical necessity. To shift financial liability to patient when tests are not medically necessary, the Advanced Beneficiary Notice (ABN) must be discussed with and signed by the patient before the service is provided to allow enough time for the patient to make an informed decision about the test(s) ordered.
You can refer to the following web sites for the most current national and local Medicare review policies related to laboratory services:

To search for Lab National Coverage Determinations (NCDs), see Centers for Medicare and Medicaid Services Medicare Coverage Database

To search for Local Coverage Determinations (LCDs) see First Coast Service Options – LCDs

Coding information was moved out of LCDs into Local Coverage Articles (LCAs), which are available via links embedded in the LCDs.

Please note that the OIG takes the position that an individual who knowingly causes a false claim to be submitted may be subject to sanctions or remedies available under civil, criminal, administrative law and/or civil monetary penalties.

ORGAN OR DISEASE RELATED PANELS

Organ or Disease Related Panels should be ordered only if all components are medically necessary.

When a test or some tests within a panel are not medically necessary, only medically necessary tests should be ordered separately.

Do not order full panels and individual components for test names found in those panels for the same specimen draw on a patient, causing duplicate orders of tests on same sample.

ICD-10

You must provide complete diagnosis information for each test you have ordered. Accurate and complete ICD-10 codes are required and necessary for proper billing. Physicians should provide the complete ICD-10 code(s) with 7 digits for the highest level of specificity, as pertinent. If a narrative reason is submitted instead, please provide enough detail so it can be coded to the highest level of specificity for ICD-10 coding.

MEDICARE CLINICAL LABORATORY FEE SCHEDULE (CLFS)

Medicare reimburses for outpatient hospital clinical diagnostic laboratory services based on the Medicare Laboratory Fee Schedule. CMS makes a separate payment under CLFS only when specific criteria are met. The CLFS can be found here. Medicaid reimbursement for laboratory services is equal to or less than the amount of Medicare reimbursement. Surgical Pathology services are paid under the Medicare Physician Fee Schedule (MPFS).

SPECIMEN COLLECTION INFORMATION

A Specimen Collection Manual is available on the UF Health Shands Bridge online. This manual includes information regarding collection requirements for all types of specimens, including tissue and cytology specimens. For non-UF Health physicians, the manual is available at this link.

REFLEX TESTING INFORMATION

Reflex Tests are additional tests performed according to the established laboratory protocols as standard of care. They are indicated when initial results meet predetermined criteria, approved by the laboratory director, necessitating a related test which is medically appropriate. They do not require an additional order from the ordering provider. Reflex tests are billed when performed. See below for the separate list of reflex tests.

For questions or concerns about reflex testing, please contact Customer Service at (352) 265-0412 or the Clinical Consultants listed below.
CLINICAL CONSULTANTS CONTACT INFORMATION

UF Health Shands Clinical Laboratory Medical Directors are available to assist you with laboratory testing questions, including ordering and interpretation:

**Core Laboratory** (Chemistry, Urinalysis, Blood Gas Lab, Hematology, and Coagulation) – Dr. Neil Harris at (352) 594-4717 or Dr. Maximo Marin at (352) 594-4953

**Microbiology** – Dr. Stacy Beal at (352) 594-4952

**Blood Bank** – Dr. Peter Pelletier at (352) 594-0490 or Dr. Faisal Mukhtar at (352) 594-0487

**Transplant (HLA)** – Dr. Steven Goldstein at (352) 627-2223

**Hematopathology** – Dr. Robert Seifert at (352) 627-2039

**Cytology** – Dr. Marino Leon at (352) 627-9260

**Histology** – Dr. Joanna Chaffin at (352) 627-2052

**Surgical Pathology** – Dr. Marie-Rivera at (352) 627-9251

**Immunohistochemistry (IHC)** – Dr. Sara Falzarano at (352) 627-9254

**Point of Care** – Dr. William Winter at (352) 294-5540

Contact Customer Service at (352) 265-0412 with any questions related to reference (Sendouts) laboratory testing.

Thank you for taking the time to review these important topics.
Reflex Tests are additional tests performed according to the established laboratory protocols as standard of care. They are indicated when initial results meet predetermined criteria, approved by laboratory director, necessitating a related test which is medically appropriate. They do not require an additional order from the ordering provider. All reflex tests are billed for. The list below includes reflex tests for UF Health Medical Laboratories. Revised 10/24/2022. For questions about specific referral laboratory reflex policies, please contact Laboratory Customer Service (352) 265-0412.

<table>
<thead>
<tr>
<th>Initial Test</th>
<th>Reflex Criteria</th>
<th>Reflex Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIV Antibody-Antigen Combo</td>
<td>Positive</td>
<td>Supplemental Confirmatory Assay</td>
</tr>
<tr>
<td>HCV Antibody</td>
<td>Positive</td>
<td>HCV Quantitative RNA PCR (If first positive.)</td>
</tr>
<tr>
<td>Hepatitis B Surface Antigen (First Time)</td>
<td>Positive</td>
<td>Hepatitis B Surface Antigen Confirmation</td>
</tr>
<tr>
<td>Hepatitis B Core Total Antibody</td>
<td>Positive</td>
<td>Hepatitis B Core IgM Antibody</td>
</tr>
<tr>
<td>Sickle Cell Screen</td>
<td>Positive</td>
<td>Hemoglobin Electrophoresis</td>
</tr>
<tr>
<td>PFA Platelet Function Assay</td>
<td>Elevated Collagen Epinephrine Closure Time (&gt;190 seconds)</td>
<td>Platelet Function Confirmation using the Collagen/ADP Cartridge</td>
</tr>
<tr>
<td>Urinalysis Screen</td>
<td>Positive for Leukocyte Esterase, Nitrite, or WBC ≥10</td>
<td>Urine Culture</td>
</tr>
<tr>
<td>Urine Drug Screen Test:</td>
<td>Positive for any of the drugs.</td>
<td>Confirmation by liquid chromatography tandem mass spectrometry:</td>
</tr>
<tr>
<td>Amphetamines</td>
<td>(NICU/34/35/95 ONLY)</td>
<td>Amphetamines</td>
</tr>
<tr>
<td>Cocaine</td>
<td></td>
<td>Cocaine</td>
</tr>
<tr>
<td>Cannabinoids</td>
<td></td>
<td>Cannabinoids</td>
</tr>
<tr>
<td>Barbiturates</td>
<td></td>
<td>Barbiturates</td>
</tr>
<tr>
<td>Benzodiazepines</td>
<td></td>
<td>Benzodiazepines</td>
</tr>
<tr>
<td>Oxycodone</td>
<td></td>
<td>Oxycodone</td>
</tr>
<tr>
<td>Methadone</td>
<td></td>
<td>Methadone</td>
</tr>
<tr>
<td>Opiates</td>
<td></td>
<td>Opiates</td>
</tr>
<tr>
<td>Fentanyl</td>
<td></td>
<td>Fentanyl</td>
</tr>
<tr>
<td>Syphilis Screen</td>
<td>Positive</td>
<td>T. pallidum EIA</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Criteria: positive</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Reflex test: RPR</td>
</tr>
<tr>
<td></td>
<td></td>
<td>If RPR positive: RPR titer</td>
</tr>
<tr>
<td></td>
<td></td>
<td>If RPR negative: TPPA</td>
</tr>
<tr>
<td>TSH</td>
<td>Increased TSH/ Free T4</td>
<td>If High: Reflex Free T4 and TPO.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>If Low: Reflex Free T4 and Total T3.</td>
</tr>
</tbody>
</table>
## Point of Care

<table>
<thead>
<tr>
<th>Test</th>
<th>Result</th>
<th>Follow-Up Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rapid Strep A Test (Waived)</td>
<td>Negative</td>
<td>Throat Culture</td>
</tr>
<tr>
<td>WB Total B-HCG (POC) (Non-Waived)</td>
<td>Indeterminant</td>
<td>HCG Quantitative Blood (Core Lab)</td>
</tr>
</tbody>
</table>

## Microbiology

<table>
<thead>
<tr>
<th>Test</th>
<th>Result</th>
<th>Follow-Up Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bacterial Culture</td>
<td>Positive</td>
<td>Identification of pathogens and susceptibility when applicable.</td>
</tr>
<tr>
<td>Cryptococcus Antigen</td>
<td>Positive</td>
<td>Cryptococcus Antigen Titer</td>
</tr>
<tr>
<td>Fungal Culture</td>
<td>Positive</td>
<td>Identification of yeast and fungi and susceptibility on yeast isolates when applicable.</td>
</tr>
<tr>
<td>AFB Culture</td>
<td>Positive</td>
<td>Identification of Mycobacteria and susceptibility when applicable. If acid-fast bacteria or mold/yeast are recovered on bacterial culture, the appropriate AFB or Fungus Culture order will be added for identification and/or susceptibility as applicable.</td>
</tr>
<tr>
<td>C. Diff PCR</td>
<td>Toxin Positive</td>
<td>Supplemental Confirmatory Toxin Test</td>
</tr>
</tbody>
</table>

## Blood Bank

<table>
<thead>
<tr>
<th>Test</th>
<th>Result</th>
<th>Follow-Up Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>All test specimens, excluding Type &amp; Screen specimens</td>
<td>Required per Regulatory Agencies (Historical ABORH is the normal parameter.)</td>
<td>ABO/Rh Confirmation</td>
</tr>
<tr>
<td>ABO/Rh</td>
<td>*Discrepancy (Forward &amp; reverse match is the normal parameter.)</td>
<td>ABO/Rh Resolution</td>
</tr>
<tr>
<td>Type &amp; Screen (ABO, Rh &amp; Antibody Screen)</td>
<td>Antibody Screen – Positive</td>
<td>Any or all the following: Antibody Identification Panel Crossmatch Neutralization Enzyme Treatment Antibody Titer Prewarmed Antibody Panel Selected Cell Antibody Panel Rare Cell Antibody Panel Differential (Triple) Adsorption Autologous Adsorption Chloroquine/AET/DTT Treatment Phenotyping/Genotyping</td>
</tr>
<tr>
<td>-----------------------------------------</td>
<td>---------------------------</td>
<td>--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Additional Packed Cell Units*</td>
<td>*Not Electronic XM Eligible (EXM is the normal parameter.)</td>
<td>ABO/Rh, Antibody Screen, Serologic XM</td>
</tr>
<tr>
<td>On-Demand Blood Products</td>
<td>Electronic Crossmatch Eligible</td>
<td>Electronic Crossmatch</td>
</tr>
<tr>
<td>Direct Antiglobulin Test (DAT)</td>
<td>Positive</td>
<td>Any or all the following: Poly DAT IgG DAT C3 DAT Elution Antibody Identification Panel Antibody Absorption (Warm &amp;/or Differential)</td>
</tr>
<tr>
<td>Rh-Ig Work Up</td>
<td>Rh negative mother or Rh Partial-D mother and Rh positive or Rh Unknown baby.</td>
<td>Mother: Fetal/Maternal Bleed Screen (Rosette Screen) Antibody Identification Panel Kleihauer-Betke Baby: DAT Chloroquine/AET/DTT/Enzyme (Ficin or Papain)</td>
</tr>
<tr>
<td>Transfusion Reaction Investigation</td>
<td>Patient exhibited certain symptoms or adverse reactions when administered blood product.</td>
<td>Any or all the following tests: Clerical &amp; Visual Check Repeat ABORH on Pre- &amp; Post Sample Repeat Antibody Screen on Pre- &amp; Post Sample CBC with Manual Differential Reticulocyte Count Urinalysis Poly DAT IgG DAT C3 DAT Haptoglobin LDH &amp; AST BUN/Creatinine Total &amp; Direct Bilirubin PT, PTT, Fibrinogen, and D-Dimer</td>
</tr>
<tr>
<td>Anatomic Pathology</td>
<td>Surgical Pathology</td>
<td></td>
</tr>
<tr>
<td>-----------------------------------</td>
<td>-------------------------------------------------------------------------------------</td>
<td></td>
</tr>
</tbody>
</table>
| Pathologist review of slides      | Invasive Breast Carcinoma  
*All anatomic sites*                                                                 |
|                                  | IHC or image analysis for ER, PR, Ki67 and Her2neu (88361 image analysis x4 or 88360 manual x4). If Her2 equivocal, FISH testing will be performed (88368) |
|                                  | Breast Ductal Carcinoma in-situ  
*All anatomic sites*                                                              |
|                                  | IHC for biomarkers ER, PR, and Her2neu. If Her2 equivocal, FISH testing will be performed |
| Colon Cancer                     | Endometrial Cancer  
Upper tract urothelial carcinoma  
Ovarian endometrioid adenocarcinoma  
Clear cell adenocarcinoma of uterus  
Small bowel adenocarcinoma  
*All anatomic sites*  |
|                                  | MMR IHC and/or MSI (88342 x4). Molecular testing at pathologist’s discretion*  
Reflex BRAF IHC and/or MLH1 promoter methylation if MLH1/PMS2 loss for colorectal carcinoma  
Reflex MLH1 promoter methylation for MLH1/PMS2 loss in endometrial cancer or ovarian endometrioid and clear cell carcinoma |
|                                  | CNS neoplasms  
Any or all the following:  
Surrogate IHC for biomarkers (IDH1, H3K27M, etc.)  
NGS – platform at pathologist’s discretion  
FISH and/or microarray for 1p/19q co-deletion  
MGMT methylation status  
Methylation profiling  |
|                                  | Melanoma  
*All anatomic sites*  |
|                                  | BRAF IHC and/or PCR (88341 x1)  |
|                                  | Non-small cell carcinoma  |
|                                  | PDL1  |
|                                  | Gastric and/or esophageal cancer  |
|                                  | Her2, PDL1 IHC  
Her2 FISH if IHC is equivocal  
EBER ish  
MMR IHC and/or MSI (88342 x4). Molecular testing at pathologist’s discretion*  
Reflex BRAF IHC and/or MLH1 promoter methylation if MLH1/PMS2 loss for colorectal carcinoma  
NGS  |
|                                  | Endometrioid serous carcinoma  |
|                                  | Her2, PDL1 IHC  
Her2 FISH if IHC is equivocal  |
<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Recommended Testing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lung adeno/non-small cell carcinoma</td>
<td>ALK, EGFR, ROS1, NGS</td>
</tr>
<tr>
<td>Pheochromocytoma and extra-adrenal paraganglioma</td>
<td>Succinate dehydrogenase (SDH)-B immunohistochemistry (send out testing)</td>
</tr>
<tr>
<td>Penile carcinoma</td>
<td>HPV in situ hybridization testing</td>
</tr>
<tr>
<td>Cervical invasive carcinoma</td>
<td>PDL1-CPS scoring</td>
</tr>
<tr>
<td>Sentinel nodes</td>
<td>If negative microscopically with cancer diagnosis at the uterus/cervix, reflex keratin IHC</td>
</tr>
<tr>
<td>Head and neck carcinoma, oropharyngeal</td>
<td>P16 or HPV in situ hybridization testing</td>
</tr>
<tr>
<td>Sarcomas or spindled cell tumors</td>
<td>Any or all the following as necessary for diagnosis/prognosis:</td>
</tr>
<tr>
<td></td>
<td>GatorSeq Sarcoma NGS</td>
</tr>
<tr>
<td></td>
<td>Cytogenetics</td>
</tr>
<tr>
<td></td>
<td>FISH</td>
</tr>
<tr>
<td>Anal squamous cell carcinoma:</td>
<td>PD-L1 IHC</td>
</tr>
<tr>
<td>Gastrointestinal stromal tumors (GIST):</td>
<td>NGS (to include at least KIT, PDGRFA, SDHA, SDHB, SDHC, SDHD, NF, BRAF, KRAS, HRAS, PIK3CA) with reflex to SDHB IHC if &quot;wild-type&quot;</td>
</tr>
</tbody>
</table>

### Cytopathology

<table>
<thead>
<tr>
<th>Test</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pap test</td>
<td>ASCUS, if requested by the clinical team as reflex test.</td>
</tr>
<tr>
<td></td>
<td>HPV</td>
</tr>
<tr>
<td>Fluids cytology</td>
<td>Lymphocytosis, R/O Lymphoma</td>
</tr>
<tr>
<td></td>
<td>Flow cytometry</td>
</tr>
<tr>
<td>Fluids cytology</td>
<td>Lymphocytosis, R/O PTLD</td>
</tr>
<tr>
<td></td>
<td>Epstein Bar Virus, EBER ISH</td>
</tr>
<tr>
<td>Neck FNAs</td>
<td>Squamous cell carcinoma</td>
</tr>
<tr>
<td></td>
<td>HPV ISH</td>
</tr>
<tr>
<td>Thyroid</td>
<td>Indeterminate result:</td>
</tr>
<tr>
<td>----------------------------------</td>
<td>-----------------------</td>
</tr>
<tr>
<td></td>
<td>- FLUS</td>
</tr>
<tr>
<td></td>
<td>- Suspicious for Follicular neoplasm</td>
</tr>
<tr>
<td></td>
<td>- Suspicious for malignancy</td>
</tr>
<tr>
<td></td>
<td>In some these cases, if requested by the clinical team as reflex test.</td>
</tr>
<tr>
<td></td>
<td>ThyroSeq, Molecular testing</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Lung FNAs</th>
<th>Adenocarcinoma</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>- NSCCA, favor adenocarcinoma</td>
</tr>
<tr>
<td></td>
<td>- Non-small cell carcinoma</td>
</tr>
<tr>
<td></td>
<td>NGS, GatorSeq ALK IHC with reflex to FISH ROS1 IHC with reflex to FISH PD-L1</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Lung FNAs</th>
<th>Squamous cell carcinoma</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>PD-L1</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Gastrointestinal FNA</th>
<th>GIST, if requested by the clinical team as reflex test.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>NGS GatorSeq</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Urine cytology</th>
<th>Atypical cells or Suspicious, if requested by the clinical team as reflex test.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Urovysion FISH (88120)</td>
</tr>
</tbody>
</table>

**Hematology/Hematopathology**

<table>
<thead>
<tr>
<th>Peripheral blood smear</th>
<th>Abnormal</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Flow cytometry</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Bone Marrow, blood, body fluid, lymph node or surgical pathology specimen review</th>
<th>Myeloid neoplasm</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>MDS/FISH panel and/or cytogenetic studies and/or targeted molecular studies (e.g., JAK2, FLT3) and/or relevant additional predictive/prognostic immunophenotyping.</td>
</tr>
</tbody>
</table>

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<tr>
<th>AML</th>
<th>AML FISH panel and/or cytogenetic studies and/or next generation sequencing and/or targeted molecular studies and/or relevant additional predictive/prognostic immunophenotyping.</th>
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<th>Myeloproliferative neoplasm</th>
<th>Targeted molecular studies (e.g., JAK2) and/or relevant studies as per Myeloid neoplasm above.</th>
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<th>ALL</th>
<th>FISH and/or cytogenetic studies and/or next generation sequencing studies and/or targeted molecular studies including IgH or TCR gene rearrangement analysis and/or additional predictive/prognostic immunophenotyping.</th>
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<th>Plasma cell neoplasm</th>
<th>Myeloma prognostic panel by FISH and/or cytogenetic studies and or additional molecular studies and/or additional predictive/prognostic immunophenotyping.</th>
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<td>FISH and/or cytogenetic studies and/or targeted molecular studies including MYD88 mutation, IgH or TCR gene rearrangement and/or next generation sequencing studies and/or additional predictive/prognostic immunophenotyping.</td>
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<td>Other hematopoietic neoplasm (e.g., mast cell neoplasm, histiocytic neoplasm)</td>
<td>Appropriate FISH panel and/or cytogenetic studies and/or next generation sequencing and/or targeted molecular studies and/or relevant additional predictive/prognostic immunophenotyping.</td>
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*In the case of tissue specimens, the requirements for reflex testing to complete the diagnosis (special stains, immunohistochemical stains, molecular testing, cytogenetics, etc.) will be determined by the pathologist attending the case. As this determination varies (differential diagnosis) and clinical scenario, among many other confounding factors, the entirety of possible reflex combinations is beyond the scope of this document. The pathologist will act as a consulting physician and subsequent tests and orders for diagnosis will be medically relevant and validated by either FDA approval or internal validation.*
Collection Guidelines

Proper patient preparation, timing of specimen collection, selection of specimen container type including preservatives and anticoagulants, correct sample volume, appropriate sample labeling, specimen transportation, and relevant patient clinical data are critical for successful testing, timely reporting of laboratory results, and proper diagnosis.

Laboratory Order: Orders may be transmitted to the laboratory electronically or in paper format.

Orders should include:
- 2 patient identifiers: Name and either Shands patient Medical Record Number or Date of Birth.
- Ordering provider Name, ID Number, and outpatient clinic location.
- Qualified signature (Ordering Physician, PA, APRN and/or Resident).
- Diagnosis code (ICD-10) for each test ordered.
- Intended specimen Collection date and time.

Patient Preparation
The patient should be instructed regarding the pre-testing requirements prior to arrival at a draw site. These may include fasting, special dietary consumption (e.g., avoidance of high-dose biotin ingestion), or other requirements.

Patient Identification
Each patient must be identified positively by means of two patient identifiers before collecting a specimen for clinical testing. Where available, a Beaker Rover device should be used to positively identify the patient by scanning the patient’s ID band. The patient’s identity should be verified by asking the patient to identify himself or herself whenever it is practical (request patient to state their name and date of birth).

Patient Safety Note: Room number or physical location cannot be used as an identifier.

Registered-Wrist-Banded Patients: Compare two identifiers (full patient name and the Shands facility medical record number) on the identification band to another document such as the order form or specimen collection label to confirm that you have identified the correct patient.

Patient Safety Note: For all inpatients, ED patients, and those outpatients having an operative or invasive procedure, a wrist band is required. If the patient wrist band is not present or is illegible, contact the primary caregiver and have the patient properly identified and wrist band applied before proceeding with specimen collection.

Non-Wrist-Banded Outpatients: Ask the patient their full name and date of birth. Compare two identifiers (full patient name and date of birth) to another document such as the order form or specimen collection label to confirm that you have identified the correct patient. For patients who are young or incoherent, a family member, guardian, nurse or physician may help identify the patient.

Special Kits for Reference Lab Testing: For tests requiring special kits, refer to the kit’s instructions for specimen collection guidelines. For more information about these kits, call the Sendouts Department at 352-594-0481 or 594-0482.
**Specimen Labels**

Each primary specimen container (innermost container that actually holds the biologic specimen) must be labeled at the time of specimen collection in the presence of the patient:

- Patient’s first and last name and a second identifier (DOB or medical record number, account number, or accession number).
- Date and time of collection of specimens. Accurate collection date and time is vital for result review and proper patient care.
- Initials or ID of the person collecting the specimen.
- Exact anatomical site description for specimens such as body fluids and tissue specimens. Slides may be accepted with one identifier so long as the secondary container has two identifiers. Two identifiers are preferred.

Computer generated labels are recommended. If preprinted labels are not available, handwritten patient information (in ink) is acceptable if legible.

**Patient Safety Note:** Every specimen tube or container must be labeled regardless of size. Place label on the container, **NOT on the LID or COVER** to minimize the risk of mis-identification if multiple specimens are being processed.
Specimen Rejection

1. Patient information on the specimen container and the order (electronic or paper order) must match. If discrepancies cannot be resolved, the specimen must be recollected.

2. Routine blood and body fluid specimens that are not labeled properly or do not meet other acceptability guidelines (inadequate specimen, improper collection, handling or transportation), will be rejected. The ordering physician/unit is to be notified with a request to recollect the specimen(s).

3. Corrections on the label or forms may be allowed in certain circumstances (e.g., downtime labels without a collection time). All errors must be corrected by the personnel involved in the collection.

4. In certain rare cases when a specimen cannot be recollected due to either the timing of the specimen collection or the site that the specimen was obtained from (i.e., CSF specimens, tissue specimen from surgery), the laboratory medical director, pathologist or pathology resident, in consultation with the ordering physician may authorize testing after the specimen is properly labeled by the person who made the initial labeling error.

5. Patient Safety and Quality Note: SUF laboratories reserves the right to reject any specimen not meeting safety, labeling, collection, transportation, minimum volume or other requirements as defined in this manual and test catalog.

Examples of Unacceptable and Rejected specimens include:

1. Specimen tube/container with no label.
2. Two or three tubes with one label wrapping all tubes.
3. Unlabeled specimens with loose labels in specimen bag.
4. A container with 2 different patient labels.
5. Tube with the wrong patient test label, but correct patient ID.
6. Specimen transportation requirement not met (i.e., not transported on ice or not protected from light when required).
7. Serum or plasma not separated from cells in timely manner (see EPIC Procedure Catalog for specific requirements).
8. Specimen syringes with needles attached.
9. Quantity of specimen is insufficient (QNS).
10. Unacceptable specimens due to contamination, (line draws, collections above IV Lines, stool in urine, etc.), hemolysis, lipemia, clotting, or other unacceptable issues per test specific guideline.
11. Wrong collection tube.
Specimen Transport

All diagnostic specimens should be submitted in properly labeled closed containers that are inside a sealed biohazard bag.

Care should be given to transport all specimens in a manner to prevent contamination of workers, other patients and the environment.

The hospital pneumatic transport system may be used to transport most specimens within the facility. Follow the current guidelines for the system. Ensure that all specimens are transported in a sealed biohazard bag. If any specimen spills during pneumatic transport, refer to current facility policy and procedure for cleanup and notification of appropriate departments.

Specimens transported by couriers should be triple packaged. The original container must be leak-tight and inserted into a secondary bag with preferably absorbing material to absorb accidental spills. The outer packaging (cooler) must be designated and labeled as biohazardous and secured during transport to prevent movement. All operators of motor vehicles that transport specimens are trained as to the proper transportation rules for the type of hazardous materials they transport.

**Safety Note:** Needles MUST be removed from all specimen collection devices before transporting. Specimens received with intact needles will be rejected.
Blood Collection Tubes or Vials

**Blood Specimen Overview:** Blood is the most frequent body fluid used for analytical testing. The most common samples of laboratory testing are whole blood, serum, or plasma. Refer to each test specific specimen requirements in the online test catalog.

Whole blood specimens are usually collected in lavender (EDTA) and dark green (sodium heparin) tubes with an anticoagulant and are not centrifuged or frozen. The whole blood lavender tube is used for Hematology tests such as complete blood counts (CBCs) and hemoglobin electrophoresis.

Serum is the clear yellowish fluid that is obtained when the blood is allowed to clot and the specimen is separated into its solid and liquid components. Serum obtained from specimens collected in the Yellow/Gold or Red tubes is the specimen of choice for many Chemistry and Microbiology tests.

Plasma is the clear yellowish fluid that is obtained when blood is collected in an anticoagulant tube (e.g., lavender (EDTA) top, light green (lithium heparin) top, or light blue (sodium citrate) top tubes) and the specimen is separated into its solid and liquid components. Plasma contains fibrinogen and other clotting factors that are absent from serum. Plasma obtained from specimens collected in light Green, lavender, and light blue top tubes is the specimen of choice for many chemistry and coagulation tests.

The preferred collection method is venipuncture using a closed vacuum tube collection method or syringe method. Blood should be obtained from a freely flowing venipuncture performed according to current nursing or laboratory venipuncture procedure. Refer to the Specimen Collection Guide (page 31-32) for general guidelines.

1. Tubes should be collected in the recommended order based on the test(s) being collected.
   a. **BLOOD CULTURE** bottles are drawn first (Aerobic (gray/blue bottle cap), Anaerobic (purple bottle cap), Fungal (if ordered) (red and white bottle cap), or Pediatric blood culture bottle (pink bottle cap).
   b. **CLEAR “Non-Additive” Tube.** Note: The RED plastic serum tubes contain a clot activator that may cause interference with coagulation testing. Thus, use the CLEAR Hemogard tube for discard.
   c. **LIGHT BLUE Tubes** (Sodium Citrate Coagulation tubes). Note: In the event that only light blue top tubes are to be collected with a butterfly collection system, a “CLEAR TOP” vacutainer tube must be used first to displace the air in the butterfly set tubing. This is to avoid a short draw fill effect with the blue tube. **It is critical that the blue tube is filled to the proper indicated fill line.**
   d. **RED, GOLD, or RED/BLACK Speckled Serum Tubes** with or without a clot activator or with or without gel.
   e. **GREEN Tube** (Lithium or Sodium Heparin) with or without a plasma gel separator.
   f. **LAVENDER/PURPLE, PINK or PEARL Top EDTA Tubes**
   g. **GRAY Top Glycolytic Inhibitor Tubes** (Sodium Fluoride or Potassium Oxalate)
   h. Other type tubes.

2. All tubes should be inverted gently several times (5-10 times) in order to mix the blood specimen with any anticoagulant.

3. Adequate volume should be collected for the number and types of tests requested. Minimum blood volumes are determined for each test. If insufficient volume is collected, call the laboratory before sending to verbally convey the priority of testing and volume requirements.

4. Label specimens per protocol.

5. Send specimen(s) immediately to the laboratory. If a delay in transporting to the laboratory will occur, the specimen may require additional processing. Review test specific specimen requirements to identify if the specimen requires immediate centrifugation, separation of serum/plasma from the red blood cells, refrigeration, freezing or other special processing.
Blood Collection Safety Notes:

1. Plastic vacutainers and syringes are preferred unless no other options are available.
2. Carefully consider the need for laboratory tests, avoiding unnecessary repetition of tests and the use of standing orders in efforts to minimize unnecessarily large blood draw volumes or tube wastage. Blood losses from phlebotomy, particularly in pediatric patients and those with repeated venipunctures, may cause iatrogenic anemia and increase the need for transfusions.
3. Adverse consequences of excess venipunctures includes: Complications during collection for both the patient and health care worker; Patient risks associated with transfusions; and increased amounts of hazardous/biological waste.
4. Collectors of specimens are responsible to assure that collection supplies such as blood collection tubes and collection devices (e.g. heel lancets, culture swabs, and transport media) are stored according to the manufacturer’s requirements and used before the manufacturer expiration date. For newborn screening collection cards, if the expiration date is not printed on the individual cards, another mechanism, such as serial numbering, may be used for tracking.
5. The basic supply list includes:
      i. Needles gauge 21-23 for general patient use.
      iii. Safety-Lok Blood Collection Sets (Butterfly).
      iv. Capillary Puncture Devices (e.g., Tenderfoot Pediatric Lancets)
   b. Disposable vacutainer needle adapters or syringe and blood transfer device.
   c. Evacuated tubes or filter paper appropriate for test ordered (vacutainers, microtainers, filter paper, etc.)
   d. Disposable single-use tourniquet (latex-free).
   e. Venipuncture site cleansing solution:
      i. Sterile alcohol preps are acceptable for most venipuncture procedures and capillary punctures.
      ii. Non-alcoholic cleanser should be used when collecting ethanol (alcohol) test specimens.
      iii. ChloraPrep Applicator (2% chlorhexidine gluconate (CHG) in 70% isopropyl alcohol) is required when collecting blood cultures.
   f. Disposable gloves.
   g. Gauze 2x2 squares.
   h. Dressing (paper tape, coverlet, corban wraps, etc.).
   i. Waste and sharps containers.
   j. Patient identification labels (Rover device labels.)
   k. Biohazard zip lock specimen transport bag.
Blood Collection Procedures

Percutaneous Venipuncture Procedure:
1. Identify self to patient.
2. Properly identify the patient using two unique identifiers.
3. Verify test(s) ordered and if there were any special preparation requirements (fasting, diet, timed collections, etc.) If yes, verify with the patient or care giver that the special preparation requirements have been met.
   **NOTE:** Phlebotomist should still proceed regardless of fasting, diet, etc.
4. Assemble the necessary collection supplies and vacutainer tubes.
5. Position the patient. Most patients should be seated or laying in a position so the arm is extended and the wrist is lower than the elbow. This should allow comfortable access to the antecubital fossa.
6. Wash hands thoroughly and apply clean gloves.
   **NOTE:** All patient blood specimens are to be treated with “Standard Precautions” as it is frequently impossible to know which specimens might be infectious. Gloves are to be worn when performing a venipuncture.
7. Apply tourniquet to extremity 2 inches proximal to desired site.
8. Select venipuncture site (usually arm veins: Cephalic, Median and Basilic. Refer to figure below). A vein with good circulation will be palpable and should spring back when palpated. Larger veins are generally palpable and not visible. Surface veins may be visible but not palpable. Choose a vein with a large diameter as not to collapse the vein while drawing blood.

![Vein Diagram](image)

9. The Median Cubital Vein is usually the vein of choice. It is the largest and fullest vein and is best anchored by the surrounding tissues of the arm.
10. The Cephalic Vein is the next largest vein and usually the second-best choice.
11. The Basilic Vein is the smaller vein and is not anchored well by the surrounding tissues. If this vein is used, the phlebotomist must ensure that they anchor the vein well by holding the skin taut just below the needle insertion point. This vein is close to the brachial artery so there is a higher risk of hitting an artery. Exercise caution.
   a. Avoid extremities with an A-V shunt or status/post mastectomy.
   b. Avoid areas with extensive scarring.
   c. Avoid sites with hematomas.
   d. Avoid using any site above an IV line.
12. Prep the overlying skin with alcohol using a circular motion starting from the center and moving outward. ChloraPrep may be used if the patient is allergic to alcohol. If the venipuncture site is touched, the site must be cleansed again.
13. Insert the blood collection tube into the holder and onto the needle up to the recessed guideline on the Vacutainer adapter, or prepare the syringe.
14. Unsheathe the needle and position the needle with the bevel up and the shaft parallel to the path of the vein.
15. Hold the patient’s arm using your thumb to draw the skin taught to anchor the vein. Verbally state to the patient that the venipuncture is starting and insert the needle at a 15-30’ angle and a ¼ to ½ inches below the intended entry into the vein.
16. While securely grasping the vacutainer holder with one hand, use the other hand to push the Vacutainer tube onto the needle inside the vacutainer. The stopper of the tube must be adequately punctured. If the venipuncture is successful, blood will start to fill the tube.
17. Remove the vacutainer tubes as they fill. The shut-off valve recovers the point (site where the needle enters the test tube cap, closes immediately), stopping blood flow until the next tube is inserted.
18. Tubes containing additives should be mixed immediately upon being drawn by inverting the tube 5-10 times. Avoid vigorous mixing because it may cause hemolysis and erroneous patient results.
19. To obtain additional specimens, insert the next tube into the holder and repeat steps 7-9. When all tubes are filled, remove last tube from the holder.
20. After all of the tubes are collected, fold a gauze pad over the needle and remove the needle in one quick motion and activate the safety device. Discard the needle and collection device into a sharp’s container.
21. Apply pressure to the phlebotomy site with a gauze pad. Check the patient’s arm to ensure that any bleeding has stopped. Apply a gauze pad secured lightly with tape to the puncture site. Instruct the patient to leave the bandage in place for at least 15 minutes.
22. Label all blood tubes in the patient’s presence. Record the time of draw and the collector’s initials or identification code on each label. Place the labeled specimens into a biohazard bag.
23. Discard gloves and wash your hands.
24. Transport specimens to the laboratory for testing.

**Venipuncture Procedure with Needle and Syringe:**
A syringe and needle set may be used in the venipuncture process instead of the vacutainer holder system outlined in venipuncture procedure.

1. Perform venipuncture. Pull back on plunger or syringe slowly until sufficient volume of sample is achieved.
2. Remove the needle from the patient’s arm and immediately activate the safety feature according to the manufacturer’s instructions and discard into a sharp’s container.
3. Attach the syringe to a blood transfer device (female luer adapter).
4. Insert the Vacutainer tubes into the transfer device. Fill to the desired level. Remove the Vacutainer tube and add the next tube. Continue until all required Vacutainer tubes are filled.

**Venipuncture Safety Notes:**
1. Venipunctures should be performed by persons who have been trained and passed competency testing in phlebotomy.
2. Phlebotomists should only attempt a venipuncture two times. If still unsuccessful, call another phlebotomist to perform the procedure.
3. Patient complications may occur during or immediately after the procedure. Refer to this list on the more common complications and the appropriate response action(s) and care recommended to address or minimize the complication.
   a. **Bruises (Ecchymosis)** – Most commonly caused by a leakage of a small amount of blood around the puncture site. Prevent by keeping the patient arm straight and applying pressure to venipuncture site for 3-5 minutes to allow a platelet plug to form after removing the needle.
   b. **Fainting (Syncope)** – The patient becomes frightened and the body goes through physical stages of increased heart rate, dilated blood vessels, and blood pools in the tissues followed by a slow heart rate. The slower heart rate deprives the brain of blood resulting in fainting. If this occurs, withdraw the needle, lower the patient’s head, and apply a wet towel to patient’s forehead and neck. If the patient does not rapidly recover and is an Outpatient, dial “69”. For Inpatients, call the nurse immediately.
   c. **Hematoma** – Caused by a leakage of a large amount of fluid around the puncture site which can cause the area to swell. This may be caused by the needle going through the vein, the bevel of the needle only partially being present in the vein, or failure to apply adequate pressure at the end of procedure. If a hematoma occurs, withdraw the needle and apply direct pressure on the puncture site.
d. **Seizures/Convulsions** – Caused by the patient’s underlying condition or a reaction to pain or fright caused by the needle. Remove the needle and protect the patient. Keep the patient from hitting his or her head or hurting himself or herself. Activate facility specific medical emergency plan if needed. Dial “69” on the landline for Outpatients and call the nurse for Inpatients.

e. **Vomiting/Choking** – The biggest danger is that the patient may aspirate some vomit. If the patient is sitting, have them lean forward and use an emesis basin or trash can. If the patient is lying down, turn their head to the side and provide an emesis basin.

f. **Infection at Venipuncture Site** – This is rare but can be caused by not using aseptic technique when performing a venipuncture. Instruct the patient to keep a bandage on for at least 15 minutes post puncture.

g. **Pain** – There is always a little pain associated with a venipuncture. Inform the patient that there will be some discomfort and communicate to them when the venipuncture will occur to avoid startled reactions. Allowing the alcohol to dry before puncture will minimize pain.

h. **Reflux of Anticoagulant** – If the last tube is not released from the multi-sample needle sleeve before removing the needle from the arm, it is possible for blood from the collection tube to back flow (reflux) into the patient’s vein. Some patients have been known to have reactions to additives in tubes, especially EDTA. If this happens, make sure to keep the patient’s arm in a downward position. If patient is lying down, raise his head or extend his arm over the edge of the bed.

i. **Nerve Damage** – Excessive or blind probing for a vein can lead to permanent damage of a main nerve. If unable to find vein, begin procedure from the beginning with a new needle. Ask for assistance if still unable to find a vein.

j. **Inadvertent Arterial Puncture** – If an artery is punctured, the blood will be bright red in color as compared to the dark red color of venous blood. If this occurs, apply direct pressure to the puncture site for a minimum of 5 minutes.

k. **Petechiae** – Blood which escapes into the epithelium will cause small, non-raised red spots on the patient’s skin. This may usually indicate a coagulation problem that may be due to defective platelets, defective von Willebrand factor, or defective capillary walls. Petechiae are common in patients with leukemia or patients undergoing chemotherapy. The phlebotomist should be alert to the possibility of prolonged bleeding in the patient.

l. **Edema** – Caused by an abnormal accumulation of fluid in the intercellular spaces of the body resulting in swelling. Edema is most commonly caused by IV infiltrations (the release of IV fluid or blood into the interstitium). Do not use the edematous arm for phlebotomy to prevent specimen contamination from tissue or IV fluid.

m. **Obesity** – Veins may be deep and hard to palpate. Consider the hand or forearm as an alternative venipuncture site. Ask the patient where the best site to obtain blood is located (many times the patient knows from previous experiences).

n. **Intravenous Therapy** – Venipunctures should never be performed above an IV site. Perform procedure on the other arm. If both arms are unavailable, consult with the nurse in charge of the patient for assistance. One alternative is to have the nurse turn the IV fluid off for 2 to 3 minutes prior to antecubital fossa phlebotomy by the phlebotomist, or if the nurse can draw through the indwelling IV line (nurses must be aware that IV fluid must be cleared from the indwelling line before a patient sample is obtained; clear the line by drawing into a discard/waste tube or syringe), or to perform the venipuncture below the IV site. In extreme circumstances, obtain permission from the clinical service (nurse contacts the doctor) for a venipuncture of the ankle or the foot.

o. **Veins Damaged by Burns, Scars or Occluded** – These veins are very sensitive and tend to have limited blood flow or may collapse and should not be used.

p. **Post Mastectomy** – Surgeons state that it is permissible to draw from the arm on the mastectomy side after 6 months to 1 year without danger of lymphostasis (a build-up of lymphatic fluid in the lymph glands). If the patient insists that the physician has told them not to have blood drawn on that side, honor the patient’s request.

q. **Allergies to Antiseptics and/or Adhesives** – Some patients may be allergic to alcohol, iodine, band aids or tape. Use an approved antimicrobial soap to cleanse skin. Paper tape or Coban wrap (Outpatient only; not to be used on Inpatients) may be used to bandage the site.
r. **Collapsed Veins** – Using a vacuum tube on a small delicate vein or pulling back on the plunger of a syringe too quickly may cause a vein to collapse. Consider the use of a smaller vacuum tube, a smaller syringe, a butterfly, or consider use of a smaller volume draw tube to enable a successful venipuncture.

s. **Thrombosis** – Blood clots at the site of the puncture can reside in blood vessels and can partially block a vein or artery. An embolus results when a thrombus fragment breaks off and moves through the body. Patients may request to have blood drawn from a certain arm if they are prone to develop clots in a certain area.

**Arterial Punctures**

Some tests require arterial blood specimens. Arterial punctures should only be performed by qualified experienced personnel. Specimens collected in this fashion are collected by non-laboratory personnel such as Nursing Staff, Anesthesiologists, Physicians, and Respiratory Therapists. Generally, arterial specimens are performed on critically ill patients, patients during surgery, and patients having special invasive procedures.

Refer to the Shands Core Policy on Arterial Punctures for guidelines: https://bridge.ufhealth.org/policies/arterial-blood-puncture-adults-pediatrics/

**Line Collections**

Specimens collected in this fashion are collected by non-laboratory personnel such as Nursing Staff, Anesthesiologists, Physicians, and Respiratory Therapists.

**NOTE**: Collection of blood for coagulation testing through intravenous lines that have been previously flushed with heparin should be avoided. If the blood must be drawn through an indwelling catheter, possible heparin contamination and specimen dilution should be considered. When obtaining specimens from indwelling lines that may contain heparin, the line should be flushed with 5 mL of saline and the first 5 mL of blood or 6-times the line volume (dead space volume of the catheter) should be drawn off and discarded before the tube is filled. For those samples collected from a normal saline lock (capped off venous port) twice the dead space volume of the catheter and extension set should be discarded.

Refer to the Shands Core Policy on the Handling of Peripheral or Central Line IV’s for guidelines: https://bridge.ufhealth.org/policies/handling-of-peripheral-or-central-line-ivs-by-trained-personnel/

**Capillary Punctures**

Capillary punctures may be used for obtaining specimens from infants or adults where venipuncture is difficult. Specimens from infants under the age of 6 months are usually collected by heel stick. Patients over the age of 6 months should have capillary puncture procedures done by fingerstick. Capillary specimens may be collected in microtainers which are color coded similar to the vacutainer tubes and sent to the laboratory for testing. The recommended order of collection for microtainer specimens:

1. Capillary blood gases
2. Slides/smears
3. Lavender/purple (EDTA)
4. Green (Lithium or Sodium Heparin)
5. Red or Gold/SST (Serum Microtainers)

**NOTE**: Capillary punctures are not suitable for blood culture testing and coagulation tests. Capillary specimens may be collected on filter paper and sent to the lab for testing (newborn screening or lead screens). Capillary specimens may be used immediately for point-of-care testing.
Capillary Puncture – Heel Stick

1. Position the infant with the head slightly elevated.
2. Warm the heel from which blood is to be obtained. A commercial heel warmer may be used.
3. Cleanse the heel with an alcohol prep, then dry with a sterile 2x2 gauze as alcohol can influence test results and cause pain if not removed.
4. Using a sterile lancet, puncture the most medial or lateral portion of the plantar surface of the heel, medial to a line drawn posteriorly from the mid great toe to the heel.
5. Puncture no deeper than 2.4mm (approximately 0.1 inches).
6. Punctures to the posterior curvature of the heel can cause damage to the bones.
7. Previous puncture sites should be avoided. Avoid bruising the infant’s heel when obtaining blood.
8. Wipe away the first drop of blood with a sterile 2x2 gauze.
9. Allow another large drop of blood to form. Lightly touch the microtainer capillary collection device (or filter paper) to the LARGE drop of blood.
10. Collect drops of blood into the collection device by gently massaging the heel. Avoid excessive pressure that may squeeze tissue fluid into the drop of blood. Fill the microtainer tube(s) as needed.
11. Cap, rotate, and invert the microtainer to mix the blood collected.
12. When finished, clean the site and apply pressure with clean gauze to stop the bleeding. Apply an adhesive bandage.
13. Label all specimens per accepted guidelines.
14. Place labeled specimens in a biohazard bag and deliver to the laboratory as soon as possible.

**NOTE:** The darkened areas (see picture below) illustrate the acceptable areas for the skin puncture. The side of the little toe is the primary area of choice.
**Capillary Puncture – Finger Stick**

1. Position the patient so that the hand is easily accessible.
2. Cleanse the fingertip of the 3rd (middle) or 4th (ring) finger with an alcohol prep pad.
3. Allow the finger to dry or wipe dry with a sterile 2x2 gauze.
4. Using a sterile lancet, puncture the fingertip in the fleshy part of the finger, slightly to the side of the center and across (perpendicular to) the grooves of the fingertip. This enables the blood to form as a drop on the fingertip.

5. If the puncture is parallel to the lines of the fingerprint, the blood will not form as a drop but will run down the finger making collection difficult.
6. Wipe away the first drop of blood with a sterile 2x2 gauze.
7. Allow another large drop of blood to form. LIGHTLY touch the microtainer capillary collection device (or filter paper) to the LARGE drop of blood. Collect drops of blood into the collection device by gently massaging the finger.
8. Avoid excessive pressure that may squeeze tissue fluid into the drop of blood. Fill the microtainer tube(s) as needed.
9. Cap, rotate, and invert the microtainer to mix the blood collected.
10. When finished, clean the site and apply pressure with a clean gauze to stop the bleeding. Apply an adhesive bandage.
11. Label all specimens per accepted guidelines.
12. Place labeled specimens in zip lock bag and deliver to the laboratory as soon as possible.

**Newborn Screening Specimen Collection:**

1. Allow the blood to soak through and completely fill the pre-printed circle on the filter paper.
2. Filter paper should touch only the blood and not the heel or finger.
3. Apply only ONE drop of blood per circle. Do not add blood to a circle already filled or partially filled with blood.
4. Allow blood to the printed side of the filter paper.
5. Make certain that the blood completely saturates all five (5) circles and is visible from both sides.
6. If the blood flow is diminished, repeat the capillary PUNCTURE to complete the collection.
7. Allow filter paper to air dry for two (2) hours at room temperature. Avoid placing the sample on hot surfaces such as Bili lights or monitors.
8. Forward the completed and dry collections to the laboratory as soon as possible.

For more information, visit the Florida Newborn Screening Program at [https://floridanewbornscreening.com/medical-professionals/how-to-collect-mail/](https://floridanewbornscreening.com/medical-professionals/how-to-collect-mail/).
**Blood Culture Collection**

**Blood Culture Overview:** The detection of microorganisms in a patient's blood has diagnostic and prognostic importance. When bacteria multiply at a rate that exceeds the capacity of the reticuloendothelial system to remove them, bacteremia results. Bacteria enter the blood from extravascular sites via lymphatic vessels. Blood cultures are essential in the diagnosis and treatment of the etiologic agent of sepsis or other bacterial processes. Bacterial sepsis constitutes one of the most serious infectious diseases and therefore, the expeditious detection and identification of blood-borne bacterial pathogens is one of the most important functions of the diagnostic microbiology laboratory. Guidelines to achieve this end are described in this procedure.

1. Blood cultures can be obtained by using the venipuncture method. Select the venipuncture site.
2. Optimal skin preparation includes cleansing with ChloraPrep. The venipuncture site should not be palpated after disinfection unless a sterile glove is used. If you must relocate the vein, apply ChloraPrep to one's fingertip and let it dry before touching the puncture site.
3. Remove the cap from culture bottles and clean with ChloraPrep. Allow this to dry for 3 minutes or longer.
4. Perform venipuncture using a sterile syringe and needle. Pull back on the plunger or syringe slowly until sufficient volume of the sample is achieved. To achieve best results, collect 20 mL of blood for an adult (Minimum 6 mL) and 6 mL of blood for a pediatric patient (minimum 4 mL). Sterile butterfly sets may also be used with a blood transfer device. Fill the blood culture bottles directly.
5. Remove the needle from patient’s arm and immediately activate the safety feature according to manufacturer’s instructions and discard the needle into a sharp’s container.
6. Attach the syringe to a sterile blood transfer device (female luer adapter).
7. Add 8 to 10 mL of blood into the blue/gray aerobic culture bottle. (Minimum 3 mL)
8. Add 8 to 10 mL of blood into the purple anaerobic lytic bottle. (Minimum 3 mL)
   a. Use a pediatric bottle if necessary to replace the blue/gray aerobic bottle. Pediatric bottles are acceptable with 1-3 mL of blood per bottle. Pediatric bottles can be used for adults that are difficult sticks.
9. Label each blood culture bottle per policy.
   a. Label should include the complete patient name, medical record number, and date and time of collection, location of venipuncture (i.e., L arm, R hand, etc.) and initials of the person collecting the specimen.
   b. Labels should not cover the bottom of the bottle.
   c. Labels should not cover or touch the bar code on the bottle’s label.
   d. Labels should run the length of the bottle (from top to bottom).
   e. The patient name should be at the top, and the label should not cover the bar code on the bottle.
10. Transport blood cultures to Microbiology within an hour of collection time. Blood culture bottles should not be refrigerated.

Refer to the Microbiology section or EPIC Procedure Catalog for more information.
Urine Collection Procedures

Random Urine Collection: Urinalysis, urine chemistry tests, drug screens, and culture and sensitivities are some tests that may be ordered. Refer to the EPIC Procedure Catalog for test specific specimen requirements.

Clean Catch Method:
1. Patient is provided with a sterile collection cup and two towelettes.
2. Upon entering the bathroom, the patient should wash hands with soap and water.
3. Remove the lid from cup; taking care NOT to touch the inside of the lid or cup, and place lid flat side down onto the counter.
4. **FEMALES**: Wash the area around the labia and around the vagina with the towelette. Wash genital area from front to back. Separate the genital folds (also known as lips or labia) with your hand. Gently wipe inside the folds with a second towelette.
5. **MALES**: Wash the area around the tip of the penis including the glands. If uncircumcised, retract the foreskin, if present, and clean the head of the penis (the glans) thoroughly with a packaged towelette.
6. For both males and females, **DO NOT USE SOAP**.
7. The patient should begin to urinate into the toilet. After the first part of the urine has gone in the toilet, place the cup under the stream. Catch 50 mL of urine. Remove the cup from the stream and finish urinating in the toilet.
8. Put the lid securely on the cup and wash hands.
9. Give sample to the health care provider.

Pediatric Patients or Infants:
1. Thoroughly wash the area around the urethra using towelettes.
   - **FEMALES**: Clean from the front to the back on a female infant.
   - **MALES**: Clean from the tip of the penis down on a male infant.
2. A Special Urine Collection bag will be provided. It is a plastic bag with a sticky strip on one end. It is made to fit over the infant's genital area. Open this bag and place it on the infant.
   - **FEMALES**: Place the bag over the labia.
   - **MALES**: Place the entire penis in the bag and attach the adhesive to the skin.
   **NOTE**: For small infants, the entire perineal area would be placed in the bag. However, for larger pediatric patients who are developmentally delayed and not potty trained, the bag can just be placed around the penis.
3. Put a diaper securely over the bag. For active infants, this procedure may take a couple of attempts; lively infants can displace the bag.
4. Check your baby often and remove the bag after the infant has urinated into it.
5. Drain the urine into a sterile container and give it to the health care provider. Do not touch the inside of the cup or lid.

Urine Specimen Collection and Transport:
Urine needs to be collected and transported in the appropriate urine preservative tubes. Collect in sterile urine preservative tubes via a transfer straw as illustrated in the picture below.

**Instructions (See pictures below)**: To suck urine into the straw, compress the bulb and place the tip into the urine. Release the bulb to draw urine into the straw. Expel the urine into the tube by compressing the bulb.

**Collect the appropriate urine tubes**:
1. Microbiology Culture and Susceptibility (C&S): **Gray top tube**. Shake vigorously. Store at room temperature.
2. Urinalysis (UA) Tube: **Red/Yellow top (speckled top) tube**. Mix by inverting 8–10 times. Store at room temperature.
3. For all other urine tests including Chemistry and Cytology: **Clear/Red top tube**. Store in refrigerator.
Urine Collection from a Foley Catheter:

NOTE: Each test must have the appropriate tube type as the type of preservative or lack of preservative is required for each test as listed above, and cannot be interchanged (i.e., a Culture cannot be performed from the UA tube, etc.).

Timed Urine Collection

Timed urine collections may be for a two (2), twelve (12), or twenty-four (24) hour time period. The normal volume of urine collected over a 24-hour period ranges from 800-2000 mL. The laboratory supplies the containers to be used for the collections with the appropriate preservative added. The requesting location should send a message or a request slip to the laboratory with the name of the patient, the patient location, and the test(s) requested so that the 24-hour urine container can be prepared.

Collection Container: Obtain a urine jug from a Shands clinic or Outpatient Lab.

Patient Collection Instructions for a 24-hour (Timed) Urine:
1. When you arise in the morning, empty your bladder into the toilet.
2. Write this date and time on the collection container label along with your full name and date of birth.
3. Collect urine, day and night, for the next 24 hours. Add all urine collected into the 24-hour container.
4. Urine may be collected in a separate CLEAN container and carefully poured into the 24-hour urine collection jug.
5. The next morning (24 hours later) collect the last urine specimen (the first voided urine). Write the finish (end) time and date of this last collection on the container label.
6. Deliver the 24-hour specimen jug and test order to one of the Shands laboratory draw stations.

Timed Urine Collection Notes:
1. IMPORTANT: Keep the urine container in the refrigerator or on ice (e.g., home collection) throughout the collection time period.
2. Collect ALL urine during the 24-hour period, or the specimen will need to be recollected. (Volume of urine is measured for testing).
3. Some 24-hour urine tests also require a blood specimen such as creatinine clearance and urea clearance. Please check with the laboratory when you drop off your urine collection to see if a blood specimen is required.
4. Follow the same guidelines for a 2-hour or 12-hour urine collection. The label and test order must match the time period for what is collected.
5. If an aliquot of urine is lost during the collection period, note this variance on the collection label. If the volume lost is less than 10% of the final volume (by the patient’s best estimate), the test may be continued. If the volume lost is greater than 10%, the entire specimen may have to be recollected.
Body Fluid Specimens

Diagnostic testing may be performed on various fluids that are present in the body. Body fluids are usually collected by the physician. Each body fluid submitted for testing should indicate the source of the fluid on the order and the specimen label. Body fluid specimens and tests may include:

1. Amniotic Fluid
2. Ascitic Fluid
3. Bile Fluid
4. Cerebral Spinal Fluid (CSF)
5. Pericardial Fluid
6. Peritoneal Fluid
7. Pleural Fluid
8. Synovial Fluid
9. Thoracentesis Fluid

General collection guidelines to follow include:
1. Lavender/purple (EDTA) top tubes for cell counts/differentials.
2. Clear/no additive tubes for Chemistry tests.
3. Sterile containers for Microbiology Cultures.
4. Sterile containers or clear/no additive tubes for Cytology and Surgical Pathology.
5. Refer to the EPIC Procedure Catalog for specific specimen collection requirements.

SAFETY NOTES:
1. **CSF SPECIMENS**: If Creutzfeldt-Jacob Disease (CJD) or any other Prion Disease is suspected, contact the laboratory before sending the specimen. For more information regarding CJD, refer to the Shands Hospital Core Policy at [https://bridge.ufhealth.org/policies/creutzfeldt-jakob-disease-cjd-or-other-prion-diseases/](https://bridge.ufhealth.org/policies/creutzfeldt-jakob-disease-cjd-or-other-prion-diseases/)
2. Needles must be removed from the specimen collection syringes prior to submission. The laboratory will reject any specimen containers received if the needle is still attached.

Bone Marrow Specimens

Bone marrow is collected by a clinician or pathologist in an aseptic environment. Specimens may be submitted for microbiology, cytology, flow cytometry and hematological evaluations. Specimens may consist of:
- Core Biopsy
- Aspirate
- Glass Slide Smears

Refer to the Hematopathology Section or the EPIC Procedure Catalog for specific Bone Marrow collection requirements.

Stool and Sputum Specimens

Refer to the Microbiology section or the EPIC Procedure Catalog for more specific stool or sputum collection requirements.

Tissue Specimens

Refer to the Surgical Pathology, Microbiology, or Cytology sections or the EPIC Procedure Catalog for more specific tissue collection requirements.
## Specimen Collection Guide

General guidelines are outlined in this chart. Refer to the EPIC Procedure Catalog for test specific collection and processing requirements.

<table>
<thead>
<tr>
<th>Laboratory</th>
<th>Test List</th>
<th>Tube Type and Additive</th>
<th>Standard Tube Minimum Volume Mixing Requirement</th>
<th>Other Collection Options and Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>CORE LAB</strong>&lt;br&gt;Chemistry&lt;br&gt;Hematology&lt;br&gt;Coagulation&lt;br&gt;Urinalysis&lt;br&gt;Molecular&lt;br&gt;352-265-0412</td>
<td>Comprehensive and Basic Metabolic Panels, Renal Panel, Hepatic Panel, Cardiac Markers, Lipid Panel, Therapeutic Drug Levels, Alpha-1-Antitrypsin, etc.</td>
<td>Light Green PST Gel and Lithium Heparin for Plasma Separation</td>
<td>Min. Vol. 2 mL Mix 8-10 X</td>
<td>Capillary Specimen&lt;br&gt;Min. Vol. 400 µL Mix 8-10 X Light protected for tests with Bilirubin.</td>
</tr>
<tr>
<td><strong>Customer Service</strong>&lt;br&gt;352-265-0412</td>
<td>Vitamin D 25-Hydroxy, Lithium, PTH, MPA, ASO, Folate, AFP, Protein Electrophoresis, Kappa/Lambda Light Chains, Hepatitis and HIV Testing, Procalcitonin, etc.</td>
<td>Serum Separator Tube (Gold) Clot Activator with Polymer Gel for Serum Separation</td>
<td>Min. Vol. 2 mL Mix 5 X</td>
<td>Capillary Specimen&lt;br&gt;Min. Vol. 400 µL Mix 5 X Light protected for tests with Bilirubin.</td>
</tr>
<tr>
<td><strong>Sendouts</strong>&lt;br&gt;352-594-0481&lt;br&gt;352-594-0482</td>
<td>Trace Elements (Copper, Zinc, Lead, etc.)</td>
<td>Royal Blue Spray Coated K$_2$EDTA</td>
<td>Min. Vol. 4 mL Mix 8-10 X</td>
<td>TIME SENSITIVE. Maintain the collected sample at 2°C to 8°C and transport to the lab within 24 hours.</td>
</tr>
<tr>
<td><strong>Medical Plaza</strong>&lt;br&gt;Cancer Center Lab&lt;br&gt;352-265-0722</td>
<td>Quantiferon-TB Gold Plus (QFT)</td>
<td>Greiner Dark Green Lithium Heparin</td>
<td>Min. Vol. 5 mL Mix 8-10 X</td>
<td>Capillary Specimen&lt;br&gt;Min. Vol. 400 µL Mix 8-10 X</td>
</tr>
<tr>
<td></td>
<td>Complete Blood Counts (CBCs), Reticulocyte Counts, Erythrocyte Sedimentation Rate (ESR), Hemoglobin A1C, Hemoglobin Electrophoresis, Tacrolimus, Cyclosporin, Sirolimus, Ammonia (ON ICE), CMV PCR, EBV PCR, etc.</td>
<td>Lavender/Purple Spray Coated K$_2$EDTA</td>
<td>Min. Vol. 2 mL Mix 8-10 X</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Random or Timed Glucose, Oral Glucose Tolerance Test (OGTT), etc.</td>
<td>Gray Sodium Fluoride Potassium Oxalate</td>
<td>Min. Vol. 2 mL Mix 8-10 X</td>
<td></td>
</tr>
</tbody>
</table>
General guidelines are outlined in this chart. Refer to the EPIC Procedure Catalog for test specific collection and processing requirements.

<table>
<thead>
<tr>
<th>Laboratory</th>
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</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Crystal Analysis (Synovial Fluid), Platelet Mapping, Special Sendout Tests (Cytogenetics), etc.</td>
<td>Dark Green Sodium Heparin</td>
<td>Min. Vol. 3 mL Mix 8-10 X</td>
<td>1.8 mL Tube (Pediatric)</td>
</tr>
<tr>
<td></td>
<td>PT/INR, PTT, Fibrinogen, Unfractionated Heparin, Low Molecular Weight Heparin (LMWH), Factor Activity Tests, Platelet Function Assay (PFA-100), TEG, Rapid TEG, Platelet Aggregation, etc.</td>
<td>Light Blue Sodium Citrate</td>
<td>2.7 mL Tube Draw to FILL LINE. Mix 3-4 X</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Platelet Function Testing for: Clopidogrel (Plavix) and ASA (Aspirin)</td>
<td>Greiner Light Blue Sodium Citrate</td>
<td>Obtain tube from Core Lab. Draw to FILL LINE. Mix 3-4 X</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Urine Chemistry Tests and Urine Drug Screens</td>
<td>Clear/Red No Additive</td>
<td>Min. Vol. 2 mL</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Random Urine for Urinalysis with Microscopy, Specific Gravity, pH, NephroCheck, etc.</td>
<td>Urinalysis Preservative Tube or Sterile Cup</td>
<td>Fill to line. Mix 5-8 X 72 Hours Room Temp.</td>
<td>1 Hour Room Temp. 24 Hours Refrigerated</td>
</tr>
<tr>
<td></td>
<td>Urine for Culture and Sensitivity</td>
<td>Culture and Sensitivity (C&amp;S) Preservative Tube</td>
<td>Fill tube. Shake tube vigorously to mix. 48 Hours Room Temp.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Timed Urine Tests (2, 12, or 24-Hour)</td>
<td>Urine Jug</td>
<td>Keep refrigerated during the entire collection.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Sweat Chloride</td>
<td>Special Collection Requirements</td>
<td>Contact Core Lab for more information.</td>
<td></td>
</tr>
</tbody>
</table>
|            | Cerebrospinal Fluid (CSF) | Sterile Containers (LABEL EACH TUBE) | CSF Tube 1: Chemistry Tests  
CSF Tube 2: PCR (Must be sterile)  
CSF Tube 3: Cell Count and Differential  
CSF Tube 4: Microbiology |
# General guidelines are outlined in this chart.
Refer to the EPIC Procedure Catalog for test specific collection and processing requirements.

<table>
<thead>
<tr>
<th>Laboratory</th>
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<th>Tube Type and Additive</th>
<th>Standard Tube Minimum Volume Mixing Requirement</th>
<th>Other Collection Options and Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Body Fluids</td>
<td>Basic test list. Not all inclusive.</td>
<td>Lavender/Purple Spray Coated K$_2$EDTA</td>
<td>Cell Count and Differential 1-3 mL</td>
<td></td>
</tr>
<tr>
<td>Capillary Puncture Blood Collections</td>
<td></td>
<td>Clear/Red No Additive</td>
<td>Chemistry Tests 1-3 mL</td>
<td>Microbiology Cultures, Cytology, other, etc.</td>
</tr>
<tr>
<td>Capillary Puncture Blood Collections</td>
<td>Lead Test Card</td>
<td>Filter Paper (Cards)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Capillary Puncture Blood Collections</td>
<td>Newborn Screening Specimen Card</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Blood Gas Lab 352-265-0199</td>
<td>Arterial, Venous, or Cord Whole Blood: Blood Gas (pH, PCO$_2$, PO$_2$), Sodium, Potassium, Glucose, Ionized Calcium, Lactic Acid, Hemoglobin, Hematocrit, Methemoglobin, Carboxyhemoglobin, etc.</td>
<td>Heparinized Blood Gas Syringe (Arterial or Venous)</td>
<td>1 mL in a heparinized blood gas syringe or 0.5 mL in a 1 mL tuberculin syringe (Pediatric).</td>
<td>Keep syringe capped (Anaerobic).</td>
</tr>
<tr>
<td>Blood Gas Lab 352-265-0199</td>
<td>Ionized Calcium</td>
<td>Serum Separator Tube (Gold)</td>
<td>Fill tube, Mix 5 X</td>
<td></td>
</tr>
<tr>
<td>Blood Gas Lab 352-265-0199</td>
<td></td>
<td></td>
<td>For Outpatient Clinics, centrifuge tube and DELIVER ON ICE immediately to the Core Lab.</td>
<td></td>
</tr>
<tr>
<td>Laboratory</td>
<td>Test List</td>
<td>Tube Type and Additive</td>
<td>Standard Tube Minimum Volume Mixing Requirement</td>
<td>Other Collection Options and Comments</td>
</tr>
<tr>
<td>-------------------</td>
<td>----------------------------------------------------------------------------</td>
<td>--------------------------------</td>
<td>-----------------------------------------------</td>
<td>------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Hemoccult</td>
<td>Stool on Hemoccult Card</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gastroccult</td>
<td>Gastric Aspirate on Gastroccult Card</td>
<td></td>
<td></td>
<td>Apply aspirate to the card and send to the Core Lab immediately.</td>
</tr>
<tr>
<td>Blood Bank</td>
<td>Type and Cross, Type and Screen, Antibody Screen, etc.</td>
<td>Pink Spray Coated K&lt;sub&gt;2&lt;/sub&gt;EDTA</td>
<td>Min. Vol. 2 mL Mix 8-10 X</td>
<td>Samples must be accompanied with a Transfusion Services Time Out Verification Form.</td>
</tr>
<tr>
<td>Microbiology</td>
<td>SARS-CoV-2 PCR, Respiratory Panel PCR</td>
<td>Viral Transport Media</td>
<td></td>
<td>Respiratory PCR: NP Swabs, NP Wash, NP Aspirates, and BAL.</td>
</tr>
<tr>
<td>Transplant</td>
<td>HLA Typing (Specimens from Donor and Patient)</td>
<td>Yellow (Glass) ACD Solution A</td>
<td>Min. Vol. 5 mL Mix 8 X</td>
<td>Both donor and recipient blood is required for HLA Typing.</td>
</tr>
<tr>
<td></td>
<td>Collect 3 ACD tubes each.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hematopathology</td>
<td>Immunophenotyping by Flow Cytometry</td>
<td>Lavender/Purple Spray Coated K&lt;sub&gt;2&lt;/sub&gt;EDTA</td>
<td>Min. Vol. 2 mL Mix 8-10 X</td>
<td></td>
</tr>
<tr>
<td>Point of Care</td>
<td>Blood Gas, PT/INR, ACT, Lactate, Creatinine, Hematocrit, Basic Metabolic w/</td>
<td></td>
<td></td>
<td>FOR APPROVED POC LOCATIONS ONLY. Refer to standard operating procedures for collection requirements for each test system.</td>
</tr>
<tr>
<td>(POC) Testing</td>
<td>Ionized Calcium, Glucose, etc.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Test</td>
<td>Container</td>
<td>Specimen</td>
<td>Collection Instructions</td>
<td>Stability with Ice</td>
</tr>
<tr>
<td>-----------------------------------</td>
<td>----------------------------------</td>
<td>-------------------</td>
<td>--------------------------------------------------------------</td>
<td>--------------------</td>
</tr>
<tr>
<td>Arterial Blood Gas (Inpatient)</td>
<td>Heparinized Syringe</td>
<td>Whole Blood, Cord Blood</td>
<td>Deliver to the Core Lab immediately on ice.</td>
<td>1 hour</td>
</tr>
<tr>
<td>Venous Blood Gas (Inpatient)</td>
<td>Heparinized Syringe</td>
<td>Whole Blood, Cord Blood</td>
<td>Deliver to the Core Lab immediately on ice.</td>
<td>1 hour</td>
</tr>
<tr>
<td>Venous Blood Gas (Outpatient)</td>
<td>Dark Green Sodium Heparin Tube</td>
<td>Whole Blood</td>
<td>Deliver to the Core Lab immediately on ice.</td>
<td>2 hours</td>
</tr>
<tr>
<td>Lactic Acid, Na, K, ICa, and Glucose (Inpatient)</td>
<td>Heparinized Syringe</td>
<td>Whole Blood</td>
<td>Deliver to the Core Lab immediately on ice.</td>
<td>1 hour</td>
</tr>
<tr>
<td>pH Body Fluid (Inpatient)</td>
<td>Heparinized Syringe</td>
<td>Body Fluid</td>
<td>Deliver to the Core Lab immediately on ice.</td>
<td>1 hour</td>
</tr>
<tr>
<td>TEG or TEG with Heparinase</td>
<td>Light Blue Sodium Citrate Tube</td>
<td>Whole Blood</td>
<td>Fill tube. Specimen is stable at room temperature for 2 hours.</td>
<td>N/A</td>
</tr>
<tr>
<td>Rapid TEG and Functional Fibrinogen</td>
<td>Light Blue Sodium Citrate Tube</td>
<td>Whole Blood</td>
<td>Fill tube. Specimen is stable at room temperature for 2 hours.</td>
<td>N/A</td>
</tr>
<tr>
<td>Platelet Mapping</td>
<td>Dark Green Sodium Heparin Tube</td>
<td>Whole Blood</td>
<td>Fill tube. Specimen is stable at room temperature for 2 hours.</td>
<td>N/A</td>
</tr>
<tr>
<td>Ionized Calcium (Outpatient)</td>
<td>SST (Serum Separator Tube)</td>
<td>Serum</td>
<td>Centrifuge within 1 hour of collection and deliver to the Core Lab.</td>
<td>7 days</td>
</tr>
</tbody>
</table>
# Order of Draw for Multiple Tube Collections

<table>
<thead>
<tr>
<th>Closure Color</th>
<th>Collection Tube</th>
<th>Mix by Inverting</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Blood Cultures</td>
<td>8 to 10 times</td>
</tr>
<tr>
<td>Red</td>
<td>Serum (glass tube)</td>
<td>—</td>
</tr>
<tr>
<td>Teal</td>
<td>Citrate</td>
<td>3 to 4 times</td>
</tr>
<tr>
<td>Red/Grey</td>
<td>BD SST™ Gel Separator Tube</td>
<td>5 times</td>
</tr>
<tr>
<td>Yellow</td>
<td>BD SST Gel Separator Tube</td>
<td>&quot;</td>
</tr>
<tr>
<td>Red</td>
<td>Serum (plastic tube)</td>
<td>&quot;</td>
</tr>
<tr>
<td>Green</td>
<td>Heparin</td>
<td>8 to 10 times</td>
</tr>
<tr>
<td>Cyan</td>
<td>BD PST™ Gel Separator Tube With Heparin</td>
<td>&quot;</td>
</tr>
<tr>
<td>Purple</td>
<td>EDTA</td>
<td>8 to 10 times</td>
</tr>
<tr>
<td>Grey</td>
<td>Fluoride (glucose tube)</td>
<td>8 to 10 times</td>
</tr>
</tbody>
</table>
# Sarstedt Collection Tubes (Pediatric)

<table>
<thead>
<tr>
<th>Department</th>
<th>Product Description</th>
<th>Product Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemistry</td>
<td>S-MONOV, 1.1 ML, LITHIUM HEPARIN-GEL, GREEN</td>
<td>06.1669.100</td>
</tr>
<tr>
<td>Chemistry</td>
<td>S-MONOV, 4.7 ML, LITHIUM HEPARIN-GEL, GREEN</td>
<td>03.1631.100</td>
</tr>
<tr>
<td>Chemistry</td>
<td>S-MONOV, 2.6 ML, SODIUM HEPARIN, GREEN</td>
<td>04.1913.100</td>
</tr>
<tr>
<td>Chemistry</td>
<td>S-MONOV, 2.6 ML, SERUM-GEL, BROWN</td>
<td>04.1905.001</td>
</tr>
<tr>
<td>Chemistry</td>
<td>S-MONOV, 1.1 ML, SERUM-GEL, BROWN</td>
<td>06.1667.001</td>
</tr>
<tr>
<td>Hematology</td>
<td>S-MONOV, 1.2 ML, EDTA, PURPLE</td>
<td>06.1664.100</td>
</tr>
<tr>
<td>Hematology</td>
<td>S-MONOV, 3.4 ML, EDTA, PURPLE</td>
<td>06.1664.100</td>
</tr>
<tr>
<td>Coagulation</td>
<td>S-MONOV, 1.4 ML, SODIUM CITRATE, BLUE</td>
<td>06.1668.100</td>
</tr>
<tr>
<td>Coagulation</td>
<td>S-MONOV, 3 ML, SODIUM CITRATE, BLUE</td>
<td>05.1165.100</td>
</tr>
</tbody>
</table>
Laboratory Departments and Contacts

Core Laboratories

**Manager:** Gloria Wilkerson  
**Email:** wilkeg@shands.ufl.edu  
**Office Phone:** 352-265-0412

**Medical Director:** Neil Harris, MD  
**Email:** harris@pathology.ufl.edu  
**Office Phone:** 352-594-4717

**Technical Coordinator:** Elisha Roberts  
**Email:** robeea@shands.ufl.edu  
**Office Phone:** 352-265-0412

**Co-Medical Director:** Maximo Marin, MD  
**Email:** maximo.marin@ufl.edu  
**Office Phone:** 352-594-4953

**Pathology Resident On-Call:**  
352-213-1201 (9am to 5pm Weekdays)  
352-213-6811 (5pm to 9am Weekdays, Weekends, and Holidays)

**Scope of Service:** UF Health Medical Core Laboratories provides full service testing in Clinical Chemistry, Special Chemistry, Hematology, Coagulation, Urinalysis, and Blood Gas Analysis. All laboratories are equipped with state-of-the-art analyzers, which are selected to produce accurate results, fast result times, and high volume throughout. Tests performed on-site are generally resulted in less than 4 hours. STAT test orders performed on-site are generally resulted within 60 minutes.

For specimen collection questions, call Customer Service: **352-265-0412**

**Core Laboratory at UF Health Shands Hospital**  
North Tower, 3rd Floor, Room 3130  
Hours of Operation: 24/7

Main Phone: 352-265-0412  
Fax: 352-265-9910

Chemistry: 352-594-0475/0476  
Hematology: 352-594-3887/0472  
Coagulation: 352-594-0479

Urinalysis: 352-594-0472  
Blood Gas Lab: 352-265-0199  
Electrophoresis: 352-594-7186

**Blood Gas Lab at UF Health Heart & Vascular and Neuromedicine Hospitals**  
HVN Tower, 7th Floor, Room 7538  
Hours of Operation: 24/7

Phone: 352-733-0574

Limited test menu includes blood gas testing, whole blood chemistries such as sodium, potassium, glucose, ionized calcium, and TEG (thromboelastograph) testing.

**Bone Marrow Transplant (BMT) Laboratory at UF Health Shands Cancer Hospital**  
South Tower, 7th Floor, Room 7018.1  
Hours of Operation: Monday to Friday, 8 AM to 3 PM

Phone: 352-733-1559

Limited Hematology test menu (CBC and CBC w/ Differential only) for Transplant Patients.

**Cancer Center Laboratory at UF Health Shands Medical Plaza**  
Medical Plaza Building, Room 2163  
Hours of Operation: Monday to Friday, 8 AM to 5 PM

Phone: 352-265-0722  
Fax: 352-265-0734

Limited Chemistry, Hematology, and Coagulation test menu for Cancer Center/Infusion patients.

**Florida Surgical Center Laboratory**  
Florida Surgical Center  
Hours of Operation: As needed.

Intraoperative PTH testing only.

**Sendout Testing at UF Health Shands Hospital Core Laboratory**  
North Tower, 3rd Floor, Room 3130  
Hours of Operation: 24/7

Phone: 352-594-0481 or 352-594-0482  
Fax: 352-265-0328
Non-urgent esoteric testing not performed on-site are referred to other acceptable laboratories for testing. Additional reference laboratories are utilized as needed to meet the needs of the patient. The Medical Director is available to consult with physicians to ensure that the testing needs are being met.

The primary reference laboratory is ARUP Laboratories. Contact Client Services at 800-522-2787 for questions about specific tests or visit their website at [https://www.aruplab.com/](https://www.aruplab.com/).

**UF Health Shands Emergency Center Medical Labs – Springhill and Kanapaha**

Springhill Main Phone: 352-627-0400, Laboratory: 352-627-0413  
Kanapaha Main Phone: 352-627-0500, Laboratory: 352-627-0516  
Hours of Operation: 24/7

**Technical Coordinator:** Nilam Patel, MT(AMT)  
**Email:** patnil@shands.ufl.edu  
Limited test menu supporting Emergency Response, including Hematology, Coagulation, Chemistry, Urinalysis, Molecular, and waived testing.

**Contact Customer Service at 352-265-0522 to request laboratory requisition forms (PS 42510).**

[https://bridge.ufhealth.org/shands-forms/medical-laboratory-request-form/](https://bridge.ufhealth.org/shands-forms/medical-laboratory-request-form/)
Microbiology Laboratory

UF Health Shands Hospital
North Tower, 3rd Floor, Room 3164
Hours of Operation: 24/7

Main Phone: 352-265-0165
Fax: 352-265-0204

Manager: Gloria Wilkerson
Email: wilkeg@shands.ufl.edu

Medical Director: Stacy Beal, MD
Email: stacygbeal@ufl.edu

Technical Coordinator: Anthea Sabol
Email: sabola@shands.ufl.edu

Office Phone: 352-594-4952

Pathology Resident On-Call:
352-213-1201 (9am to 5pm Weekdays)
352-213-6811 (5pm to 9am Weekdays, Weekends, and Holidays)

Scope of Service: The Microbiology Laboratory provides full-service Bacteriology, Mycology, Mycobacteriology, Parasitology, Serology, and Virology testing for UF Health Shands Hospital and multiple outpatient facilities. Specimens of blood, body fluids, CSF, surgical biopsies, tissues, wounds, respiratory, feces, and urine are processed for isolation/identification of potential pathogenic infectious agents. Antimicrobial susceptibility testing is performed for appropriate organisms/sources.

USE OUTPATIENT REQUEST FORM (PS 42510)
https://bridge.ufhealth.org/shands-forms/medical-laboratory-request-form/

Collection Guidelines:

1. Each specimen should be considered potentially infectious; handle using Standard Precautions.

2. Each specimen requires collection in a STERILE and tightly capped/sealed container to avoid leakage and possible rejection of specimen due to contaminated exterior of container.

3. Specimens requested for Anaerobic Culture are to be collected in the Anaerobic Transport tubes.

4. BLOOD CULTURES for bacteria consist of one (1) Silver labeled AEROBIC bottle and one (1) Purple labeled LYTIC/ANAEROBIC bottle, with recommended blood volume of 8-10 mL each.

5. PEDIATRIC draws (1-3 mL) can be inoculated into a Pink-labeled PEDS PLUS (aerobic) bottle.

6. When ordering microbiology test(s) and test(s) for other Lab sections (e.g., Cytology), whenever feasible (e.g., urine specimen), please provide 2 separate containers — one designated for Microbiology testing (i.e., urine culture), and the other for the additional tests. Affix appropriate labels on each container.

7. Tissue samples for bacterial culturing MUST NOT be placed into formalin fixative. Send the samples in a dry sterile container or with 1-5 mL of sterile saline solution in a sterile container to the Microbiology Laboratory directly.

8. Specimens with needles attached will be rejected per UF Health Shands Hospital Infection Control Policy. Recapping of needles is contrary to UF Health Shands Hospital Infection Control policy and will also be rejected.
### Instructions for Microbiology Specimen Collection and Transport

<table>
<thead>
<tr>
<th>Specimen</th>
<th>Collection Equipment</th>
<th>Transport</th>
<th>Instructions (Comments)</th>
</tr>
</thead>
</table>
| **Aerobic/Anaerobic Culture with Gram Stain** | Optimum recovery of anaerobes occurs with tissue or curetting, which can be placed into the anaerobic collection container. Aspirates collected in syringe (submitted without needles) are the next best specimen. Swabs are the least likely to yield clinically relevant results. | DO NOT refrigerate. Use anaerobe transport tube or syringe without needle. | • Avoid all O₂ exposure.  
• Use anaerobic transport tubes or expel air from syringe.  
• DO NOT submit needle-syringe or a syringe with cap only.  
• Label properly.  
• Submit (2) Tubes: One for CULTURE and one for STAT GRAM STAIN.  
• Deliver promptly to lab. |
| **Bone Marrow**                   | Collect in a STERILE container AND order as an Aerobic/Anaerobic Culture with Gram Stain. | Sterile Container          | • Collect in Sterile Container and order as an Aerobic/Anaerobic Culture with Gram Stain.  
• Lab will process on plated media, broth media, and perform Gram Stain. |
| **Blood**                         | Bactec Blood culture collection kit. Needle & syringe.                                 | Aerobic F and Anaerobic Lytic F bottles require 8-10 mL of blood per bottle. May use minimum of 3 mL. Pediatric Plus/F bottles used for short draws (1-3 mL). DO NOT REFRIGERATE. | • Decontaminate puncture site.  
• Do not palpate disinfected site.  
• Decontaminate bottle stopper.  
• Label properly.  
• Deliver promptly to lab. |

<table>
<thead>
<tr>
<th>Adult Set</th>
<th>Pediatric Patients</th>
<th>AFB – Red</th>
<th>Fungal – Red</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gray/Blue Top Aerobic F</td>
<td>Purple Top Lytic Anaerobic</td>
<td>Peds Plus Aerobic F</td>
<td>Myco F Lytic</td>
</tr>
<tr>
<td>8-10 mL of whole blood</td>
<td>8-10 mL of whole blood</td>
<td>1-3 mL of whole blood per bottle</td>
<td>3-5 mL of whole blood per bottle</td>
</tr>
<tr>
<td>No less than 3 mL per bottle. No more than 10 mL per bottle.</td>
<td>May pair with Purple Lytic F bottle to give anaerobic result.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**LABELING:**

1. PLEASE DO NOT COVER THE BOTTLE BARCODE! This is what the instrument “reads”.
2. PLEASE LABEL “LENGTH-WISE”, NOT WRAPPED AROUND THE BOTTLE, for the lab to be able to scan patient label.
3. There is a picture of a clock & a patient in a bed, with lines. Please place label here.
<table>
<thead>
<tr>
<th>Specimen</th>
<th>Collection Equipment</th>
<th>Transport</th>
<th>Instructions (Comments)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Brucella Blood</strong></td>
<td>Collect as appropriate for the source in question.</td>
<td></td>
<td>• Notify Microbiology at 352-265-0165 and Infection Control if Brucella is suspected.</td>
</tr>
<tr>
<td>Culture or suspected Brucella culture</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>from other source.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>CSF Culture and Gram Stain</strong></td>
<td>Surgical prep &amp; collection by physician.</td>
<td>Transport in CSF collection tube.</td>
<td>• Surgical prep of puncture site.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Obtain 4-5 mL for adult patients.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Obtain 0.5-1.0 mL for pediatric patients.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Handle as a PRIORITY specimen; hand deliver to the laboratory.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• <strong>Only one tube available</strong>: Deliver to Microbiology for Culture FIRST.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Tube 4 and/or Tube 2, routinely send to Bacteriology and Molecular.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Label properly.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Deliver promptly to lab.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• DO NOT refrigerate.</td>
</tr>
<tr>
<td><strong>Ear Culture</strong></td>
<td>Aspirate from Tympanocentesis.</td>
<td>Transport Medium</td>
<td>• Clean external ear surface.</td>
</tr>
<tr>
<td></td>
<td>Swab of drainage.</td>
<td></td>
<td>• CAREFULLY culture representative area.</td>
</tr>
<tr>
<td><strong>Eye Culture</strong></td>
<td>Small swab for each eye.</td>
<td>Transport Medium</td>
<td>• Do not touch external skin.</td>
</tr>
<tr>
<td></td>
<td>Corneal scraping (by physician).</td>
<td></td>
<td>• Obtain maximum material.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Label properly.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Deliver to lab promptly.</td>
</tr>
<tr>
<td><strong>Nasopharynx Culture</strong></td>
<td>Calcium alginate swab.</td>
<td>DO NOT refrigerate.</td>
<td>• Nasal speculum helpful.</td>
</tr>
<tr>
<td></td>
<td>Transport medium.</td>
<td></td>
<td>• Pass through the nose into nasopharynx.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Allow to remain for a few seconds.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Carefully withdraw.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Label properly.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Deliver to lab promptly.</td>
</tr>
<tr>
<td><strong>Nose Culture</strong></td>
<td>Swab</td>
<td>Transport Medium</td>
<td>• Swab anterior nares only.</td>
</tr>
<tr>
<td><strong>Sinus Culture</strong></td>
<td>Small swab.</td>
<td>Transport Medium</td>
<td>• Culture quickly.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Label properly.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Deliver promptly to lab.</td>
</tr>
<tr>
<td><strong>Sputum Culture</strong></td>
<td>Sterile cup (Minimum 5 mL).</td>
<td>Refrigerate if needed.</td>
<td>• Carefully instruct patient to cough deeply (not to spit).</td>
</tr>
<tr>
<td><strong>Respiratory Culture</strong></td>
<td></td>
<td>Transport in collection cup.</td>
<td>• First morning specimen is best. No 24-hour collection.</td>
</tr>
<tr>
<td><strong>BAL/Bronch Culture</strong></td>
<td></td>
<td></td>
<td>• Seal container tightly and transport immediately.</td>
</tr>
<tr>
<td><strong>ETT Culture</strong></td>
<td></td>
<td></td>
<td>• Consider sputum contaminated with TB.</td>
</tr>
<tr>
<td><strong>CF Respiratory Culture</strong></td>
<td></td>
<td></td>
<td>• Label properly.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Deliver promptly to lab.</td>
</tr>
<tr>
<td><strong>Respiratory Samples for AFB Culture</strong></td>
<td><strong>Adults</strong>: 5-10 ML of sample is the CDC recommendation.</td>
<td></td>
<td>• Respiratory sample-send first morning sample.</td>
</tr>
<tr>
<td></td>
<td><strong>Pediatrics</strong>: Any amount is accepted.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Throat

- Swab
- Transport medium if more than 2-hour delay.
  - Use tongue blade.
  - Sample only back of throat between & around tonsil area thoroughly.
  - Avoid cheeks, teeth, etc.
  - Label properly.
  - Deliver to lab promptly.

Urine

- Transport gray top tube with Urine Culture and Susceptibility (C&S) Preservative (Boric Acid/ Sodium Formate/Sodium Borate).
  - Minimum 4 mL of urine.

  **Pediatric and OR Patients:**
  - May submit sterile cup with less than 4 mL.
  - Must be delivered to the lab within 2 hours of collection.

  **Note:** Cups from other locations will be rejected (Due to probability of false positive results.)

- Transport in collection container.
  - Give patient clear and detailed instructions.
  - Clean with soap and NOT disinfectant.
  - Seal container tightly.
  - Label properly.
  - Deliver promptly to lab.

Superficial Wound

- Sterile container; swab or syringe.
  - Transport to lab quickly.
  - Disinfect surface.
  - Aspirate deepest portion of lesion.
  - Swab affected area.
  - Deliver to lab promptly.

Burn Wound

- Sterile container; swab.
  - Transport to lab quickly.
  - Disinfect surface.
  - Swab affected area.
  - Deliver to lab promptly.

Catheter Tip

- Sterile Container
  - Transport to lab quickly.
  - Do NOT submit more than 3 inches. Greater than 3 inches cannot be properly cultured.
  - ONLY suitable for bacterial culture.

O & P is not performed in the Microbiology Lab. The GI PCR Panel encompasses the most common parasites.

Stool culture is not performed in the Microbiology Lab. The GI PCR Panel encompasses the stool pathogens.

**NOTE:** *C. difficile* is not included in the GI PCR Panel and is a separate test order (EPIC).

The GI PCR Panel includes:

<table>
<thead>
<tr>
<th>Bacteria Detected</th>
<th>Parasites Detected</th>
<th>Viruses Detected</th>
</tr>
</thead>
<tbody>
<tr>
<td>Campylobacter (jejuni, coli, and upsaliensis)</td>
<td>Cryptosporidium</td>
<td>Adenovirus F 40/41</td>
</tr>
<tr>
<td>Plesiomonas shigelloides</td>
<td>Cyclospora cayetanensis</td>
<td>Astrovirus</td>
</tr>
<tr>
<td>Salmonella</td>
<td>Entamoeba histolytica</td>
<td>Norovirus GI/GII</td>
</tr>
<tr>
<td>Yersinia enterocolitica</td>
<td>Giardia lamblia</td>
<td>Rotavirus A</td>
</tr>
<tr>
<td>Vibrio (parahaemolyticus, vulnificus, and cholerae)</td>
<td></td>
<td>Sapovirus (I, II, IV, and V)</td>
</tr>
<tr>
<td>Diarrheagenic E. coli/Shigella</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Enteraggregative E. coli (EAEC)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Enteropathogenic E. coli (EPEC)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Enterotoxigenic E. coli (ETEC) II/st</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Shiga-like toxin-producing E. coli (STEC) stx1/stx2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>E. coli O157</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Shigella/Enteroinvasive E. coli (EIEC)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Stool Requirements for GI PCR Panel:
- Submit 1-2 mL/grams of stool in a clean plastic screw cap container (tightly sealed).

Rejection Criteria for GI PCR Panel:
- Duplicate orders within 14 days are cancelled (Infection Control policy).
- Samples submitted in white "commode" bowls are not accepted; this are not biosafety compliant due to leakage.

Stool Requirements for C. difficile PCR:
- Submit 1 mL of liquid or semi-solid stool in a clean plastic screw cap container (tightly sealed).

Rejection Criteria for C. difficile PCR:
- Formed/hard stool is rejected as inappropriate.
- Not performed on children less than 2 years of age.
- Duplicate orders within 7 days are cancelled (Infection Control policy).
- Samples submitted in white "commode" bowls are not accepted; this are not biosafety compliant due to leakage.

Respiratory PCR with CoV (RP2)
- Appropriate samples: NP SWABS, NP WASH, NP Aspirates, and BAL specimens in Viral Transport Media.
- Other sample types are not FDA approved for this method.
- Obtain specimen with flocked swab (available in the Viral Transport pack).
- After specimen collection, insert the swab into the liquid Viral Transport medium and then break off the end carefully. Cap the vial securely to avoid leakage.
- Tests offered:
  
  **VIRUSES:**
  - Adenovirus
  - Coronavirus 229E
  - Coronavirus HKU1
  - Coronavirus NL63
  - Coronavirus OC43
  - Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2)
  - Human Metapneumovirus
  - Human Rhinovirus/Enterovirus

  **BACTERIA:**
  - Influenza A virus
  - Influenza A virus A/H1
  - Influenza A virus A/H3
  - Influenza A virus A/H1-2009
  - Influenza B virus
  - Parainfluenza virus 1
  - Parainfluenza virus 2
  - Parainfluenza virus 3
  - Parainfluenza virus 4
  - Respiratory syncytial virus

HSV 1 & 2 PCR
- HSV PCR: CSF in a Sterile CSF Collection Tube.
- HSV PCR: Cutaneous or Muco-Cutaneous specimens in Viral Transport Media.
- Obtain specimen with flocked swab contained in the Viral Transport pack. After specimen collection, insert the swab into the liquid Viral Transport medium and then break off the end carefully. Cap the vial securely to avoid leakage.
- When swabbing a lesion, it is best to scrape the base of a fresh lesion after lancing, using sterile techniques.

Cryptococcal Antigen
- Serum or CSF (1 mL).
- Note for CSF: If ordering for Cryptococcal Antigen, also order CSF Culture.

Meningitis/Encephalitis PCR
- Appropriate sample is CSF collected in a Sterile CSF Collection Tube.
- Other sample types are not FDA approved for this method.

**BACTERIA:**
- *Escherichia coli* K1
- *Haemophilus influenzae*
- *Listeria monocytogenes*
- *Neisseria meningitidis*
- *Streptococcus agalactiae*
- *Streptococcus pneumoniae*

**VIRUSES:**
- Cytomegalovirus (CMV)
- Enterovirus (EV)
- Herpes simplex virus 1 (HSV-1)
- Herpes simplex virus 2 (HSV-2)
- Human herpesvirus 6 (HHV-6)
- Human parechovirus (HPeV)
- Varicella zoster virus (VZV)

**YEAST:**
- *Cryptococcus (C. neoformans/C. gattii)*
**Pneumonia PCR**

- **Appropriate samples:** Sputum or BAL (Bronchial Lavage). Do NOT place in Viral Transport media. Sample MUST be undiluted.
- **Other sample types are not FDA approved for this method.**
- **Obtain specimen in a sterile cup.** Tighten the lid of the cup securely to avoid leakage. Consider specimens potentially infectious with COVID-19.

**BACTERIA:** (Semiquantitative)
- Acinetobacter calcoaceticus-baumanii complex
- Enterobacter cloacae complex
- Escherichia coli
- Haemophilus influenzae
- Klebsiella aerogenes
- Klebsiella oxytoca
- Klebsiella pneumoniae group
- Moraxella catarrhalis
- Proteus spp.
- Pseudomonas aeruginosa
- Serratia marcescens
- Staphylococcus aureus
- Streptococcus agalactiae
- Streptococcus pneumoniae
- Streptococcus pyogenes

**ATYPICAL BACTERIA:** (Qualitative)
- Chlamydia pneumoniae
- Legionella pneumophila
- Mycoplasma pneumoniae

**VIRUSES:**
- Adenovirus
- Coronavirus
- Human metapneumovirus
- Human rhinovirus/enterovirus
- Influenza A virus
- Influenza B virus
- Para influenza virus
- Respiratory syncytial virus

**ANTIMICROBIAL RESISTANCE GENES:**
- Carbapenemases:
  - IMP
  - KPC
  - NDM
  - OXA-48-like
  - VIM
- ESBL:
  - CTX-M
- Methicillin resistance:
  - mecA and MREJ (MRSA)
Point of Care

UF Health Shands Hospital
Main Operations Location: North Tower, Room 3101 and HVN Tower, Room G540

Hours of Operation: 0630 AM to 0530 PM Weekdays

Main Phone: 352-594-3707
Manager: Abby Estilong, MT (ASCP)
Email: estila@shands.ufl.edu
Office Phone: 352-594-4873

On-Call Phone: 352-256-7031
Medical Director: William Winter, MD
Email: winter@pathology.ufl.edu
Office Phone: 352-294-5540

Scope of Service: The Point of Care (POC) Department within UF Health Shands Hospital provides support for waived and alternate site testing in the following UF Health Shands locations: Women and Children’s Hospital, Cancer Hospital, HVN Hospitals, Medical Plaza, Cancer Center, Florida Surgical, Children’s Surgical, Oaks Surgical, Shands Endoscopy, Inpatient and Outpatient Dialysis, Wound Care, Pain Management Clinic, ShandsCair and Psychiatric Hospital. All point of care locations are equipped with state-of-the-art testing devices which are validated to produce accurate and fast result times.

All POC tests require a provider order. New Point of Care test requests follow a “Needs Assessment” process prior to implementation. Please visit the UF Health Shands Bridge: https://bridge.ufhealth.org/policies/poc-needs-assessment-form-65053-2549/
Transfusion Services (Blood Bank) Laboratory

UF Health Shands Hospital
South Tower, Ground Floor, Room G110

Hours of Operation: 24/7   Fax: 352-733-0812
Main Phone: 352-733-0900   Medical Director: Peter Pelletier, MD
Supervisor On-Call: 352-260-3358   Email: pelletierp@ufl.edu
Manager: Michael Passwater   Office Phone: 352-594-0490
Email: mpas0001@shands.ufl.edu   Co-Medical Director: Faisal Mukhtar, MD
Cell Phone: 252-917-2295   Email: fmukhtar@ufl.edu

Scope of Service: The Blood Bank department provides a wide array of immunohematology services using the most advanced technology to assist the physician in obtaining quality test results as well as a variety of blood products available to manage the diversified group of patients that are encountered at UF Health Shands Cancer Hospital.

Services Offered:
- Blood Bank Laboratory Tests
- Blood Products
- Pathology Consultations
- Remote (Point of Service) Emergency Blood Refrigerator Locations: SHED, KED, AED Trauma/Resuscitation Bay Area, STOR, NTOR 2352, and PCICU).

Additional Requirements:
- For pre-transfusion Type and Screen tests performed in the Blood Bank, the specimen must be sent with a completed Type and Screen Time-Out Verification Form to be accepted for compatibility testing. (Form 100030156: https://bridge.ufhealth.org/shands-forms/transfusion-services-time-out-verification-form/)
- A physician’s written or electronic order is to accompany the patient sample when ordering Blood Bank tests and/or blood products.
- Samples with any errors or missing information on the specimen label or verification form will be rejected.
Cytopathology Laboratory

UF Health Medical Lab – Rocky Point

Hours of Operation: Monday to Friday 0800 AM to 0430 PM
Main Phone: 352-627-2119 or 352-627-2120
Fax: 352-627-2017

Fine Needle Aspiration (FNA) Laboratory at UF Health Shands Hospital
North Tower, 2nd Floor, Room 2092/2093
Hours of Operation: 0830 AM to 0330 PM
Cell Phone: 352-246-5358

Pathology Resident On-Call: 352-213-6811 (5 PM to 9 AM Weekdays, Weekends, and Holidays)

Manager: Pamela Gillard, SCT (ASCP)
Email: pgil0002@shands.ufl.edu
Office Phone: 352-627-2115

Technical Supervisor: Amy Ratermann, SCT (ASCP)
Email: ratera@shands.ufl.edu
Office Phone: 352-627-2126

Medical Director: Marino Leon, MD
Email: marino.leon@ufl.edu
Office Phone: 352-627-9260

Scope of Service: The function of the Cytology Laboratory is to evaluate exfoliated or aspirated cells for abnormalities. These abnormalities include the presence of cancer, precancerous conditions, infection due to fungus, virus, parasites, bacteria, etc. The cytology services include processing, evaluating, and performing diagnostic interpretation on the specimens submitted. All specimens are examined and interpreted by the cytotechnologists and given to the pathologist for review and final diagnosis. The cytology laboratory staff assists in Fine Needle Aspirate (FNA) procedures in various areas stationed only in UF Health Shands and only during regular hours (8:30 AM to 3:30 PM). Please be aware that staff available to assist with FNA procedures is limited. Patience with scheduling assistance is appreciated. Should an FNA be anticipated after 3:30 PM, please contact FNA service during operating hours for needed supplies. Residents are available for questions but do not assist with FNA slide preparation and assessment of adequacy.

STAT specimens are processed between 7 AM and 3 PM. Contact Lab Customer Service at 352-265-0522 for rush pick-up and delivery to Rocky Point.

After hours, contact on-call Pathology Resident at 352-213-6811. STAT specimens MUST have a direct contact phone number of requesting clinician on the requisition.

Collection Guidelines (Other than Fine Needle Aspiration)
1. The cytology orders should be placed in Epic, and the printed order submitted along with the specimen.
2. Contact laboratory before obtaining CSF specimen on patient suspected to have CJ disease.
3. All specimens must be capped/sealed tightly.
4. When ordering cytologic evaluation and tests for other labs, whenever feasible, please provide a separate specimen for the Cytology Laboratory. If one specimen is to be shared between two laboratories, please indicate so.
5. Refrigerate specimens that cannot be sent immediately.

Breast Secretions:
Secretion from the nipple can be obtained in up to 70% of women who have borne children. There are two procedures that are acceptable for handling of the breast cytology specimen.
1. **Six-slide technique**: Secretion from the nipple is expressed on six slides, labeled with the patient’s last name and 2nd identifier. As the drop of secretion appears, the first slide is gently brought to the drop and the secretion is smeared on the slide using a slide push technique as employed in Hematology. In this technique, a second slide is simply brought up to the drop, the drop is permitted to spread across the joining edges of the slide and, at that point, the forwarding slide is pushed across the surface smearing the sample. Alternatively, make the smear by using another slide laid on top of the drop. After the drop spreads from the weight of the slide, pull the slides apart in opposite directions. The sample is immediately placed into alcohol reagent (95% alcohol) or sprayed using an appropriate fixative, being certain the spraying nozzle is at least 12 inches away from the sample. The material should be submitted directly to Cytopathology (Core Lab).

2. **Breast secretion employing the cytocentrifuge technique**: Collection of the sample employing these technologies requires that the sample preferably be collected fresh in a clean covered container and submitted directly to Cytopathology (Core Lab). In these cases, at least 2 mL of sample is generally required to perform cytologic evaluation. If a delay is anticipated, the collected fluid should be added to a CytoLyt™ (ThinPrep preservative) vial or CytoLyt fluid should be added to the rinsed fluid to fixed/preserve the material. The minimum ratio of CytoLyt to sample is 1-part CytoLyt to 3 parts sample. If the sample cannot be submitted directly to Cytopathology, the sample must be refrigerated until it can be delivered to Cytopathology (Core Lab).

3. **Fine needle aspiration (FNA)** may also be used for breast masses. Please see FNA guidelines below.

**Corneal (Eye)**: Samples are collected by the ophthalmology clinicians and submitted dependent of the clinical differential. If looking **ONLY** for fungi or Acanthamoeba, the slide(s) should be submitted as air-dried smears accompanied by a request for GMS (silver) stain. The slide, which must have the patient’s last name and 2nd identifier written on the frosted end, is given an accession number and submitted to Histology for a Gomori methenamine silver (GMS) stain and evaluated for the presence of fungi or Acanthamoeba. The sample should be submitted to the section of Cytopathology (Core Lab).

**Effusions-Ascites, Pleural OR Pericardial**: If a specimen can be transported promptly to the lab, we prefer the fresh fluid. If it cannot be brought immediately, add 3 units of heparin per mL of fluid as precaution against clotting, and place in refrigerator until it can be delivered. We prefer **at least 75 mL** of sample or more if possible (up to 100 mL).

**Female Genital Tract – Monolayer Paps**: Obtain an adequate sample. (See ThinPrep Pap kit for detailed collection information.) Rinse spatula/broom in preservative solution and discard collection device. Tighten the cap on vial and label with the patient’s name before placing in transport bag. HPV, GC, and CT testing is now available.

**Gastrointestinal Tract**: Brushing material may be smeared directly on slides, which should have the patient’s last name and a second identifier printed in pencil on one end. If prepared, the smears should be fixed **IMMEDIATELY** in 2% solution of Acetic Acid in Reagent Alcohol (AARA) and the slides sent to the Cytopathology Lab (Core Lab). If the brush is used in multiple passes in the same site, the brush should be rinsed in a sterile container with 5 mL of sterile Plasma-lyte or sterile balanced electrolyte solution (BSS; e.g. Hanks’ Balanced Salt solution). Immediately, after the procedure is finished, cellgro™ may be added to this rinse fluid. If a delay is anticipated, the rinse fluid should be added to the CytoLyt™ (ThinPrep preservative) vial or CytoLyt should be added to the rinsed fluid to fixed/preserve the material. The minimum ratio of CytoLyt to sample is 1-part CytoLyt to 3 parts sample. The brush used in the procedure may be submitted in CytoLyt (ThinPrep preservative) preservative fluid (provided by the Lab) for processing with prepared slides.

**Respiratory Tract**: Sputum – Instruct the patient to cough deeply (from the diaphragm) to expectorate a deep cough specimen and not saliva. We prefer a fresh sample. If a delay is anticipated, the fluid should be added to a CytoLyt (ThinPrep preservative) vial or CytoLyt should be added to the rinsed fluid to fixed/preserve the material. The minimum ratio of CytoLyt to sample is 1-part CytoLyt to 3 parts sample.
Please send specimen to the lab immediately. The specimen may be refrigerated until it can be delivered to the Cytopathology lab (Core Lab). For best results, a series of early morning specimens should be submitted each morning for 3 consecutive days.

**Bronchial**: Fresh bronchial secretions or washings are used. We prefer a fresh sample. If a delay is anticipated, the fluid should be added to the CytoLyt (ThinPrep preservative) vial or CytoLyt should be added to the rinsed fluid to fixed/preserve the material. The minimum ratio of CytoLyt to sample is 1-part CytoLyt to 3 parts sample. Please send specimen to the lab immediately or refrigerate until specimen can be delivered to Cytopathology for processing.

If slides are made, print the patient’s last name and 2nd identifier with pencil on one end of all-frosted slides, smear brushing or aspirated material and fix the slide immediately in alcohol reagent (95% ethanol). **DO NOT ALLOW SMEAR TO AIR DRY**! The brush may also be placed in saline and submitted. Three post-bronchoscopy sputum specimens obtained over the next 3 days may be sent to the lab. These are rich in exfoliated cells from the bronchial epithelium and are of great diagnostic value.

**NOTES:**
1. Bronchoalveolar lavage is preferred for detection of Pneumocystis carinii.
2. In cases where a sample is to be shared between Cytology and Microbiology, a cytology order should be placed in EPIC and submitted with the specimen to the lab.

**Spinal Fluid**: Bring the fresh specimen **PROMPTLY** to the lab for processing. A sample size of at least 1-3 mL is needed. If a lymphoproliferative disorder is suspected, submit the CSF to Hematopathology for analysis.

**Urinary Tract**: For Cancer Detection, send fresh urine or bladder washing immediately to the Cytopathology Lab (Core Lab). Please indicate whether specimen is voided or catheterized urine or bladder washing. If specimen cannot be brought immediately to the lab, it **MUST** be refrigerated.

**For Cytomegalic Inclusion Disease (CMV) or Polyoma (BK virus) Detection**: Fresh urine should be sent **IMMEDIATELY** to the Cytopathology Lab after collection. A 35 mL minimum volume is required.

PCR testing is the preferred method of detection for BKV and CMV. BKV and CMV are performed on plasma specimens and BKV is also done on urine specimens.

**Wound or Lesion Scrapes**: Print patient’s last name and 2nd identifier with pencil on one end of all-frosted slide, scrape the wound with moistened tongue blade, and place the material directly on the slides. Place the slides **IMMEDIATELY** in alcohol reagent (95% ethanol), or spray with an appropriate fixative, keeping the spray nozzle 12 inches away from the slide surface. If the wound is hard and crusted it should be soaked with warm saline prior to obtaining the scrape. These will be Pap stained.

**Testing Note**: Old style “Tzanck” smears for viral changes are of low quality and we no longer will interpret.

**Fine Needle Aspiration Procedure**

**Purpose**: The purpose of Fine Needle Aspiration (FNA) is to obtain diagnostic cells from a designated site without using open biopsy techniques.

**Principle**: Tissue is obtained from a specific anatomic site with or without the aid of radiological assistance.

**Specimen**: Fine needle aspiration of masses for cytological examination.

**Safety Note**: All specimens must be submitted in closed containers, properly labeled, and transported in biohazard bags.
The aspirate should be placed directly into cellgro™ (DMEM Liquid Classical Cell Culture Media; similar to RPMI) when immediate assistance is NOT available. This cell transport fluid may be obtained from the Cytopathology FNA Lab.

**Smears:** Smears are labeled with last name and 2nd identifier. The smears are prepared from a small drop of the semisolid aspirate placed on a glass slide. If using a syringe, the FNA syringe should have at least 2 mL of air before starting the FNA pass. After withdrawing the needle from the patient, advance the plunger of the syringe to express a small drop of the aspirated material on the center of a labeled glass side. Place the bevel of the needle against the slide while expressing this drop so that there is no intervening airspace which will cause drying artifacts in the alcohol fixed smears.

Make the smear by using another slide laid on top of the drop. After the drop spreads from the weight of the slide, pull the slides apart in opposite directions. Immediately after separating the slides, place one slide into reagent alcohol and allow the second slide to air dry for rapid staining. The rest of the FNA material can then be placed in the transport fluid.

Cyst fluid or predominately bloody specimens that fill the syringe can be submitted in a sterile container properly labeled or placed in transport solution and submitted to the Cytopathology Lab (Core Lab).

Smears should be fixed in alcohol reagent or spray fixed while wet for Papanicolaou stain. Air-dried smears are helpful for special stains and for immediate evaluation for adequacy using rapid stains. It is preferable to make only 2 slides per aspiration attempt (one air-dried and one fixed). If submitting spray-fixed smear slides it is important to indicate which are spray-fixed and which are air-dried, as these are handled differently.

As much of the aspirate as possible should be placed in cellgro™ (DMEM or RPMI) for possible Flow Cytometry in suspected cases of lymphoma. Additional passes are recommended. If cultures for bacteria or virus are needed, a separate sample should be submitted directly to Microbiology for appropriate studies.

**EACH SPECIMEN IS TO BE SUBMITTED WITH AN APPROPRIATE EPIC ORDER FORM.**
Surgical Pathology

UF Health Shands Hospital (North Tower, Room 2350)
UF Health Shands Cancer Hospital (South Tower, Room UA2325)
UF Health Heart & Vascular and Neuromedicine Hospitals (East Tower, Room UB2555)

Hours of Operation: Monday to Friday 0800 AM to 0500 PM
Main Phone: 352-627-9268
Fax: 352-627-9271

Pathology Resident On-Call: 352-213-6811 (5 PM to 9 AM Weekdays, Weekends, and Holidays)

Manager: Pamela Gillard, SCT (ASCP)
Email: pgil0002@shands.ufl.edu
Office Phone: 352-627-2115

Anatomic Pathology Director: Jesse Kresak, MD
Email: jkresak@ufl.edu
Office Phone: 352-627-9253

Associate Director of Surgical Pathology:
Melanie Zona
Email: mzona@pathology.ufl.edu
Office Phone: 352-627-9240

Surgical Pathology Director: Marie Rivera-Zengotita, MD
Email: mriveraz@ufl.edu
Office Phone: 352-627-9251

Scope of Service: Surgical Pathology processes surgical specimens from inpatients, outpatients, and autopsies for a wide variety of tests on tissue sections for demonstration of organisms, substances, and structures. The tests include the demonstration of bacteria, fungi, protozoans, and inclusion bodies; pigments and minerals; carbohydrates and mucoproteins; fats and lipids; nerve cells and fibers; hematologic and nuclear elements; cytoplasmic granules and connective tissue elements, and enzymes. Preparations are made for light microscopy, fluorescent antibody tests and immunoperoxidase techniques using paraffin and frozen section techniques, respectively.

Specimen Submission Guidelines:

PREFERRED: EPIC SURGICAL PATHOLOGY TISSUE ORDER (LAB8)

SURGICAL PATHOLOGY REQUESTION (DOWNTIME FORM) (PS 106575):
https://bridge.ufhealth.org/shands-forms/surgical-pathology-requisition/

Each form is to include: Patient’s first and last name, DOB, UF Health medical record number, pertinent clinical history, submitting physician’s name (legible) and signature, date of collection/service, exact anatomic source of specimen, service/department/clinic/OR#. If patient does not have a UF Health medical record number, provide patient’s address, insurance information, and social security number.

The specimen must be labeled with the patient’s full name, MR#, or DOB, and exact anatomical specimen source (e.g., left breast biopsy).

Deliver specimens with appropriate forms:

Regular Hours: Monday – Friday, 8 AM to 5 PM, to either the Surgical Pathology Lab at UF Health Shands Hospital North Tower (Room 2350) or at the UF Health Shands Cancer Hospital South Tower (Room 2325).

After Hours: Monday – Friday, 5 PM to 8 AM and weekends or holidays, deliver to the Core Lab window at North Tower (3rd Floor, Room 3130).

Contact on-call Pathology Resident at 352-213-6811 about STAT specimens after hours.
**Tissue Samples for Bacterial or Fungal Culture:**
- MUST NOT be placed into formalin fixative.
- Send the samples in a dry sterile container or with 1-5 mL of sterile saline solution in a sterile container to the Microbiology Laboratory (North Tower, Room 3165) directly.

**Fresh tissue (kidney, heart, or skin) specimens for Immunofluorescence Testing (kidney, heart, or skin), Flow Cytometry (lymphoma work-up), and Muscle/Nerve Biopsies:**
- Deliver on saline-soaked gauze to UF Health Shands North Tower Surgical Pathology Gross Room (Room 2350) or South Tower Gross Room (Room 2325).
- **NOTE:** To ensure proper handling, contact the North Tower Gross Room (352-265-0212) or South Tower Gross Room (352-733-0901) when sending fresh specimens.

**Specimens for Routine Light Microscopy:**
- Place tissue in 10% neutral buffered formalin (NBF) 20 times tissue volume in a leak proof container that is properly labeled and deliver to the Gross Room either at UF Health Shands Hospital North Tower, Room 2350 or UF Health Shands Cancer Hospital South Tower, Room 2325.

**Surgical Pathology Consults:**
- Submit slides, a copy of the corresponding Pathology Report from the referring location, and a completed Outpatient UF Health Shands Surgical Pathology request. Deliver to the Surgical Pathology office at UF Health Shands Hospital (North Tower), MSB Building, Room N1-10.

**Outpatient Muscle Biopsies or Medical Renal Biopsies:**
- Contact Histology Laboratory at the UF Health Medical Lab – Rocky Point facility before obtaining a specimen. Call 352-265-0680, extension 72117.
Histopathology Laboratory

UF Health Medical Lab – Rocky Point

Hours of Operation: Monday 2 AM through Saturday 930 AM
Main Phone: 352-627-2118

Pathology Resident On-Call: 352-213-6811 (5 PM to 9 AM Weekdays, Weekends, and Holidays)

Manager: Pamela Gillard, SCT (ASCP)
Email: pgil0002@shands.ufl.edu
Office Phone: 352-627-2115

Histology Medical Director: Joanna Chaffin, MD
Email: jomchaffin@ufl.edu
Office Phone: 352-627-2052

Technical Supervisor: Greder Lemke, HTL (ASCP)
Email: plaseg@shands.ufl.edu
Office Phone: 352-627-2113

IHC Medical Director: Sara Falzarano, MD
Email: sfalzarano@ufl.edu
Office Phone: 352-627-9240

Scope of Service: The Histopathology Laboratory processes surgical specimens from inpatient and outpatient populations. Preparations are made for light microscopy, fluorescent antibody tests, and immunoperoxidase techniques using paraffin and frozen section techniques respectively. This laboratory also prepares microscopic sections from all autopsies performed at UF Health Shands Hospital.

The Histopathology Laboratory performs a wide variety of tests on tissue sections for demonstration of many organisms, substances and structures. These tests include the demonstration of bacteria, fungi, protozoans, and inclusion bodies; pigments and minerals; carbohydrates and mucoproteins; fats and lipids; nerve cells and fibers; hematologic and nuclear elements; cytoplasmic granules and connective tissue elements. The laboratory also performs test for enzymes including the phosphatases and esterases.

The turnaround time (TAT) for the Histopathology Laboratory is 1 to 5 days.
Hematopathology Laboratory

UF Health Medical Lab – Rocky Point

Hours of Operation:
Monday to Friday 0730 AM to 0930 PM
Saturdays 0800 AM to 0400 PM

Main Phone: 352-265-0071
Fax: 352-265-1063

Pathology Resident On-Call: 352-213-6811 (5 PM to 9 AM Weekdays, Weekends, and Holidays)

Manager: Michael Passwater
Email: mpas0001@shands.ufl.edu
Office Phone: 252-917-2295

Medical Director: Robert Seifert, MD
Email: rseifert@ufl.edu
Office Phone: 352-627-2039

Scope of Service: The Hematopathology laboratory provides comprehensive diagnostic testing for hematologic malignancies using state-of-the-art technology including conventional microscopy, immunohistochemistry, flow cytometry, molecular genetic testing, cytogenetics and fluorescence in situ hybridization (FISH).

Consultations Offered:
1. Comprehensive leukemia myelodysplasia or cytopenia evaluation.
2. Comprehensive lymphoma/lymphoproliferative evaluation.
3. Comprehensive plasma cell disorder evaluation.
4. Disease Monitoring.
5. Consultation on pathologic materials (slides).
6. Performance of specialized hematologic laboratory tests on blood, bone marrow, or other fluids.
7. CD34(+) stem/progenitor cell quantitation.
8. Immunophenotyping.

Expert pathologists are available 24/7 for a personalized service and consultation. Special arrangements must be made for off-hours and Sunday specimens. Diagnoses of diseases that require prompt management are routinely reported via telephone by one of the consulting physicians. Reports are faxed and original reports are sent by regular mail.

STAT Requests:
• During regular hours, call laboratory at 352-627-2101 and Customer Service at 352-265-0522 for rush pick-up and delivery to Rocky Point.
• After hours (5 PM to 9 AM Weekdays, Weekends, and Holidays), call the Pathology Resident on-call at 352-213-6811.

EACH SPECIMEN IS TO BE ACCOMPANIED BY A HEMATOPATHOLOGY REQUEST FORM (PS 105674: https://bridge.ufhealth.org/shands-forms/hematopathology-request-form/)

IF CYTOGENETIC EVALUATIONS ARE TO BE REQUESTED, REFER TO SPECIMEN REQUIREMENTS AND THE CONSULTATION REQUEST FORM HERE: https://pathlabs.ufl.edu/specialties/consultation-service/

The UF Cytogenetics laboratory can be contacted at 352-265-9900.
# Hematopathology Specimen Submission Guideline

Notify Laboratory staff when sending a rush specimen. Special arrangements must be made for specimens arriving during off-hours.

<table>
<thead>
<tr>
<th>Sample Type</th>
<th>Sample Requirements</th>
<th>Instructions</th>
</tr>
</thead>
</table>
| Cytogenetic Analysis: Peripheral blood, bone marrow aspirate, or fresh bone marrow biopsy. (Sent to UF Health Pathology Laboratories.) | Tube type is **green top** (**sodium heparin**).  
**Children and adults:** 5-7 mL of blood or 1-2 mL of bone marrow, or fresh, unfixed biopsy core, collected aseptically, in RPMI or similar culture medium or saline.  
**Infants:** 2 mL of blood or 0.5-1 mL of bone marrow or fresh, unfixed biopsy core, collected aseptically, in RPMI or similar culture medium or saline. | Room temperature.  
If shipped, use cold pack. No dry ice. Do not put specimen directly against ice pack. |
| Peripheral Blood                | 1-2 tubes in **EDTA** (**lavender top**) and freshly prepared smear.  
Provide WBC and differential count results or order those tests. | Room temperature.  
If shipped, use cold pack. No dry ice. Do not put specimen directly against ice pack. |
| Bone Marrow Aspirate            | 3-5 mL in **EDTA** (**lavender top**) and freshly prepared smear.  
Provide WBC and differential count results or order those tests. | Room temperature.  
If shipped, use cold pack. No dry ice. Do not put specimen directly against ice pack. |
| Bone Marrow Biopsy              | Fresh, unfixed biopsy core in RPMI, similar culture medium, or saline.               | Room temperature.  
If shipped, use cold pack. No dry ice. Do not put specimen directly against ice pack. |
| Fine Needle Aspirate            | Collect in RPMI or similar culture medium and freshly prepared smear or cytology evaluation. | Room temperature.  
If shipped, use cold pack. No dry ice. Do not put specimen directly against ice pack. |
| Fluids (CSF, pleural, etc.)     | Collect in sterile container, tube, or bag.  
Do not use anticoagulant unless grossly contaminated with blood. | Room temperature.  
If shipped, use cold pack. No dry ice. Do not put specimen directly against ice pack. |
| Fresh Tissue (unfixed)          | Keep moist in RPMI or saline at all times.  
Send a representative portion of the biopsy fixed in formalin, if available. | Room temperature. If shipped, use cold pack. No dry ice. Do not put specimen directly against ice pack. |
| Histology slides for consultation | Place slides in unbreakable container. Submit corresponding paraffin blocks.       | Room temperature only.                                        |
| Immunophenotyping               | 3-5 mL in **EDTA** (**lavender top**).  
Provide WBC and differential count results from a specimen **collected at the same time** as the immunophenotyping specimens. | Room temperature. If shipped, use cold pack. No dry ice. Do not put specimen directly against ice pack. |
Transplant Laboratory

UF Health Medical Lab – Rocky Point

Hours of Availability: Monday to Sunday, 24 hours
Main Phone: 352-265-0072
Fax: 352-265-0626
After-Hours On-Call Technologist: 352-258-3856

Manager: Michael Passwater
Email: mpas0001@shands.ufl.edu
Office Phone: 252-917-2295

Medical Director: Steven Goldstein, MD
Email: goldss@ufl.edu
Office Phone: 252-627-2223

Technical Coordinator: Mai Ta
Email: tamh@shands.ufl.edu
Office Phone: 352-265-0072

Associate Medical Director: Gregory Olsen, MD
Email: golsen@ufl.edu
Office Phone: 352-627-2030

Scope of Service: The Transplant Laboratory performs compatibility tests, transplant monitoring for bone marrow, kidney, pancreas, heart, lung, liver transplantation, and other immunological testing using the following methodologies: molecular, flow cytometric, and serologic. The tests offered are utilized according to the clinical application.

Services Provided:
1. Solid Organ Transplant Evaluation for:
   - Heart, Liver, Kidney, Lung, Pancreas
2. Bone Marrow Transplant Evaluation
3. Other Immunological Evaluation:
   - Disease association (B27, DR15, etc.)
   - HLA typing for platelet transfusions.

STAT Requests:
- During regular hours, call laboratory at 352-265-0072 and Customer Service at 352-265-0522 for rush pick-up and delivery to Rocky Point.
- After hours, call on-call technologist at 352-258-3856.

UF Health Shands Transplant Programs request all transplant-related testing. Please contact individual transplant program for any questions.

<table>
<thead>
<tr>
<th>Type of Patient</th>
<th>Sample Requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Deceased Donor Workups</td>
<td>7 ACD-A tubes</td>
</tr>
<tr>
<td>HLA Typing</td>
<td>3 ACD-A tubes</td>
</tr>
<tr>
<td>HLA Antibody Testing</td>
<td>1 SST tube</td>
</tr>
<tr>
<td>Living Renal or Liver Donor Evaluation</td>
<td>5 ACD-A tubes</td>
</tr>
<tr>
<td>Crossmatch</td>
<td>1 SST tube</td>
</tr>
<tr>
<td>HLA Typing for Platelets</td>
<td>3 ACD-A tubes</td>
</tr>
<tr>
<td>Disease Association</td>
<td>1 ACD-A tube</td>
</tr>
<tr>
<td>Identity Confirmation, Post-Bone Marrow Transplant Engraftment, or GVHD Evaluation</td>
<td>1 ACD-A tube</td>
</tr>
<tr>
<td>HLA Typing Confirmation</td>
<td>2 ACD-A tubes</td>
</tr>
</tbody>
</table>
# Clinical Consultants

<table>
<thead>
<tr>
<th>Medical Director</th>
<th>Department</th>
<th>Telephone</th>
<th>Fax</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jesse Kresak, MD</td>
<td>CLIA Director – Shands Hospital, Medical Plaza, and Rocky Point Director of Anatomic Pathology</td>
<td>352-627-9253</td>
<td>352-627-9271</td>
</tr>
<tr>
<td>William Winter, MD</td>
<td>Clinical Laboratory Support Center (CLSC) and Point of Care (POC)</td>
<td>352-294-5540</td>
<td>352-265-0447</td>
</tr>
<tr>
<td>Neil Harris, MD</td>
<td>Core Lab, SHED, KED, Florida Surgical Center (FSC), Oaks Surgical Center (OSC), and ShandsCair Pensacola</td>
<td>352-594-4717</td>
<td>352-265-0447</td>
</tr>
<tr>
<td>Stacy Beal, MD</td>
<td>Microbiology, Florida Surgical Center (FSC), and Oaks Surgical Center (OSC)</td>
<td>352-594-4952</td>
<td>352-265-0447</td>
</tr>
<tr>
<td>Maximo Marin, MD</td>
<td>Core Lab and Cancer Center Lab (CCL – Medical Plaza)</td>
<td>352-594-4953</td>
<td>352-265-0447</td>
</tr>
<tr>
<td>Danielle Petty, DO</td>
<td>Autopsy</td>
<td>352-273-5891</td>
<td>352-627-9271</td>
</tr>
<tr>
<td>Robert Seifert, MD</td>
<td>Hematopathology</td>
<td>352-627-2039</td>
<td>352-265-1063</td>
</tr>
<tr>
<td>Marie Rivera-Zengotita, MD</td>
<td>Surgical Pathology</td>
<td>352-672-9251</td>
<td>352-627-9271</td>
</tr>
<tr>
<td>Marino Leon, MD</td>
<td>Cytopathology</td>
<td>352-627-9260</td>
<td>352-627-9271</td>
</tr>
<tr>
<td>Sara Falzarano, MD, PhD</td>
<td>Immunohistochemistry (IHC)</td>
<td>352-627-9254</td>
<td>352-627-9271</td>
</tr>
<tr>
<td>Steven Goldstein, MD</td>
<td>Transplant (HLA)</td>
<td>352-627-2223</td>
<td>352-265-9901</td>
</tr>
<tr>
<td>Joanna Chaffin, MD</td>
<td>Histology</td>
<td>352-627-2052</td>
<td>352-627-9271</td>
</tr>
<tr>
<td>Peter Pelletier, MD</td>
<td>Blood Bank</td>
<td>352-594-0490</td>
<td>352-265-0447</td>
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<tr>
<td>Faisal Mukhtar, MD</td>
<td>Blood Bank</td>
<td>352-594-0487</td>
<td>352-265-0447</td>
</tr>
<tr>
<td>Gregory Olsen, MD</td>
<td>Blood Bank and Transplant</td>
<td>352-627-2030</td>
<td>352-265-0626</td>
</tr>
</tbody>
</table>

**Pathology Resident On-Call:**

352-213-1201 (9 AM to 5 PM Weekdays)

352-213-6811 (5 PM to 9 AM Weekdays, Weekends, and Holidays)
Patient Information Sheets for SARS-CoV-2 Assays

FACT SHEET FOR PATIENTS
BioFire Diagnostics, LLC
BioFire® Respiratory Panel 2.1-EZ (RP2.1-EZ)

Updated: August 30, 2021
Coronavirus Disease 2019 (COVID-19)

You are being given this Fact Sheet because your sample(s) was tested for the Coronavirus Disease 2019 (COVID-19) using the BioFire Respiratory Panel 2.1-EZ (RP2.1-EZ). The BioFire RP2.1-EZ is a molecular (PCR) test authorized for use on respiratory specimens collected from individuals suspected of COVID-19 by their healthcare provider.

This Fact Sheet contains information to help you understand the risks and benefits of using this test for the diagnosis of COVID-19. After reading this Fact Sheet, if you have questions or would like to discuss the information provided, please talk to your healthcare provider.

For the most up to date information on COVID-19 please visit the CDC Coronavirus Disease 2019 (COVID-19) webpage:
https://www.cdc.gov/COVID19

What is COVID-19?
COVID-19 is caused by the SARS-CoV-2 virus which is a new virus in humans causing a contagious respiratory illness. COVID-19 can present with a mild to severe illness, although some people infected with COVID-19 may have no symptoms at all. Older adults and people of any age who have underlying medical conditions have a higher risk of severe illness from COVID-19. Serious outcomes of COVID-19 include hospitalization and death. The SARS-CoV-2 virus can be spread to others not just while one is sick, but even before a person shows signs or symptoms of being sick (e.g., fever, coughing, difficulty breathing, etc.). A full list of symptoms of COVID-19 can be found at the following link: https://www.cdc.gov/-coronavirus/2019-ncov/symptoms-testing/symptoms.html

What is the BioFire RP2.1-EZ?
The test is designed to detect the virus that causes COVID-19 in nasopharyngeal swabs. This test can also detect 15 other common pathogens that cause respiratory infections.

Why was my sample tested?
You were tested because your healthcare provider believes you may have been exposed to the virus that causes COVID-19 based on your signs and symptoms (e.g., fever, cough, difficulty breathing), and/or because:

- You live in or have recently traveled to a place where transmission of COVID-19 is known to occur, and/or
- You have been in close contact with an individual suspected of or confirmed to have COVID-19.

Testing of the samples will help find out if you may have COVID-19.

What are the known and potential risks and benefits of the test?
Potential risks include:

- Possible discomfort or other complications that can happen during sample collection.
- Possible incorrect test result (see below for more information).

Potential benefits include:

- The results, along with other information, can help your healthcare provider make informed recommendations about your care.
- The results of this test may help limit the spread of COVID-19 to your family and those you come in contact with.

Where can I go for updates and more information? The most up-to-date information on COVID-19 is available at the CDC General webpage: https://www.cdc.gov/COVID19. In addition, please also contact your healthcare provider with any questions/concerns.
FACT SHEET FOR PATIENTS
BioFire Diagnostics, LLC
BioFire® Respiratory Panel 2.1-EZ (RP2.1-EZ)

What does it mean if I have a positive test result?
If you have a positive test result for SARS-CoV-2, it is very likely that you have COVID-19. Therefore, it is also likely that you may be placed in isolation to avoid spreading the virus to others. You should follow CDC guidance to reduce the potential transmission of disease.

There is a smaller possibility that this test can give a positive result that is wrong (a false positive result) particularly when used in a population without many cases of COVID-19 infection. Your healthcare provider will work with you to determine how best to care for you based on the test results along with medical history, and your symptoms.

If you have a positive result for another respiratory pathogen (e.g., Influenza A), your healthcare provider will determine the best way to care for you based on the test results along with other factors in your medical history.

What does it mean if I have a negative test result?
A negative test result for SARS-CoV-2 means that the virus that causes COVID-19 was not found in your sample.

This test can also detect 15 other common pathogens that cause respiratory infections. If you have a negative result for the other 15 pathogens, it means that those pathogens were not found in your sample.

However, it is possible for this test to give a negative result that is incorrect (false negative) in some people with COVID-19. You might test negative if the sample was collected early during your infection. You could also be exposed to COVID-19 after your sample was collected and then have become infected.

This means that you could possibly still have COVID-19 even though the test result is negative. If your test is negative, your healthcare provider will consider the test result together with all other aspects of your medical history (such as symptoms, possible exposures, and geographical location of places you have recently traveled) in deciding how to care for you.

It is important that you work with your healthcare provider to help you understand the next steps you should take.

Is this test FDA-approved or cleared?
No. This test is not yet approved or cleared by the United States FDA. FDA may issue an Emergency Use Authorization (EUA) when certain criteria are met, which includes that there are no adequate, approved, available alternatives. The EUA for this test is supported by the Secretary of Health and Human Service’s (HHS’s) declaration that circumstances exist to justify the emergency use of in vitro diagnostics for the detection and/or diagnosis of the virus that causes COVID-19. This EUA will remain in effect (meaning this test can be used) for the duration of the COVID-19 declaration justifying emergency of IVDs, unless it is terminated or revoked by FDA (after which the test may no longer be used).

What are the approved alternatives?
Any tests that have received full marketing status (e.g., cleared, approved), as opposed to an EUA, by FDA can be found by searching the medical device databases here: https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/medical-device-databases. A cleared or approved test should be used instead of a test made available under an EUA, when appropriate and available. FDA has issued EUAs for other tests that can be found at: https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization

Where can I go for updates and more information? The most up-to-date information on COVID-19 is available at the CDC General webpage: https://www.cdc.gov/COVID19. In addition, please also contact your healthcare provider with any questions/concerns.
You are being given this Fact Sheet because your sample(s) was tested for the Coronavirus Disease 2019 (COVID-19) using the Xpert Xpress CoV-2/Flu/RSV plus test.

This Fact Sheet contains information to help you understand the risks and benefits of using this test for the diagnosis of COVID-19. After reading this Fact Sheet, if you have questions or would like to discuss the information provided, please talk to your healthcare provider.

For the most up to date information on COVID-19 please visit the CDC Coronavirus Disease 2019 (COVID-19) webpage:
https://www.cdc.gov/COVID19

What is COVID-19?
COVID-19 is caused by the SARS-CoV-2 virus which is a new virus in humans causing a contagious respiratory illness. COVID-19 can present with a mild to severe illness, although some people infected with COVID-19 may have no symptoms at all. Older adults and people of any age who have underlying medical conditions have a higher risk of severe illness from COVID-19. Serious outcomes of COVID-19 include hospitalization and death. The SARS-CoV-2 virus can be spread to others not just while one is sick, but even before a person shows signs or symptoms of being sick (e.g., fever, coughing, difficulty breathing, etc.). A full list of symptoms of COVID-19 can be found at the following link: https://www.cdc.gov/Coronavirus/2019-ncov/symptoms-testing/symptoms.html.

What is Influenza?
Influenza (flu) is a contagious respiratory illness caused by influenza viruses. Influenza viruses can cause mild to severe illness. Serious outcomes of the flu can result in hospitalization or death. Some people, such as older people, young children, and people with certain underlying health conditions, are at higher risk for serious flu complications. There are two main types of influenza viruses: types A and B. Both type A and B influenza viruses regularly spread in people, and are responsible for seasonal flu each year. Influenza viruses can be spread to others before and after a person shows signs and symptoms of being sick.

What is the Xpert Xpress CoV-2/Flu/RSV plus test?
The test is designed to simultaneously detect four types of viruses: two types that cause influenza (type A and Type B), RSV and the virus that causes COVID-19 (SARS-CoV-2) in nasopharyngeal swabs, nasal swabs, or nasal wash/aspirate specimens.

Where can I go for updates and more information? The most up-to-date information on COVID-19 is available at the CDC General webpage: https://www.cdc.gov/COVID19. In addition, please also contact your healthcare provider with any questions/concerns.
FACT SHEET FOR PATIENTS
Cepheid
Xpert® Xpress CoV-2/Flu/RSV plus

September 10, 2021
Coronavirus Disease 2019 (COVID-19)

What are the known and potential risks and benefits of the test?

Potential risks include:
- Possible discomfort or other complications that can happen during sample collection.
- Possible incorrect test result (see below for more information).

Potential benefits include:
- The results, along with other information, can help your healthcare provider make informed recommendations about your care.
- The results of this test may help limit the spread of COVID-19 to your family and those with whom you come in contact.

What does it mean if I have a positive test result for SARS-CoV-2?
If you have a positive test result, it is very likely that you have COVID-19. Therefore, it is also likely that specific isolation or social distancing action will be recommended so that you can avoid spreading the virus to others. You should follow CDC guidance to reduce the potential transmission of disease.

There is a smaller possibility that this test can give a positive result that is wrong (a false positive result) particularly when used in a population without many cases of COVID-19 infection. Your healthcare provider will work with you to determine how best to care for you based on the test results along with medical history and your symptoms.

What does it mean if I have a positive test result for influenza A, influenza B, and/or RSV?
If you have a positive test result for the presence of influenza A, influenza B, and/or RSV viruses, it is very likely that you have a viral infection. If you have a positive result for one of these viruses, your healthcare provider will determine the best way to care for you based on the test results along with other factors in your medical history. There is a very small chance that this test can give a positive result that is wrong (a false positive result). Your healthcare provider will work with you to determine how best to care for you based on the test results, medical history, and your symptoms.

What does it mean if I have a positive test result for SARS-CoV and influenza A, influenza B, and/or RSV viruses?
It is possible for an individual to be infected with one or more viruses at the same time. Your healthcare provider will work with you to determine how best to care for you based on these test results, your medical history, and your symptoms.

What does it mean if I have a negative test result for SARS-CoV-2, influenza A, influenza B, and/or RSV viruses?
A negative test result for any of the viruses detected by this test means that these viruses were not found in your sample. For COVID-19, influenza A, influenza B, or RSV, a negative test result for a sample collected while a person has symptoms usually means that SARS-CoV-2, influenza A, influenza B, or RSV viruses are unlikely to be the cause of your current illness.

However, it is possible for this test to give a negative result that is incorrect (false negative) in some people with COVID-19, influenza or RSV. You might test negative if the sample was collected early during your infection. You could also be exposed to these viruses after your sample was collected and then have become infected.

Your healthcare provider will consider the test result together with your symptoms, possible exposures and other health information in deciding how to care for you.

Where can I go for updates and more information? The most up-to-date information on COVID-19 is available at the CDC General webpage: https://www.cdc.gov/COVID19. In addition, please also contact your healthcare provider with any questions/concerns.

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Cepheid
Xpert® Xpress CoV-2/Flu/RSV plus
September 10, 2021
Coronavirus Disease 2019 (COVID-19)

It is possible that your healthcare provider may collect another sample in order to repeat the test or conduct other tests.

It is important that you talk with your healthcare provider to help you understand what your results mean and the next steps you should take.

Is this test FDA-approved or cleared?
No. This test is not yet approved or cleared by the United States FDA. FDA may issue an Emergency Use Authorization (EUA) when certain criteria are met, which includes that there are no adequate, approved, available alternatives. The EUA for this test is supported by the Secretary of Health and Human Service’s (HHS’s) declaration that circumstances exist to justify the emergency use of in vitro diagnostics for the detection and/or diagnosis of the virus that causes COVID-19. This EUA will remain in effect (meaning this test can be used) for the duration of the COVID-19 declaration justifying emergency of IVDs, unless it is terminated or revoked by FDA (after which the test may no longer be used).

What are the approved alternatives?
There are approved/cleared influenza and RSV tests. Any tests that have received full marketing status (e.g., cleared, approved), as opposed to an EUA, by FDA can be found by searching the medical device databases here: https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/medical-device-databases. A cleared or approved test should be used instead of a test made available under an EUA, when appropriate and available. FDA has issued EUAs for other tests that can be found at: https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.

Where can I go for updates and more information? The most up-to-date information on COVID-19 is available at the CDC General webpage: https://www.cdc.gov/COVID19. In addition, please also contact your healthcare provider with any questions/concerns.
You are being given this Fact Sheet because your sample(s) was tested for the Coronavirus Disease 2019 (COVID-19) using the GeneFinder COVID-19 Plus RealAmp Kit.

This Fact Sheet contains information to help you understand the risks and benefits of using this test for the diagnosis of COVID-19. After reading this Fact Sheet, if you have questions or would like to discuss the information provided, please talk to your healthcare provider.

For the most up to date information on COVID-19 please visit the CDC Coronavirus Disease 2019 (COVID-19) webpage: https://www.cdc.gov/COVID19

What is COVID-19?
COVID-19 is caused by the SARS-CoV-2 virus which is a new virus in human causing a contagious respiratory illness. COVID-19 can present with a mild to severe illness, although some people infected with COVID-19 may have no symptoms at all. Older adults and people of any age who have underlying medical conditions have a higher risk of severe illness from COVID-19. Serious outcomes of COVID-19 include hospitalization and death. The SARS-CoV-2 virus can be spread to others not just while one is sick, but even before a person shows signs or symptoms of being sick (e.g., fever, coughing, difficulty breathing, etc.). A full list of symptoms of COVID-19 can be found at the following link: https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html.

What is the GeneFinder COVID-19 Plus RealAmp Kit?
The test is designed to detect the virus that causes COVID-19 in respiratory specimens, for example nasal or oral swabs.

Why was my sample tested?
You were tested because your healthcare provider believes you may have been exposed to the virus that causes COVID-19 based on your signs and symptoms (e.g., fever, cough, difficulty breathing), and/or because:

- You live in or have recently traveled to a place where transmission of COVID-19 is known to occur, and/or
- You have been in close contact with an individual suspected of or confirmed to have COVID-19.

Testing of the samples will help find out if you may have COVID-19.

What are the known and potential risks and benefits of the test?
Potential risks include:
- Possible discomfort or other complications that can happen during sample collection.
- Possible incorrect test result (see below for more information).

Potential benefits include:
- The results, along with other information, can help your healthcare provider make informed recommendations about your care.
- The results of this test may help limit the spread of COVID-19 to your family and those you come in contact with.

What does it mean if I have a positive test result?
If you have a positive test result, it is very likely that you have COVID-19. Therefore, it is also likely that you may be placed in isolation to avoid spreading the virus to others. You should follow CDC guidance to reduce the potential transmission of disease.

There is a smaller possibility that this test can give a positive result that is wrong (a false positive result) particularly when used in a population without many cases of COVID-19 infection. Your healthcare provider

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FACT SHEET FOR PATIENTS
OSANG Healthcare
GeneFinder COVID-19 Plus RealAmp Kit

Will work with you to determine how best to care for you based on the test results along with medical history, and your symptoms.

What does it mean if I have a negative test result? A negative test result means that the virus that causes COVID-19 was not found in your sample.

However, it is possible for this test to give a negative result that is incorrect (false negative) in some people with COVID-19. You might test negative if the sample was collected early during your infection. You could also be exposed to COVID-19 after your sample was collected and then have become infected.

This means that you could possibly still have COVID-19 even though the test result is negative. If your test is negative, your healthcare provider will consider the test result together with all other aspects of your medical history (such as symptoms, possible exposures, and geographical location of places you have recently traveled) in deciding how to care for you.

It is important that you work with your healthcare provider to help you understand the next steps you should take.

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What are the approved alternatives? Any tests that have received full marketing status (e.g., cleared, approved), as opposed to an EUA, by FDA can be found by searching the medical device databases here: https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/medical-device-databases. A cleared or approved test should be used instead of a test made available under an EUA, when appropriate and available. FDA has issued EUAs for other tests that can be found at: https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.

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