

THE DELTA PATHOLOGY GROUP, L.L.C.

Specimen Service Manual



Patient Preparation
Specimen Collection
Labeling
Fixation
Handling
Transportation



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Contact Information

Client Services:

Location	Address	Phone
Shreveport	2915 Missouri	318-621-8820
Alexandria	211 Fourth St.	318-769-3219
Monroe	309 Jackson Street	318-966-4886
W. Monroe	503 McMillan Road	318-329-8830
Lafayette	4801 Ambassador Caffery	337-470-4638
Gretna	1141 Whitney Ave., Bldg. 3	504-361-3757
Meridian	1512 20 th Ave., Meridian, MS	601-483-8300

Billing Information: 318-841-9526

Director: Debbie Rhodes

Assistant Director: Becky Hunter

Supply Orders:

Shreveport	Fax: 318-621-0108	Phone: 318-364-2087
Alexandria	Fax: 318-769-3907	Phone: 318-769-3219
Monroe	Fax: 318-966-4423	Phone: 318-966-4886
West Monroe	Fax: 318-329-8833	Phone: 318-329-8830
Lafayette	Fax: 337-470-4051	Phone: 337-470-4638
Gretna	Fax: 504-361-3132	Phone: 504-361-3757
Meridian, MS	Fax: 601-484-7776	Phone: 601-483-8300

Websites:

www.deltapathology.com

Medical Staff Directory

The Delta Pathology Group, L.L.C., is an independent pathology group with services and laboratories throughout Louisiana. The group is comprised of pathologists with boards in anatomic and clinical pathology. Specialties represented in the group include Dermatopathology, Cytopathology, Hematopathology, Breast and GI Pathology providing extensive diagnostic abilities for clinicians and patients.

The Delta Pathology Group, L.L.C. provides services for hospitals throughout Louisiana. The pathologists serve as Laboratory Directors and provide twenty-four hour coverage for the needs of staff, physicians and patients.

The Delta Pathology Group, L.L.C. facilities are accredited by the College of American Pathologists and/or CLIA accrediting bodies. The pathologists also serve as inspectors for other laboratories through the CAP peer review program.

Shreveport:

Delta Pathology Group, LLC, 2915 Missouri St., Shreveport, LA 71109
CAP # 20113-02 CLIA # 19D0463379

Delta Pathology Group, LLC, 2219 Line Avenue, Shreveport, LA 71104
CAP # 20101-01 CLIA # 19D0664460

Delta Pathology Group, LLC @ Shreveport Surgery, 745 Olive Street, Shreveport, LA 71104
CAP # 7225076 CLIA # 19D1099427

Abreo, Fleurette – Anatomic and Clinical Pathology

Ferguson, Jill – Cytopathology, Anatomic and Clinical Pathology

Heard, J. Steven – Cytopathology, Anatomic and Clinical Pathology

Khare, Vivek – Dermatopathology, Anatomic and Clinical Pathology

Koehler, Jonathan – Anatomic and Clinical Pathology

McLaren, Bernadette – Anatomic and Clinical Pathology, Fellowship Training Breast Pathology

Mastrodomenico, Matthew – Hematopathology, Anatomic and Clinical Pathology

Owings, Richard – Anatomic and Clinical Pathology, Fellowship Training Breast Pathology

Patel, Kirtesh – Hematopathology, Anatomic and Clinical Pathology

Sardenga, Louis – Anatomic and Clinical Pathology

Sholl, Andrew B. – Cytopathology, Anatomic and Clinical Pathology

Siskron, F., III – Anatomic and Clinical Pathology

Wellman, Gregory – Anatomic and Clinical Pathology, Fellowship Training GI & Liver
Pathology

Wesche, William – Dermatopathology, Anatomic & Clinical Pathology

Monroe/ W. Monroe:

Delta Pathology Group, LLC @ St. Francis Medical, 309 Jackson St., Monroe, LA 71201
CAP # 7204273 CLIA # 19D1075141

Delta Pathology Group, LLC @ Glenwood Regional Medical Center, 503 McMillan Road, West
Monroe, LA 71291
CAP # 2013902 CLIA # 19D0966840

Blanchard, Richard – Anatomic and Clinical Pathology
Blanchard, Stephen – Anatomic and Clinical Pathology
Kidd, Laura R. – Anatomic and Clinical Pathology, Fellowship Training Renal Pathology
Liles, William, Jr. – Anatomic and Clinical Pathology
Maxwell, John, II – Anatomic and Clinical Pathology
Pankey, Lee – Anatomic and Clinical Pathology
Smith, Nancy – Anatomic and Clinical Pathology

Alexandria:

Delta Pathology Group, LLC @ Rapides Regional, 211 Fourth St., Alexandria, LA 71301
CAP # 2014404 CLIA # 19D0935738

Delta Pathology Group, LLC @ St. Francis Cabrini, 3330 Masonic Dr., Alexandria, LA 71301
CAP # 7523234 CLIA # 19D2014888

Barker, Jared – Anatomic and Clinical Pathology, Fellowship Training GI & Liver Pathology
Collins, George R. – Anatomic and Clinical Pathology, Dermatopathology
Eggers, Jordan – Anatomic and Clinical Pathology
Herrington, Bruce – Cytopathology, Anatomic and Clinical Pathology
Marrazzo, Joseph C. – Anatomic and Clinical Pathology
Miguez, Michael – Cytopathology, Anatomic and Clinical Pathology
Redfield, Samantha – Hematopathology, Anatomic and Clinical Pathology

Lafayette:

Delta Pathology Group, LLC @ Our Lady of Lourdes, 4801 Ambassador Caffery, Lafayette, LA 70508

CAP # 7520585 CLIA # 19D2010173

Delta Pathology Group, LLC @ Our Lady of Lourdes Womens and Childrens Hospital, 4600 Ambassador Caffery, Lafayette, LA 70508

CAP # 7524918 CLIA # 19D2014889

Crosier, M'Liss – Anatomic and Clinical Pathology

Hanson, Stephanie – Anatomic and Clinical Pathology

Langford, Erin – Hematopathology, Cytopathology, Anatomic and Clinical Pathology

Williams, R. Bruce – Anatomic and Clinical Pathology

Lake Charles:

Delta Pathology Group, LLC @ Lake Charles Memorial Hospital, 1701 Oak Park Blvd., Lake Charles, LA 70601

CAP # 2004301 CLIA # 19D0461791

Best, Anna – Anatomic and Clinical Pathology

Thibodeaux, Joel – Anatomic and Clinical Pathology

Covington/Slidell:

Delta Pathology Group @ Lakeview Hospital, 95 Judge Tanner Blvd., Covington, LA 70433
CLIA # 19D2050551

Delta Pathology Group, LLC @ St. Tammany Parish Hospital, 1202 S. Tyler St., Covington, LA
70433
CAP# 8067283 CLIA # 19D0663180

Delta Dermatopathology, 229 West Causeway Approach, Ste. 209, Mandeville, LA 70448
CLIA #19D1056551

Delta Pathology Group, LLC @ Slidell Memorial Hospital, 1001 Gause Blvd., Slidell, LA
70458
CAP# 8537355 CLIA# 19D2160872

Bartholomew, Pamela – Anatomic and Clinical Pathology
Henderson, Jeremy – Hematopathology, Anatomic and Clinical Pathology
Loose, Jeffrey – Anatomic and Clinical Pathology
Nicotri, Thomas, Jr. – Dermatology, Dermatopathology
Roberts, Jordan A. – Anatomic and Clinical Pathology, Fellowship Training in GI Pathology
Candal, Rebecca – Anatomic and Clinical Pathology

Gretna/NOLA:

Delta Pathology Group, LLC, 1141 Whitney Ave., Bldg. #3, Gretna, LA 70056
CAP # 7209452 CLIA # 19D0458894

Delta Pathology Group, LLC @ West Jefferson Medical Center, 1101 Medical Center Blvd.,
Marrero, LA 70072
CAP # 8037427 CLIA # 19D2036128

Delta Pathology Group, LLC @ Touro Infirmary, 1401 Foucher St., New Orleans, LA 70115
CAP# 8236658 CLIA# 19D2135612

Brown, James, Jr. – Anatomic and Clinical Pathology
Casey, Terence T. – Hematopathology, Anatomic and Clinical Pathology
Farris, K. Barton – Anatomic and Clinical Pathology
LeRoy, Michael A. – Anatomic and Clinical Pathology, Blood Banking/Transfusion Medicine
Long, William Paul – Dermatopathology, Anatomic and Clinical Pathology
Luer, William – Anatomic and Clinical Pathology

Meridian/Laurel, MS:

DTCG - Delta Pathology Group, LLC, 1512 20th Ave., Meridian, MS 39301
CAP# 1606811 CLIA# 25D0651894

DTCG - Delta Pathology Group, LLC @ Anderson Regional Medical Center, 2124 14th St.,
Meridian, MS 39301
CAP# 7183429 CLIA# 25D1011258

DTCG - Delta Pathology Group, LLC @ South Central Regional Medical Center, 1220 Jefferson
St., Laurel, MS 39440
CLIA# 25D0980061

Brents, Melissa J. – Anatomic and Clinical Pathology

Hicks, Karen – Cytopathology, Anatomic and Clinical Pathology

Hughes, III, R. Condon – Dermatopathology, Anatomic and Clinical Pathology

Sims, Hillary Brooke – Cytopathology, Anatomic and Clinical Pathology

Sprabery, A. Patrick – Cytopathology, Anatomic and Clinical Pathology

Wilkinson, Brian L. – Anatomic and Clinical Pathology

Scope of Services

Diagnostic Services and Consultation

- Anatomic and clinical pathology
- Full service anatomic pathology laboratory serving local and regional clients
- Advanced testing methodologies available in-house
- Rapid test reporting through our electronic reporting system
- Rapid turn-around time of test results

Anatomic Pathology Service

- Breast Pathology
- Cytopathology, including thin layer technology
- Dermatopathology
- Gastrointestinal Pathology
- Genitourinary Pathology
- Gynecologic Pathology
- Hematopathology
- Pediatric Pathology
- Surgical Pathology
- Veterinary Pathology
- Flow Cytometry Service
- Immunohistochemistry and FISH Technology
- Molecular & Cytogenetic testing

Support Service

- Consultative Services through Pathology Resource Network, L.L.C.
 - Administrative Consultation
 - Management
 - Compliance Service
 - Billing Services
 - Accounting /Payroll
 - Human Resources
- Stat Service
- Courier Representative
- Client Service
- Client Representative
- Pathologist availability 24/7
- Laboratory Directorship
- Information Technology
- Connectivity
- EMR
- Web Portal

Quality Control and Quality Assurance Practice

Anatomic Pathology:

- I. Quality Assessment
 - Random review of all surgical pathology diagnoses.
 - 100% review of all frozen section diagnoses.
 - 100% review of consultations from outside sources.
- II. Daily intradepartmental consultations.
- III. Clinical information and previous test results are compared with the current testing for internal quality assurance.
- IV. Pathologists participate in the College of American Pathologists proficiency testing surveys and Performance Improvement Program (PIP).

Cytology:

- I. The quality control rescreen of negative PAP smears exceeding the CLIA mandated minimum of 10%.
- I. Continuous monitoring of cytotechnologists' performance with appropriate remedial actions including reassessment of workload limits and focused quality control procedures resulting in quality improvement.
- III. Clinical information and previous test results are compared with the current testing for internal quality assurance.
- IV. The cytotechnologists and pathologists participate in two national glass slide programs designed by cytopathology educators and professionals to provide diagnostic assessment, continuing education, and quality assurance within the laboratory. Workshops, seminars, and ASCP teleconferences are also attended.

Flow Cytometry and MDx:

- I. Extensive procedural and instrumental quality control.
- II. Subscribe to College of American Pathologists proficiency testing service to ensure competency of staff and quality of results.
- III. Clinical information and previous test results are compared with the current testing for internal quality assurance



NOTICE OF PRIVACY PRACTICES (Effective 8-19-13)
THIS NOTICE DESCRIBES HOW MEDICAL INFORMATION ABOUT YOU MAY BE USED AND DISCLOSED AND HOW YOU CAN GET ACCESS TO THIS INFORMATION. PLEASE READ IT

CHANGES TO THIS NOTICE

The Delta Pathology Group, L.L.C. may change policies and privacy practices at any time. Changes will apply to your protected health information (PHI) we already have, as well as new information obtained after the change occurs. You will receive a copy of this notice each time you register at one of our sites for laboratory services

HOW WE MAY USE AND DISCLOSE YOUR PROTECTED HEALTH INFORMATION

Business Associates of Delta must now also comply with these same privacy practices. We may use and disclose medical and billing information about you for treatment (such as sending medical information about you to a specialist as part of a referral); to obtain payment for treatment (such as sending billing information to your insurance company or Medicare); and to support our health care operations (such as comparing patient data to improve treatment methods).

We may use or disclose medical and billing information about you without your prior authorization for several other reasons, subject to certain requirements for: public health purposes, abuse or neglect reporting, health oversight audits or inspections, research studies, funeral arrangements, organ donation, workers/ compensation purposes, or during emergencies. We may also disclose PHI when required by law, such as in response to a request from law enforcement officials in specific circumstances, or in response to valid judicial or administrative orders.

We may disclose medical and billing information about you to a friend or family member who is involved in your medical care or to disaster relief authorities so that your family can be notified of your location and condition.

OTHER USES OF MEDICAL INFORMATION

In any other situation not covered by this Notice, we will ask for your written permission before using or disclosing your PHI; disclosures for marketing purposes or that constitute a sale of PHI will require your authorization. If you choose to authorize our use or disclosure of your PHI, you can later revoke that permission by notifying us in writing of your decision.

YOUR RIGHTS REGARDING MEDICAL INFORMATION ABOUT YOU

You may opt out of receiving fundraising communications, restrict certain PHI disclosures to a health plan when you pay out of pocket in full for the health care item or service, and you will be notified if there is any breach of unsecured PHI.

In most cases, you have the right to look at or obtain a copy of your medical and billing information contained in the designated record set that we use. If you request copies, we may charge the cost of copying, related supplies or postage. If we deny your request to review or obtain a copy, you may submit a written request for a review of that decision.

If you believe information in your record is incorrect or if important information is missing, you have the right to request that we correct the record. Your request may be submitted in writing. A request for amendment must provide your reason for the amendment. We could deny the request to amend a record if the information was not created by us, if it is not part of the medical or billing information maintained by us, or if we determine that the record is accurate. You may appeal, in writing, a decision by us not to amend a record.

You have the right to a list of those instances where we have disclosed medical and billing information about you, other than treatment, payment, health care operations, or where you specifically authorized a disclosure. When you submit a written request, the request must state the time period desired for the accounting, which must be less than a 6 year period. You may receive the list in paper or electronic form. The first disclosure list request in a 12 month period will be provided to you at no cost; other requests will be charged in accordance with our cost to produce the list and we will inform you of the cost before you incur any charges.

You have the right to request that your medical and billing information be communicated to you in a confidential manner, such as sending mail to an address other than your home. You must notify us in writing of the specific way or location for us to use to communicate with you. You may request, in writing, that we not use or disclose PHI about you for treatment, payment or healthcare operations or to persons involved in your care except when specifically authorized by you, or when required by law, or in an emergency. We will inform you of our decision. You may request additional restrictions on the use or disclosure of information for treatment, payment or healthcare operations. We are not required to agree to the requested restriction except in the limited situation in which you or someone on your behalf pays in full for an item or service, and you request that information concerning such item or service not be disclosed to a health insurer.

COMPLAINTS

If you have any questions or if you are concerned that your privacy rights may have been violated, or you disagree with a decision we made about access to your records, you may contact our Privacy Office at 318-364-2042. You may send a written complaint to the U.S. Department of Health and Human Services Office of Civil Rights; the address will be given to you upon request. Under no circumstances will you be penalized or retaliated against for filing a complaint.

OUR PLEDGE TO YOU

We understand that medical and billing information about you is personal. We are committed to protecting the privacy of your medical and billing information. We create test report records and information needed to provide quality care and to comply with legal requirements. This Notice applies to all of your records we maintain, whether created by our staff, your personal physician, or reference laboratory. Your physician may have different policies or Notices regarding the doctor's use and disclosure of your medical and billing information created in his/her office. We are required by law to:

- Keep medical and billing information about you private
- Give you this Notice of our legal duties and privacy practices with respect to your PHI
- Follow the terms of the Notice currently in effect

Release of/or Burial of Fetal Demise Tissue

Release of Fetal Demise Tissue DOES NOT APPLY to a fetus of >20 weeks or >350 grams. Those must be buried by law.

Policy & Procedure Summary:

1. The law allows parents to dispose of any products of conception or fetal remains, if they so choose.
2. The Act **requires** the **facility in which the delivery occurred** to notify the parent(s) of this right.
 - The facility must provide a Notice of Parental Rights form to the parent(s) within 24 hours of the miscarriage/fetal demise.
 - That form must be returned by the parent(s) to the facility within 48 hours of receipt of the notification if the parent(s) wish to arrange for disposition of the remains.

Note: If the form is not received within 48 hours, disposal of the remains will be in accordance with LA Dept. of Health & Hospitals rules and regulation.
3. A copy of the Parental Rights Form **must be given to Delta Pathology** if the parent(s) completes and wishes to make arrangements with the funeral home.
 - If it is received after the specimen is sent to pathology, the Parental Rights Form should be delivered personally to Delta.
 - If the Delta site is off site from the hospital and can't be delivered personally, the form should be faxed and a phone call made to Delta (the next business day if after hours) that they are faxing/having faxed the Parental Rights Form.
 - If the form is incomplete, the facility will be contacted and the form returned to the facility to be properly completed.

Burial of the remains may be returned to the family, but if through a funeral home:

- Delta will contact the funeral home when the specimen is ready for pick up (after completion of the pathology report).
- If there are no POC in the specimen, Delta will notify the physician and the facility.
- If only blocks remain after the gross, Delta will notify the facility that no tissue remains for interment.
- If the funeral home does not pick up the specimen within 72 hours of notification that the remains are ready to be released, the specimen(s) is disposed of by the normal process.

Client Instructions for Completing Requisition

The information required is essential to assure positive patient identification, improve diagnostic accuracy, compare clinical information, and to compare the current findings with other test results. ***Italics text = Required Information***

The histology requisition requirements are as follows:

1. The *patient's legal name* (no nicknames). If prior specimens have been submitted with another name within the past ten years, please include this information in parentheses.
2. Patient's address and phone number.
3. The *Social Security Number, if available or other unique identifier such as the patient medical record number* (vital for positive patient identification).
4. The *date of birth* (vital for positive patient identification).
5. *Sex* of patient.
6. Name and address of the *physician, legally authorized person ordering the test*, or name and address of the *laboratory referring the specimen*.
7. *Date of collection* and time. (Time of collection must be entered for breast tissue due to regulations regarding proper fixation time.)
8. *Mark test requested*. (Refer to specified testing sections of Service Manual)
9. *Specimen Source*
10. Individual responsible for bill.
11. *Insurance information* for billing.
12. *Any pertinent medical history*.

Additional cytology requisition requirements are as follows:

1. The *source of the specimen* is essential when assessing specimen adequacy of PAP smears (i.e., vaginal, cervix, endocervix, vaginal cuff, cervical stump). The specimen source must also be provided for non-gynecological specimens.
2. Indicate if a Pap is a conventional glass slide or a liquid based methodology.

3. If special stains are required on non-gynecological specimens, specify the type under “other.”
4. *Advanced Beneficiary Notice (ABN)* is a separate form required for a *Medicare patient* that does not have a diagnosis placing them at risk for gynecological cancer.
5. *Applicable clinical information* and the *LMP (last menstrual period)*.
6. *Medicare information regarding the type of PAP* under MEDICARE ONLY.
7. *High risk factors for gynecological cancer*.
8. *Previous abnormal PAP(s), treatment, or gynecological biopsies* (this includes chemotherapy, radiation, and history of cancer).
9. *Any pertinent patient history*.

Custom printed requisitions available are:

- **Histology**
- **Cytology**
- **Dermatopathology**
- **Gastroenterology**
- **Breast**

Always verify your hospital/ clinic/ physician name on your custom printed requisitions upon receipt to ensure you have the correct account information. This ensures that patient reports are directed back to the correct account.

Client Specimen Labeling Requirements

Surgical pathology specimens must be labeled and requisitions prepared in the room where the surgical procedure is performed at the time of collection.

This applies to labeling for:

- All surgical pathology
- All non-gynecological cytology specimens
- All gynecological cytology specimens
- HPV, GC, CT testing
- All flow cytometry
- All cytogenetics and molecular testing, as applicable

The specimen container may be in the form of a pathology specimen container, collection tube, a cup, swab, slide or other form of specimen storage.

The patient's name is a mandatory requirement. The patient's name and second identifier should match the information on the submitting requisition. Secondary identifiers include:

- Date of birth
- Social security number
- Unique random identifier (i.e. patient medical record number)

Personnel must positively identify the patient by checking at least two identifiers at the time of specimen collection. Identify specimen by clearly labeling the specimen container(s) with patient's first and last name and second identifier, in addition to the specimen site (as applicable).

Multiple containers should be identified with the specimen site (as applicable) and **TWO** identifiers.

IMPORTANT NOTE: If preprinted labels are utilized, verify patient information before specimen labeling. The identifying label with two patient identifiers must be attached to the specimen container(s) AT THE TIME OF COLLECTION. DO NOT PRE-LABEL SPECIMEN CONTAINER(S).

Client Slide Labeling

Personnel must positively identify the patient by checking at least two identifiers at the time of specimen collection. Write the patient's first and last name and a second identifier on the frosted end of a glass slide with a #2 lead pencil **AT THE TIME OF COLLECTION. DO NOT PRE-LABEL SLIDE(S).**

NOTE: Prepared slides submitted to the laboratory - if the slides only contain one identifier, they MUST BE securely submitted in a container labeled with two identifiers.

Labeling of cardboard slide holder IS NOT acceptable labeling; be sure that the slide is labeled.

Surgical Pathology

Preparation, Collection, Fixation and Transportation

Universal Precautions Required

PATIENT PREPARATION

Patient preparation for all histology specimens is according to the instructions specified by the patient's physician, unless otherwise specified in the procedure for each specimen type.

REQUISITION REQUIREMENTS

Refer to instructions for completing requisition section.

SPECIMEN LABELING

1. Identify tissue specimens by clearly labeling the specimen containers with patient's first and last name and another identifier. Each container must have two patient identifiers. These identifiers must be documented on the requisition. **SEE CLIENT SPECIMEN LABELING REQUIREMENTS SECTION IN THIS MANUAL.**
2. Containers must be identified with the specimen site on the container and the corresponding information on the requisition.
3. Use facility guidelines for obtaining proper patient identification.

COLLECTION, HANDLING, FIXATION AND TRANSPORTATION

NOTE: Unfixed specimens and/or large fixed specimens held overnight should be refrigerated.

Gross and Microscopic Examination

1. Surgical specimens for routine gross and microscopic examination are submitted in 10% neutral buffered formalin (NBF). The amount of 10% formalin should be 10 times the amount of tissue.
2. **DO NOT ADD 10% formalin** to cytology, flow, cytogenetics, and frozen section specimens, cultures, or specimens tested by another methodology that may require another fixative or no fixative.
3. Label specimen according to labeling instructions. Complete requisition according to requirements. Place the specimen container in the large section of a biohazard transport bag and seal the completed requisition in the outer section. Submit specimen to the laboratory.

Test Name:	Surgical Pathology
Methodology:	Standard Histology Process(es)
Performed:	Monday-Saturday. After hours and weekends, next business day
Reporting time:	Usually within 24-48 hours of receipt. Special studies may require more time
Specimen Collection Supplies:	10% Neutral Buffered Formalin If Flow Cytometry is requested on a surgical pathology specimen, please refer to the Flow Cytometry section in this manual. If DIF is requested, please refer below.
Specimen Collection:	Surgical collection as deemed by appropriate physician/surgeon
Handling:	Immediately place biopsy in 10% NBF. Maintain at room temperature; unfixed specimens or large fixed specimens held overnight should be refrigerated
Specimen Requirements:	Two patient identifiers; see client specimen labeling requirements in this manual
Transport:	Room temperature
Rejection Criteria:	Unlabeled specimen or inappropriate fixative
Department:	Histology

Test Name:	Frozen Section
Methodology:	Diagnosis of tissue by pathologist while surgery is being performed
Performed:	Monday-Saturday. After hours and weekends: see table of contents for “contact information” section. Schedule with laboratory prior to procedure
Reporting time:	Evaluation of routine specimens within 20 minutes of receipt
Specimen Collection Supplies:	Petri dish (sterile preferred)
Specimen Collection:	Specimen submitted fresh
Handling:	See above. Immediately transport to laboratory or frozen section site. Notify personnel of delivery
Specimen Requirements:	Fresh tissue or submitted in saline; two patient identifiers; see client specimen labeling requirements in this manual
Transport:	Room temperature unless delayed transport then refrigerate
Rejection Criteria:	Formalin fixation
Department:	Histology

***Note: If frozen section is transported to the lab, place tissue in a saline filled container.**

Test Name:	Amputated Limbs
Methodology:	Standard Histology Process(es)
Performed:	Monday-Saturday. After hours and weekends, next business day
Reporting time:	Usually within 24-48 hours of receipt. Special studies may require more time
Specimen Collection Supplies:	Absorbent cloth, large biohazard bag x2
Specimen Collection:	Surgical collection as deemed by appropriate physician/surgeon
Handling:	Maintain at room temperature; specimens held overnight should be refrigerated
Specimen Requirements:	Ensure specimen is contained with no leakage and properly labeled; two patient identifiers; see client specimen labeling requirements in this manual
Transport:	Room temperature; see above for delays
Rejection Criteria:	Unlabeled specimen
Department:	Histology

Test Name:	Bone Marrow Aspiration and biopsy
Methodology:	Microscopic examination by pathologist
Performed:	Monday-Saturday. After hours and weekends, next business day
Reporting time:	Usually within 24-48 hours of receipt. Special studies may require more time
Specimen Collection Supplies:	10% Neutral Buffered Formalin, slides
Specimen Collection:	<ul style="list-style-type: none"> • Immediately place biopsy in 10% NBF • Minimum of six smears from aspirate if made at bedside. • 1 cc of bone marrow aspirate in sodium heparin (green top) or EDTA (purple top), if flow cytometry is requested • 1 cc of bone marrow aspirate in sodium heparin (green top), if cytogenetics are requested • Allow aspirate to clot and then place in 10% NBF • Submit at least two peripheral blood smears and most recent CBC
Handling:	Maintain bone marrow, peripheral blood and solid tissue at room temperature.
Specimen Requirements:	See above for minimum volumes. Two patient identifiers; see client specimen labeling requirements in this manual
Transport:	Room temperature
Rejection Criteria:	Unlabeled specimen or inappropriate fixative
Department:	Histology, Flow Cytometry and MDx (cytogenetics)

Surgical Procedure performed by Pathologist- Nursing instructions:

- Schedule by telephone at least 18-24 hours in advance when possible.
- Provide a surgery permit form signed by patient.
- Order necessary medication and bone marrow tray from hospital central supply.

Test Name:	Breast Tissue
Methodology:	Standard Histology Process(es)
Performed:	Monday-Saturday. After hours and weekends, next business day
Reporting time:	Usually within 24-48 hours of receipt. Special studies may require more time
Specimen Collection Supplies:	10% Neutral Buffered Formalin (10x the amount of tissue) Use Breast requisition
Specimen Collection*:	Specimen should be immersed in fixative within one hour of excision. Time of collection and time placed in fixative must be clearly written on the breast requisition.
Handling:	A minimum of six hours and a maximum of 72 hours fixation for valid results. Maintain at room temperature.
Specimen Requirements:	Excision time and time placed in formalin. See above for minimum and maximum fixation time. Two patient identifiers; see client specimen labeling requirements in this manual
Transport:	Room temperature
Rejection Criteria:	Unlabeled specimen or inappropriate fixative
Department:	Histology

***Note: If delivery of a resection specimen to pathology is delayed, the tumor should be bisected prior to immersion in fixative.**

Test Name:	DIF (Direct Immunofluorescence) Tissue Examination
Methodology:	Immunofluorescence Microscopy examination
Performed:	Monday-Saturday. After hours and weekends, next business day
Reporting time:	Usually after 24-48 hours of receipt.
Specimen Collection Supplies:	Saline
Specimen Collection:	Immediately cover with saline
Handling:	A minimum of six hours and a maximum of 48 hours fixation for valid results. Maintain at room temperature.
Specimen Requirements:	Two patient identifiers; see client specimen labeling requirements in this manual
Transport:	Room temperature
Rejection Criteria:	Unlabeled specimen or inappropriate fixative
Department:	Histology

Test Name:	Kidney Biopsy
Methodology:	Light, electron, and immunofluorescence microscopy examination
Performed:	Referred to designated reference facility
Reporting time:	2-5 days
Specimen Collection Supplies:	Provided renal biopsy kit (LSUHSC) or saline
Specimen Collection:	Immediately place in saline soaked gauze
Handling:	Specimen will be forwarded, unaltered to designated reference facility
Specimen Requirements:	Two patient identifiers; see client specimen labeling requirements in this manual
Transport:	Room temperature
Rejection Criteria:	Unlabeled specimen or inappropriate fixative
Department:	Histology

Test Name:	Muscle Biopsy
Methodology:	Light, electron, and immunofluorescence Microscopy examination
Performed:	Referred to designated reference facility
Reporting time:	Two weeks after receipt of specimen
Specimen Collection Supplies:	Saline; DO NOT SCHEDULE Friday-Sunday
Specimen Collection:	<ul style="list-style-type: none"> • Dampen two gauze sponges (4x4) • Remove one to three muscle tissue specimens approximately 1cm in length and 0.5 to 1.0 cm in diameter - do not traumatize specimen • Place muscle biopsy between wet gauze sponges • Place in Petri dish/ screw cap container and put in a container of WET ice
Handling:	Submit to laboratory immediately. See above for correct amount of tissue
Specimen Requirements:	See above for correct amount of tissue. Two patient identifiers; see client specimen labeling requirements in this manual
Transport:	Room temperature
Rejection Criteria:	Collection instructions not followed. Unlabeled specimen or inappropriate fixative
Department:	Histology

Surgical Procedure instructions:

- Schedule by telephone at least 24 hours in advance. Monday-Wednesday preferred.

Test Name:	Nerve Biopsy
Methodology:	Light, electron, and immunofluorescence Microscopy examination
Performed:	Referred to designated reference facility
Reporting time:	Two weeks after receipt of specimen
Specimen Collection Supplies:	Saline; DO NOT SCHEDULE Friday-Sunday
Specimen Collection:	<ul style="list-style-type: none"> • Dampen two gauze sponges (4x4) • Remove a 2- 3 cm sural nerve tagged at proximal end – do not traumatize specimen • Place nerve biopsy between wet gauze sponges • Place in Petri dish/screw cap container and put in a container of WET ice
Handling:	Submit to laboratory immediately. See above for correct amount of tissue
Specimen Requirements:	See above for correct amount of tissue. Two patient identifiers; see client specimen labeling requirements in this manual
Transport:	Room temperature
Rejection Criteria:	Unlabeled specimen or inappropriate fixative
Department:	Histology

Surgical Procedure instructions:

- Schedule by telephone at least 24 hours in advance, Monday-Wednesday preferred.

Test Name:	Prostate Biopsy
Methodology:	Standard histology process(es)
Performed:	Monday-Saturday. After hours and weekends, next business day
Reporting time:	24-48 hours after receipt of specimen
Specimen Collection Supplies:	10% Neutral Buffered Formalin
Specimen Collection:	Prostate biopsy collections kits
Handling:	Immediately place biopsy in 10% NBF. Maintain at room temperature
Specimen Requirements:	Two patient identifiers; see client specimen labeling requirements in this manual
Transport:	Room temperature
Rejection Criteria:	Unlabeled specimen or inappropriate fixative
Department:	Histology

Test Name:	Crystal Identification
Methodology:	Microscopic Examination of Fluid/Tissue to determine presence and type of crystals
Performed:	Monday-Friday
Reporting time:	Typically 24 hours upon receipt, unless STAT protocol requested
Specimen Collection Supplies:	Clean dry tube and/or container
Specimen Collection:	Fluid is placed in a clean, dry tube. Tissue is placed in a clean, dry container
Handling:	Routine
Specimen Requirements:	Fluid samples are to be received in the fresh state. Tissue samples are to be received FRESH or in 100% Alcohol
Transport:	Room Temperature if same day delivery is expected. Refrigerate otherwise
Rejection Criteria:	If tissue is received in formalin, the test cannot be performed
Department:	Histology

Non-gynecological Cytology

Preparation, Collection, Fixation and Transportation

Universal Precautions Required

PATIENT PREPARATION

Patient preparation for all non-gynecological specimens is according to the instructions specified by the patient's physician, unless otherwise specified in the collection, fixation, and handling and transportation procedure for each specimen type.

REQUISITION REQUIREMENTS

Refer to instructions for completing requisition section.

SPECIMEN LABELING

Smears on Glass Slides

1. Write the patient's first and last name and second identifier on the frosted end of a glass slide with a #2 lead pencil. Labeling the slide holder is not properly labeling the specimen, since it is discarded upon receipt in the laboratory. **SEE CLIENT SPECIMEN LABELING REQUIREMENTS SECTION.**
2. Use facility guidelines for obtaining proper patient identification (patient name, social security number).
3. If smears are taken from different anatomic sites (i.e., right and left), identify the site on the frosted end of the slide with the corresponding information on the requisition.
4. Refer to fixation instructions.
5. Label specimen according to labeling instructions. Complete requisition according to requirements. Place the specimen container in the large section of a biohazard transport bag and the completed requisition in the outer section. Submit to the laboratory

Specimen Containers

1. Identify fluid specimens by clearly labeling the specimen containers with patient's name and second identifier. A printed label with patient's name and second identifier can be affixed to the container.
SEE CLIENT SPECIMEN LABELING REQUIREMENTS SECTION.

2. Use facility guidelines for obtaining proper patient identification
3. Multiple containers must be identified with the specimen source on the container and the corresponding information on the requisition.
4. Label specimen according to labeling instructions. Complete requisition according to requirements. Place the specimen container in the large section of a biohazard transport bag and the completed requisition in the outer section. Submit to the laboratory.

COLLECTION, HANDLING, FIXATION AND TRANSPORTATION

FIXATION FOR NONGYNECOLOGICAL SPECIMENS

Smears on glass slides:

1. **Immediately spray fix smear** with cytology spray fixative. **Do not spray fix smears for Diff Quik staining.**
2. Allow specimen to dry before closing slide holder.
3. Close cover and secure with rubber band.

Fluids and Aspirations:

1. Use only CytoLyt fixative (for all fluid specimens) or PreservCyt.
2. If CytoLyt or PreservCyt is not available, **DO NOT** add any other type of fixative. **If you do not have CytoLyt, call the lab for fixation instructions.**
3. **DO NOT ADD FIXATIVE TO SPECIMENS THAT MAY REQUIRE MICROBIOLOGIC TESTING.**

Test Name:	Body Cavity, Joint, and Cerebrospinal
Methodology:	Cytology, Hologic ThinPrep
Performed:	Monday-Friday. After hours and weekends, next business day
Reporting time:	2-3 business days
Specimen Collection Supplies:	Syringe and needle; clean 100ml-1000ml container
Specimen Collection:	Collect in a container with 3 units of Heparin per ml
Handling:	<ul style="list-style-type: none"> • Pleural fluids and synovial fluids can be refrigerated • Do not submit more than 200ml • Tighten lids securely to prevent leakage
Specimen Requirements:	If a delay in processing (more than 8 hours), refrigerate. Do not add a fixative. Label according to labeling instructions. Two patient identifiers; see client specimen labeling requirements in this manual
Transport:	Room temperature
Rejection Criteria:	Unlabeled specimen or inappropriate fixative
Department:	Cytology

Test Name:	Breast Fluids
Methodology:	Cytology
Performed:	Monday-Friday. After hours and weekends, next business day
Reporting time:	2-3 business days
Specimen Collection Supplies:	Touch Preps: Glass slides; spray fixative or 95% alcohol Aspirations: Syringe and Needle; CytoLyt
Specimen Collection:	<ul style="list-style-type: none"> • Touch preparation on glass • Immediately place slide in a container of 95% alcohol or spray fix. Slide should not air dry. • Place slides in a slide holder and close securely • If aspirated, collect a minimum of 2ml • Place in a CytoLyt vial • Tighten lid securely to prevent leakage
Handling:	<ul style="list-style-type: none"> • See Above
Specimen Requirements:	Label according to labeling instructions. Two patient identifiers; see client specimen labeling requirements in this manual
Transport:	Room temperature
Rejection Criteria:	Unlabeled specimen or inappropriate fixative
Department:	Cytology

Test Name:	Brushings- bronchial, esophageal, gastric & ureteropelvic
Methodology:	Cytology, Hologic ThinPrep
Performed:	Monday-Friday. After hours and weekends, next business day
Reporting time:	2-3 business days
Specimen Collection Supplies:	CytoLyt fixative; brush
Specimen Collection:	Brush is passed through the scope. After brush is withdrawn, if conventional smears are desired, rapidly rotate the brush onto a slide and immediately place smear in a container of 95% alcohol or spray fix. Slide should not air dry. The brush may be placed in CytoLyt fixative and submitted
Handling:	See above
Specimen Requirements:	Label according to labeling instructions. Two patient identifiers; see client specimen labeling requirements in this manual
Transport:	Room temperature
Rejection Criteria:	Unlabeled specimen or inappropriate fixative
Department:	Cytology

Test Name:	Cerebrospinal Fluid
Methodology:	Cytology, Hologic ThinPrep
Performed:	Monday-Friday. After hours and weekends, next business day
Reporting time:	2-3 business days
Specimen Collection Supplies:	CytoLyt fixative
Specimen Collection:	<ul style="list-style-type: none"> • Collect 2-5 ml • Do NOT add fixative to specimen that may require microbiologic testing or flow analysis • Tighten lid securely to prevent leakage
Handling:	See above
Specimen Requirements:	Label according to labeling instructions. Two patient identifiers; see client specimen labeling requirements in this manual
Transport:	Room temperature
Rejection Criteria:	Unlabeled specimen or inappropriate fixative
Department:	Cytology

Test Name:	Fine Needle Aspirate
Methodology:	Cytology, Hologic ThinPrep
Performed:	Monday-Friday. After hours and weekends, next business day
Reporting time:	2-3 business days
Specimen Collection Supplies:	Needle (22 gauge or smaller recommend); 10-20 cc syringe; slides; spray fixative; slide folder; CytoLyt fixative
Specimen Collection:	<ul style="list-style-type: none"> • Perform 2 to 4 “passes” from the lesion, expel a small droplet opposite the frosted end. Place another slide over the droplet. Quickly pull the top and bottom slides apart to spread. Prepare ONE spray fixed and ONE air-dried slide per pass. Prepare no more than 6-8 total slides on any site. • Immediately spray fix one slide and allow the other slide to air dry. • Rinse remaining material from syringe in a small container of CytoLyt or RPMI (for Flow Cytometry) for thin layer preparation and/or cell block • Tighten lid securely <p>SPECIAL NOTE: If Afirma is needed on a Thyroid FNA, expel the third or fourth pass totally in the Afirma vial.</p>
Handling:	See above
Specimen Requirements:	Label according to labeling instructions. Two patient identifiers; see client specimen labeling requirements in this manual
Transport:	Room temperature
Rejection Criteria:	Unlabeled specimen or inappropriate fixative
Department:	Cytology

Test Name:	Urine
Methodology:	Cytology, Hologic ThinPrep
Performed:	Monday-Friday. After hours and weekends, next business day
Reporting time:	2-3 business days
Specimen Collection Supplies:	Urine container or CytoLyt fixative
Specimen Collection:	<ul style="list-style-type: none"> • Catheterized or voided specimens as directed by physician • Collect 50-100 ml • Add CytoLyt to specimen in equal volume • Tighten lid securely to prevent leakage
Handling:	See above
Specimen Requirements:	Label according to labeling instructions. Two patient identifiers; see client specimen labeling requirements in this manual
Transport:	Room temperature
Rejection Criteria:	Unlabeled specimen or inappropriate fixative
Department:	Cytology

Test Name:	Sputum
Methodology:	Cytology, Hologic ThinPrep
Performed:	Monday-Friday. After hours and weekends, next business day
Reporting time:	2-3 business days
Specimen Collection Supplies:	Cytolyt Fixative
Specimen Collection:	<ul style="list-style-type: none"> • Overnight accumulation yield the best diagnostic results • Collect one specimen a day for 3 consecutive days to ensure maximum of diagnostic accuracy • Post bronchoscopy sputum are more likely to contain diagnostic material
Handling:	<ul style="list-style-type: none"> • Add CytoLyt to the specimen – Do not add CytoLyt if microbiology tests are ordered. • Tighten lid securely • If only one container and cultures are ordered send to microbiology first
Specimen Requirements:	Label according to labeling instructions. Two patient identifiers; see client specimen labeling requirements in this manual
Transport:	Room temperature
Rejection Criteria:	Unlabeled specimen or inappropriate fixative
Department:	Cytology

Test Name:	Tzanck Smear
Methodology:	Cytology
Performed:	Monday-Friday. After hours and weekends, next business day
Reporting time:	2-3 business days
Specimen Collection Supplies:	Slides; wooden spatula or tongue blade; spray fixative; slide folder
Specimen Collection:	<ul style="list-style-type: none"> • Scrape lesion with wooden spatula or tongue blade and spread cellular material obtained on glass slide • Immediately spray fix smears with cytology fixative • Place in cardboard cover and allow to dry before closing cover
Handling:	See above
Specimen Requirements:	Label according to labeling instructions. Two patient identifiers; see client specimen labeling requirements in this manual
Transport:	Room temperature
Rejection Criteria:	Unlabeled specimen or inappropriate fixative
Department:	Cytology

Test Name:	Washing- bronchial, esophageal, gastric & ureteropelvic
Methodology:	Cytology, Hologic ThinPrep
Performed:	Monday-Friday. After hours and weekends, next business day
Reporting time:	2-3 business days
Specimen Collection Supplies:	Sterile specimen container
Specimen Collection:	<ul style="list-style-type: none"> • Collect in sterile container • Use separate containers for cytology and microbiology (include site) • Do not add fixative to specimens • Tighten lids securely to prevent leakage • Include special stain information when requested
Handling:	See above
Specimen Requirements:	Label according to labeling instructions. Two patient identifiers; see client specimen labeling requirements in this manual
Transport:	Room temperature
Rejection Criteria:	Unlabeled specimen or inappropriate fixative
Department:	Cytology

Gynecological Cytology – PAP Test

Preparation, Collection, Fixation and Transportation

Universal Precautions Required

PATIENT PREPARATION

For an optimal Pap test the patient should be instructed to:

1. Schedule the appointment at mid-cycle.
2. Do not use vaginal medication, vaginal contraceptives, or douches for 48 hours prior to appointment.
3. Do not have intercourse for 24 hours before the appointment.

REQUISITION REQUIREMENTS

Refer to instructions for completing requisition section. **Verify that the patient requisition information is for the correct patient just prior to specimen collection.**

SPECIMEN LABELING

Conventional Smears

1. **Personnel must positively identify the patient by checking at least two identifiers at the time of specimen collection. Write the patient's first and last name and second identifier on the frosted end of a glass slide with a #2 lead AT THE TIME OF COLLECTION. DO NOT PRE-LABEL SLIDE.**
2. Labeling the slide holder **is not** proper labeling, since the holder is discarded upon receipt in the laboratory.

Liquid Based Methodology

Personnel must positively identify the patient by checking at least two identifiers at the time of specimen collection. Identify specimen by clearly labeling the specimen vial with patient's first and last name and second identifier. If preprinted labels are utilized, verify patient information before specimen labeling. The identifying label with two patient identifiers must be attached to the specimen vial(s) AT THE TIME OF COLLECTION. DO NOT PRE-LABEL SPECIMEN VIAL(S).

SPECIMEN COLLECTION AND FIXATION

CONVENTIONAL SMEARS

Spatula and Cervical Brush Combination, Smear Preparation, and Fixation

Spatula

1. Begin rotation of the spatula starting and ending at the 9 o' clock (or counterclockwise rotation starting and ending at 3 o' clock) to position the spatula so that collected material is retained on the upper horizontal surface as the instrument is removed.
2. Rotate the spatula 360° around the circumference of the cervical os and ectocervix, while maintaining firm contact with the epithelial surface.
3. To prepare a one slide smear, do not smear and spray fix the spatula specimen at this time.
4. Rest the spatula, specimen side down, on the labeled glass slide.

Cervical Brush

1. To prevent drying of the first specimen, collect the brush specimen immediately.
2. Insert the cervical brush into the os with gentle pressure and rotate only 90° to 180° to minimize bleeding.

Note: Cervical brushes are not approved for use on pregnant patients or inflamed tissue.

Broom Collection, Smear Preparation and Fixation

1. Insert central bristles into os until lateral bristles bend against the ectocervix.
2. Maintaining gentle pressure, rotate broom 360° three to five times in the same direction.
3. Transfer sample to a labeled glass slide using one paint stroke with each side of brush in the same direction to exact same area of slide.
4. Holding the spray nozzle about 12 inches from the slide, immediately spray fix the smear with a cytology spray fixative.

5. Place in a cardboard slide holder.
6. Do not cover cardboard slide holder until specimen has dried.

Liquid Based Methodology

1. Patient should not douche for 24hrs before the PAP smear is obtained.
2. Ideally the smear should be obtained at mid cycle because morphology is most easily interpreted at this time, although it is not essential.
3. Always avoid the use of lubrication jellies. These materials significantly obscure cellular detail.
4. Materials listed may be obtained from the cytology laboratory upon request.

Test Name:	Conventional PAP
Methodology:	Cytology
Performed:	Monday-Friday
Reporting time:	3-5 business days
Specimen Collection Supplies:	Spatula; Cervical brush
Specimen Collection:	<p>Spatula and Cervical brush</p> <ul style="list-style-type: none"> • With a single stroke, spread material with spatula evenly • Start from the frosted area to the end of slide • Cover only half of slide - leave the remainder for the brush specimen • On remaining half of slide, roll brush across by twirling handle • Immediately spray fix the smear with cytology spray fixative holding 12 inches away • Place in cardboard holder • Do Not cover cardboard slide holder until specimen has dried <p>Broom</p> <ul style="list-style-type: none"> • Insert until bristles bend against ectocervix • Maintain gentle pressure, rotate 360 degrees, three to five times in same direction • Transfer sample to glass slide using paint stroke with each side of brush in same direction to same area of slide • Immediately spray fix the smear with cytology spray fixative • Place in cardboard slide holder • Do Not cover cardboard slide holder until specimen has dried
Handling:	See above
Specimen Requirements:	Label according to labeling instructions. Two patient identifiers; see client specimen labeling requirements in this manual
Transport:	Room temperature
Rejection Criteria:	Unlabeled specimen or inappropriate fixative
Department:	Cytology

Test Name:	ThinPrep
Methodology:	Liquid based Hologic ThinPrep Pap Test
Performed:	Monday-Friday
Reporting time:	3-5 business days
Specimen Collection Supplies:	Spatula; cervical brush; broom
Specimen Collection:	<ul style="list-style-type: none"> • Collect cervical specimen according to collection specification • Rinse cellular material off collection device by pressing the bristles of brush on the bottom of vial about ten times • Twirl the brush between thumb and forefinger to assure complete rinsing of specimen into PreservCyt • If spatula/brush combination is used, swish brush and spatula in the same vial enough times to completely dislodge cellular material • Cap vial by lining torque mark on lid and vial
Handling:	See above
Specimen Requirements:	Label according to labeling instructions. Two patient identifiers; see client specimen labeling requirements in this manual
Transport:	Room temperature
Rejection Criteria:	Unlabeled specimen or inappropriate fixative
Department:	Cytology

HPV-DNA

Preparation, Collection, Fixation and Transportation

Universal Precautions Required

PATIENT PREPARATION

For an optimal PAP and HPV-DNA test the patient should be instructed to:

1. Schedule the appointment at mid-cycle.
2. Do not use vaginal medication, vaginal contraceptives, or douches for 48 hours prior to appointment.
3. Do not have intercourse for 24 hours before the appointment.

REQUISITION REQUIREMENTS

Refer to instructions for completing requisition section.

SPECIMEN LABELING

1. Identify specimen by clearly labeling the specimen vial with patient's first and last name and a second identifier. **SEE CLIENT SPECIMEN LABELING REQUIREMENTS SECTION.**
2. A printed label with patient's name and second identifier can be affixed to the vial.

SPECIMEN COLLECTION AND FIXATION

Liquid Based Vial for PAP Test

Collect the PAP specimen according to instructions in GYN-PAP section of this manual and add supplemental HPV testing orders to the GYN cytopathology requisition.

If the HPV testing sample is to be collected at the time of colposcopy, collect the sample before acetic acid or any other type of solution is applied.

ORDERING, HANDLING, AND TRANSPORTATION

1. Under COLLECTION METHOD on GYN cytology requisition, indicate Liquid Based.
2. Under REQUEST FOR CYTOLOGY, indicate if testing is for PAP & HPV-DNA (regardless of diagnosis) or HPV-DNA only.
3. Note: Only High Risk HPV testing with Reflex to 16/18 genotype will be performed unless Low Risk testing is indicated by the clinician on the requisition in the space labeled as "Other".
4. For reflex testing check for HPV only if Pap is ASCUS or ASCUS/Low Grade.
5. Reflex Orders for HPV-DNA testing on all ASCUS, ASCUS/Low Grade PAPS can be requested.
6. Label specimen according to labeling instructions. Complete the requisition according to requirements. Place the specimen container in the large section of a biohazard transport bag and the completed requisition in the outer section. Submit to the laboratory.

Test Name:	HPV-DNA
Methodology:	Roche Cobas 4800
Performed:	Monday-Friday
Reporting time:	2 business days from date of order
Specimen Collection Supplies:	Spatula, Cervical brush
Specimen Collection:	<ul style="list-style-type: none"> • Collect cervical specimen according to collection specification • Rinse cellular material off collection device by pressing the bristles of brush on the bottom of vial about ten times • Twirl the brush between thumb and forefinger to assure complete rinsing of specimen into PreservCyt • If spatula/brush combination is used, swish brush and spatula in the same vial enough times to completely dislodge cellular material • Cap vial by lining torque mark on the lid and vial • One aliquot from the vial will be used
Handling:	Indicate liquid based
Specimen Requirements:	Label according to labeling instructions. Two patient identifiers; see client specimen labeling requirements in this manual
Transport:	Room temperature
Rejection Criteria:	Unlabeled specimen or out of date vial
Department:	Cytology

ADDITIONAL ANCILLARY TESTING

Gonorrhea & Chlamydia Bacterial Vaginosis Panel Trichomonas HSV 1&2

Preparation, Collection, Fixation and Transportation

Universal Precautions Required

PATIENT PREPARATION

1. Schedule the appointment at mid-cycle.
2. Do not use vaginal medication, vaginal contraceptives, or douches for 48 hours prior to appointment.
3. Do not have intercourse for 24 hours before the appointment.

REQUISITION REQUIREMENTS

Refer to instructions for completing requisition section.

SPECIMEN LABELING

1. Identify specimen by clearly labeling the specimen vial with patient's first and last name and a second identifier. **SEE CLIENT SPECIMEN LABELING REQUIREMENTS SECTION.**
2. A printed label with patient's name and second identifier can be affixed to the vial.

SPECIMEN COLLECTION AND FIXATION

Liquid Based Vial for PAP Test

Collect the PAP specimen according to instructions in GYN-PAP section of this manual. One aliquot from the vial will be used for each of the ancillary testing that is requested.

ORDERING, HANDLING, AND TRANSPORTATION

1. Under COLLECTION METHOD on GYN cytology requisition, indicate Liquid Based.
2. Under REQUEST FOR CYTOLOGY, indicate the additional ancillary testing that is being requested.
3. If ordering Trichomonas, be sure to indicate if the submitted specimen is a ThinPrep vial or urine. If submitting urine, submit a fresh urine specimen according to the urine collection instructions in the Non-GYN section of this manual.

Test Name:	Gonorrhea & Chlamydia
Methodology:	Roche Cobas 4800
Performed:	Monday-Friday
Reporting time:	3 business days from date of order
Specimen Collection Supplies:	ThinPrep vial
Specimen Collection:	<ul style="list-style-type: none"> • Collect cervical specimen according to collection specification • Rinse cellular material off collection device by pressing the bristles of brush on the bottom of vial about ten times • Twirl the brush between thumb and forefinger to assure complete rinsing of specimen into PreservCyt • If spatula/brush combination is used, swish brush and spatula in the same vial enough times to completely dislodge cellular material • Cap vial by lining torque mark on the lid and vial • One aliquot from the vial will be used
Handling:	Indicate liquid based. Urine specimen must be submitted within 24 hours
Specimen Requirements:	Label according to labeling instructions. Two patient identifiers; see client specimen labeling requirements in this manual
Transport:	Room temperature
Rejection Criteria:	Unlabeled specimen; out of date vial
Department:	Cytology

Test Name:	Bacterial Vaginosis Panel (BVP)
Methodology:	Referred to designated reference facility
Performed:	Monday-Friday
Reporting time:	3-5 business days from date of order
Specimen Collection Supplies:	ThinPrep vial
Specimen Collection:	<ul style="list-style-type: none"> • Collect cervical specimen according to collection specification • Rinse cellular material off collection device by pressing the bristles of brush on the bottom of vial about ten times • Twirl the brush between thumb and forefinger to assure complete rinsing of specimen into PreservCyt • If spatula/brush combination is used, swish brush and spatula in the same vial enough times to completely dislodge cellular material • Cap vial by lining torque mark on the lid and vial • One aliquot from the vial will be used
Handling:	Indicate liquid based
Specimen Requirements:	Label according to labeling instructions. Two patient identifiers; see client specimen labeling requirements in this manual
Transport:	Room temperature
Rejection Criteria:	Unlabeled specimen; out of date vial
Department:	Cytology

Test Name:	Trichomonas
Methodology:	Referred to designated reference facility
Performed:	Monday-Friday
Reporting time:	3-5 business days from the date of order
Specimen Collection Supplies:	ThinPrep vial; urine cup
Specimen Collection:	<ul style="list-style-type: none"> • Collect cervical specimen according to collection specification • Rinse cellular material off collection device by pressing the bristles of brush on the bottom of vial about ten times • Twirl the brush between thumb and forefinger to assure complete rinsing of specimen into PreservCyt • If spatula/brush combination is used, swish brush and spatula in the same vial enough times to completely dislodge cellular material • Cap vial by lining torque mark on the lid and vial • One aliquot from the vial will be used
Handling:	Indicate liquid based. Urine specimen must be submitted within 24 hours
Specimen Requirements:	Label according to labeling instructions. Two patient identifiers; see client specimen labeling requirements in this manual
Transport:	Room temperature
Rejection Criteria:	Unlabeled specimen; out of date vial
Department:	Cytology

Test Name:	HSV 1&2
Methodology:	Referred to designated reference facility
Performed:	Monday-Friday
Reporting time:	3-5 business days from the date of order
Specimen Collection Supplies:	Thin prep vial
Specimen Collection:	<ul style="list-style-type: none"> • Collect cervical specimen according to collection specification • Rinse cellular material off collection device by pressing the bristles of brush on the bottom of vial about ten times • Twirl the brush between thumb and forefinger to assure complete rinsing of specimen into PreservCyt • If spatula/brush combination is used, swish brush and spatula in the same vial enough times to completely dislodge cellular material • Cap vial by lining torque mark on the lid and vial • One aliquot from the vial will be used
Handling:	Indicate liquid based
Specimen Requirements:	Label according to labeling instructions. Two patient identifiers; see client specimen labeling requirements in this manual
Transport:	Room temperature
Rejection Criteria:	Unlabeled specimen; out of date vial
Department	Cytology

Flow Cytometry

CD4 Panel (CD4/CD8/CD3) Leukemia/Lymphoma Immunophenotyping

Flow cytometry utilizes the most up to date instrumentation available to sort and analyze cells from peripheral blood, bone marrow and tissue specimens.

Cell surface markers present in suspected leukemia/lymphoma cases may aid in identifying the tumor lineage for diagnostic and prognostic purposes. Identification of cell types present can give an adequate assessment of a patient's immune status.

The testing personnel and pathologists participate in the College of American Pathologist Proficiency Testing program that is designed to provide diagnostic assessment, continuing education, and quality assurance within the laboratory. Workshops, seminars, and teleconferences are attended.

Flow Cytometry

Preparation, Collection, Fixation and Transportation

Universal Precautions Required

PATIENT PREPARATION

Patient preparation for all flow cytometry specimens is according to the instructions specified by the patient's physician.

REQUISITION REQUIREMENTS

1. Refer to the requisition requirements for Histopathology requisition.
2. Include both date and time of collection.

SPECIMEN LABELING

1. Use facility's guidelines for obtaining proper patient identification.
2. Use facility's guidelines for specimen labeling, but must include patient name, second identifier, date and time collected.
3. Collector's initials are required on label if a blood specimen.

COLLECTION, HANDLING, FIXATION AND TRANSPORTATION

1. Collect specimen according to each of the following sections.
2. Mix specimen according to each of the following sections.
3. Label specimen according to labeling instructions, complete requisition according to requirements, place the specimen container in the large section of a biohazard transport bag and the completed requisition in the outer section and submit to the laboratory.
4. Transport to the laboratory at room temperature as soon as possible.

Test Name:	CD4 Panel (CD4/CD8/CD3)
Methodology:	Flow Cytometry
Performed:	Monday-Saturday
Reporting time:	2 business days of receipt
Specimen Collection Supplies:	EDTA (lavender top)
Specimen Collection:	<ul style="list-style-type: none"> • Collect one EDTA tube of blood • Mix by inverting tube 6-10 times • Minimum draw or 0.5 ml is adequate, if patient has normal WBC parameters (full draw preferred)
Handling:	Do not refrigerate
Specimen Requirements:	See above. Follow all requirements. Two patient identifiers; see client specimen labeling requirements in this manual
Transport:	Room temperature; transport immediately
Rejection Criteria:	Clotted; refrigerated; hemolyzed; frozen; wrong anticoagulant; collected more than 48 hours
Department:	Flow Cytometry

Test Name:	Blood - Leukemia/Lymphoma Immunophenotyping
Methodology:	Flow Cytometry
Performed:	Monday-Saturday
Reporting time:	2 business days of receipt
Specimen Collection Supplies:	EDTA (lavender top)
Specimen Collection:	<ul style="list-style-type: none"> • Collect two EDTA tubes of blood • Mix by inverting tube 6-10 times • Minimum draw of 3 ml is adequate, if patient has significant abnormal cell population present (full draw preferred)
Handling:	Do not refrigerate
Specimen Requirements:	See above. Follow all requirements. Two patient identifiers; see client specimen labeling requirements in this manual
Transport:	Room temperature, transport immediately
Rejection Criteria:	Clotted; refrigerated; hemolyzed; frozen; wrong anticoagulant collected; insufficient cell recovery; samples too old for adequate cell viability
Department:	Flow Cytometry

Test Name:	Bone Marrow Aspirate - Leukemia/Lymphoma Immunophenotyping
Methodology:	Flow Cytometry
Performed:	Monday-Saturday
Reporting time:	2 business days of receipt
Specimen Collection Supplies:	<u>SODIUM HEPARIN</u> (green top)
Specimen Collection:	<ul style="list-style-type: none"> • Collect 1ml of bone marrow aspirate • Minimum volume is dependent upon the cell count of the specimen. The processed cell count should be at least 0.5×10^6 mononucleated cells for setup of a complete monoclonal battery. • Place in Sodium Heparin (green top) tube (<i>EDTA-lavender top may be used if Sodium Heparin is not available</i>) • Mix tube 6-10 times to inhibit coagulation
Handling:	Do not refrigerate
Specimen Requirements:	See above. Follow all requirements. Two patient identifiers; see client specimen labeling requirements in this manual
Transport:	Room temperature; transport immediately
Rejection Criteria:	Clotted; refrigerated; hemolyzed; frozen; wrong anticoagulant collected; insufficient cell recovery; samples too old for adequate cell viability
Department:	Flow Cytometry

Test Name:	Tissue (node) - Leukemia/Lymphoma Immunophenotyping
Methodology:	Flow Cytometry
Performed:	Monday-Saturday
Reporting time:	2 business days of receipt
Specimen Collection Supplies:	RPMI or equivalent medium Note: Sterile saline without a preservative is acceptable for short term usage and transport; must be received in the lab within 2 hours
Specimen Collection:	<ul style="list-style-type: none"> • At least 0.5×10^6 to the sixth mononucleated cells (as a general rule, the equivalent of a 3mm cube of tissue with abundant lymphocytes is adequate). • Maximum cell viability obtained within 24 hours • Store in a 2-8 degree centigrade refrigerator
Handling:	Store in a 2-8 degree centigrade refrigerator
Specimen Requirements:	See above. Follow all requirements. Two patient identifiers; see client specimen labeling requirements in this manual
Transport:	Wet ice ; transport immediately
Rejection Criteria:	Incorrect or inadequate storage and/or preservative; insufficient cell recovery; sample too old for adequate cell viability
Department	Flow Cytometry

Test Name:	Cerebral Spinal Fluid - Leukemia/Lymphoma Immunophenotyping
Methodology:	Flow Cytometry
Performed:	Monday-Saturday
Reporting time:	2 business days of receipt
Specimen Collection Supplies:	Tube provided by client laboratory or hospital
Specimen Collection:	<ul style="list-style-type: none"> • Minimum volume dependent on the cell count • 1.5 ml of CSF is usually sufficient • Smaller volumes may be used if there is a high cell count
Handling:	Specimen cannot be frozen
Specimen Requirements:	When cell counts are low the analysis may not be successful. See above. Two patient identifiers; see client specimen labeling requirements in this manual
Transport:	Room temperature; transport immediately
Rejection Criteria:	Frozen
Department	Flow Cytometry

Test Name:	Body Fluids - Leukemia/Lymphoma Immunophenotyping
Methodology:	Flow Cytometry
Performed:	Monday-Saturday
Reporting time:	2 business days of receipt
Specimen Collection Supplies:	Specimen is sent neat (undiluted)
Specimen Collection:	20 ml of pleural fluid is usually sufficient
Handling:	Specimen cannot be frozen
Specimen Requirements:	Minimum volume of body fluid needed dependent on the cell count in specimen. Smaller volumes may be used if there is a high cell count. When cell counts are low the analysis may not be successful. Two patient identifiers; see client specimen labeling requirements in this manual
Transport:	Wet ice ; transport immediately
Rejection Criteria:	Incorrect or inadequate storage and/or preservative; insufficient cell recovery; sample too old for adequate cell viability
Department	Flow Cytometry

Delta MDX Molecular & Cytogenetic Testing

CYTOGENETIC ANALYSIS

FISH

BCR/ABL

EGFR

JAK2 V617F

KRAS

BRAF

Next-Generation Sequencing

Delta MDX provides comprehensive cytogenetic analysis of neoplastic blood and bone marrow and constitutional blood using traditional chromosome techniques.

Molecular pathology is a specialty within the field of anatomic and clinical pathology that uses DNA/RNA analysis and specialized molecular techniques for the accurate classification and diagnosis of malignancies and infectious disease.

Additional tests are added to the Molecular & Cytogenetics test menu continually. Please contact the respective area for turn around times and available assays.

Molecular & Cytogenetic Testing

Preparation, Collection, Fixation and Transportation

Universal Precautions Required

PATIENT PREPARATION

Patient preparation for all molecular and cytogenetic specimens is according to the instructions specified by the patient's physician.

REQUISITION REQUIREMENTS

1. Refer to the requisition requirements for Histopathology requisition.
2. Include both date and time of collection.

SPECIMEN LABELING

1. Use facilities guidelines for obtaining proper patient identification.
2. Label the blood collection tube with the first and last name and second identifier in pen, or affix a printed label or an addressograph label. Indicate date/time collected on specimen. **SEE SPECIMEN LABELING SECTION.**

COLLECTION, HANDLING, FIXATION AND TRANSPORTATION

1. Collect specimens according to each of the following sections.
2. Ensure proper mixing of Blood/BM specimens.
3. Label specimen according to labeling instructions, complete requisition according to requirements, place the specimen container in the large section of a biohazard transport bag and the completed requisition in the outer section and submit to the laboratory.
4. Transport to the laboratory at room temperature immediately.

Test Name:	Cytogenetic Analysis – Constitutional Blood Detection of chromosomal gains and/or losses, as well as deletions, inversions, or translocations
Methodology:	Chromosome Analysis
Performed:	Monday-Friday
Reporting Time:	7 days from insurance approval
Specimen Collection Supplies:	One green top (sodium heparin) peripheral blood
Specimen Collection:	Venous blood draw
Handling:	Peripheral blood - room temperature.
Specimen Requirements:	Preferred: 3-5ml whole blood Minimum: 1ml whole blood
Transport:	Inside biohazard bag
Suboptimal Specimen:	Frozen; wrong anticoagulant
Department:	Molecular Diagnostics and Cytogenetics

Test Name:	Cytogenetic Analysis – Leukemia/Lymphoma Detection of chromosomal gains and/or losses, as well as deletions, inversions, or translocations specific to hematopoietic disorders and malignancies
Methodology:	Chromosome Analysis
Performed:	Monday- Friday
Reporting Time:	7 days from insurance approval
Specimen Collection Supplies:	One green top (sodium heparin) tube of bone marrow aspirate; one green top (sodium heparin) peripheral blood (blast count should be >5%)
Specimen Collection:	Bone marrow aspirate; venous blood draw
Handling:	Bone marrow aspirate; peripheral blood - room temperature.
Specimen Requirements:	Preferred: 3-5ml whole blood/bone marrow aspirate Minimum: 1ml whole blood/bone marrow aspirate
Transport:	Inside biohazard bag
Suboptimal Specimen:	Frozen; wrong anticoagulant
Department:	Molecular Diagnostics and Cytogenetics

Test Name:	Cytogenetic Analysis – Products of Conception Detection of chromosomal gains and/or losses, as well as deletions, inversions , or translocations
Methodology:	Chromosome Analysis
Performed:	Monday-Friday
Reporting Time:	30 days from insurance approval
Specimen Collection Supplies:	Fresh tissue in RPMI
Specimen Collection:	Surgical Specimen placed in RPMI
Handling:	Refrigerate fresh tissue
Specimen Requirements:	Fetal demise
Transport:	Keep ambient, refrigerate for extended storage
Suboptimal Specimen:	Frozen; fixed tissue
Department:	Molecular Diagnostics and Cytogenetics

Note: Currently outsourced in conjunction with chromosomal microarray testing, as indicated.

Test Name:	Cytogenetic Analysis- Oncology Detection of chromosomal gains and/or losses, as well as deletions, inversions, or translocations specific to hematopoietic disorders and malignancies
Methodology:	Chromosome Analysis
Performed:	Monday-Friday
Reporting Time:	7 days from insurance approval
Specimen Collection Supplies:	One green top (sodium heparin) tube of bone marrow aspirate; one green top (sodium heparin) peripheral blood (blast count should be >5%)
Specimen Collection:	Bone marrow aspirate; Venous blood draw
Handling:	Bone marrow aspirate; peripheral blood - room temperature.
Specimen Requirements:	Preferred: 3 ml-5 ml whole blood/bone marrow aspirate Minimum: 1 ml whole blood/bone marrow aspirate
Transport:	Inside biohazard bag
Suboptimal Specimen	Frozen; wrong coagulant
Department:	Molecular Diagnostics & Cytogenetics

Test Name:	Cytogenetic Analysis – Solid Tumor Detection of chromosomal gains and/or losses, as well as deletions, inversions, or translocations specific to malignancies
Methodology:	Chromosome Analysis
Performed:	Monday-Friday
Reporting Time:	7 days from insurance approval
Specimen Collection Supplies:	Fresh tissue in RPMI
Specimen Collection:	Surgical Specimen placed in RPMI
Handling:	Refrigerate fresh tissue
Specimen Requirements:	Tumor in tissue
Transport:	Keep ambient, refrigerate for extended storage
Suboptimal Specimen:	No tumor present in tissue; frozen; fixed tissue
Department:	Molecular Diagnostics and Cytogenetics

Note: Currently outsourced.

Test Name:	FISH – FFPE Fluorophore-labeled probes for DNA specific targeting of aberrant chromosomes in leukemia, lymphoma, myeloma myeloproliferative/myelodysplastic disorders, and solid tumors
Methodology:	Fluorescence In Situ Hybridization
Performed:	Monday-Friday
Reporting Time	3-5 days from insurance approval
Specimen Collection Supplies:	Paraffin embedded tissue block or minimum of 4 slides
Specimen Collection:	Universal precautions required
Handling:	Keep block cool, avoid excessive heat
Specimen Requirements:	Minimum 4 positively charged slides
Transport:	Ship with ice pack (only in hot weather)
Suboptimal Specimen:	No tumor present in tissue; labeling specifications not followed; incorrect fixative; frozen specimen
Department:	Molecular Diagnostics and Cytogenetics

Test Name:	FISH – Fresh Fluorophore-labeled probes for DNA specific targeting of aberrant chromosomes in leukemia, lymphoma, myeloproliferative/myelodysplastic disorders, and solid tumors
Methodology:	Fluorescence In Situ Hybridization
Performed:	Monday-Friday
Reporting Time:	3 days from insurance approval
Specimen Collection Supplies:	One heparinized tube; touch prep; fresh tissue in RPMI
Specimen Collection:	Universal precautions required
Handling:	Avoid excessive heat; whole blood room temperature; refrigerate fresh tissue; bone marrow aspirate room temperature
Specimen Requirements:	Preferred specimen: touch preps; 5ml whole blood; 1ml bone marrow Minimum: 0.5ml heparinized or EDTA bone marrow
Transport:	Keep ambient,
Suboptimal Specimen:	No tissue on slide; labeling specifications not followed; incorrect fixative; frozen specimen
Department:	Molecular Diagnostics and Cytogenetics

Test Name:	FISH - Lymphoma Fluorophore-labeled probes for DNA specific targeting of aberrant chromosomes in leukemia, lymphoma, myeloproliferative/myelodysplastic disorders, and solid tumors
Methodology:	Fluorescence In Situ Hybridization
Performed:	Monday-Friday
Reporting Time:	3-5 days from insurance approval
Specimen Collection Supplies:	Paraffin embedded tissues or 4 positively charged slides; touch prep; fresh tissue, minimum 0.5 ml heparinized bone marrow, 5 ml heparinized blood, or fresh tissue in RPMI
Specimen Collection:	Universal precautions required
Handling:	Keep block cool, avoid excessive heat; whole blood room temperature; refrigerated fresh tissue
Specimen Requirements:	Tumor in tissue; minimum 4 slides; 5 ml whole blood; 1 ml bone marrow; touch preps
Transport:	Refrigerate fresh tissue and ship within 24 hours with cold pack
Suboptimal Specimen	No tumor present in tissue; tissue has been decalcified; labeling specifications not followed; incorrect fixative; frozen specimen
Department:	Molecular Diagnostics & Cytogenetics

Test Name:	FISH – Urothelial Cell Fluorophore-labeled probes for DNA specific targeting of aberrant chromosomes in Urothelial cell cancers
Methodology:	Fluorescence In Situ Hybridization (UroVysion)
Performed:	Monday-Friday
Reporting Time:	3 days from insurance approval
Specimen Collection Supplies:	Collect specimen according to the standard operating procedures of the facility
Specimen Collection:	Universal precautions required
Handling:	Keep specimen cool, avoid excessive heat
Specimen Requirements:	5-20ml of urine; thin prep (prepared by cytology)
Transport:	Refrigerate and ship within 24 hours with ice pack
Suboptimal Specimen:	No cells in specimen/slide; labeling specifications not followed; incorrect fixative; frozen specimen
Department:	Molecular Diagnostics and Cytogenetics

Test Name:	BCR/ABL by PCR Quantitative real-time PCR used for the detection of t(9;22) BCR/ABL1 fusion transcripts that result in CML. Analytical sensitivity is 10⁻⁵ on the International Scale (IS)
Methodology:	Quantitative RT-PCR
Performed:	Monday-Friday
Reporting Time:	5-7 days from insurance approval
Specimen Collection Supplies:	One purple EDTA tube preferred
Specimen Collection:	Bone marrow aspirate; venous blood draw
Handling:	Whole blood - room temperature, on weekend store in refrigerator
Specimen Requirements:	Minimum: 4mL whole blood/bone marrow aspirate
Transport:	Inside biohazard bag
Suboptimal Specimen:	Frozen. Wrong anticoagulant.
Department:	Molecular Diagnostics and Cytogenetics

Note: Currently outsourced.

Test Name:	EGFR Mutational Analysis – Lung Cancer
Methodology:	Polymerase Chain Reaction (PCR)
Performed:	Monday-Friday
Reporting Time:	7-10 days from insurance approval
Specimen Collection Supplies:	Paraffin embedded tissue; 4 positively charged slides; paraffin embedded scrolls
Specimen Collection:	Universal precautions required
Handling:	Keep block cool, avoid excessive heat
Specimen Requirements:	Tumor in tissue, minimum of 4 slides
Transport:	Keep cool, place inside biohazard bag
Suboptimal Specimen	No tumor present in tissue; tissue has been decalcified; labeling specifications not followed; incorrect fixative; frozen
Department:	Molecular Diagnostics and Cytogenetics

Note: Currently outsourced in conjunction with multigene targeted disease panels.

***A liquid biopsy (peripheral blood) may be used if tissue is limited and/or insufficient for molecular testing.**

Test Name:	JAK2 V617F JAK2 mutation testing to confirm polycythemia vera or other myeloproliferative neoplasms
Methodology:	Polymerase Chain Reaction (PCR)
Performed:	Monday-Friday
Reporting Time:	5-7 days from insurance approval
Specimen Collection Supplies:	One purple EDTA tube
Specimen Collection:	Bone marrow aspirate; venous blood draw
Handling:	Whole blood - room temperature, on weekend store in refrigerator
Specimen Requirements:	Preferred: 3ml whole blood/bone marrow aspirate Minimum: 1ml whole blood/bone marrow aspirate
Transport:	Room temperature in biohazard bag
Suboptimal Specimen	Frozen; wrong anticoagulant
Department:	Molecular Diagnostics and Cytogenetics

Note: Currently outsourced in conjunction with multigene targeted disease panels.

Exon 12 JAK2 mutations may be pursued if JAK2 V617F mutation is negative.

Test Name:	KRAS – Colorectal Cancer, Lung Cancer
Methodology:	Polymerase Chain Reaction (PCR)
Performed:	Monday-Friday
Reporting Time:	7-10 days from insurance approval
Specimen Collection Supplies:	Paraffin embedded tissue; 4 positively charged slides; paraffin embedded scrolls
Specimen Collection:	Universal precautions required
Handling:	Keep block cool, avoid excessive heat
Specimen Requirements:	Tumor in tissue; minimum of 4 slides
Transport:	Keep cool, place inside of biohazard bag
Suboptimal Specimen	No tumor present in tissue; tissue has been decalcified; labeling specifications not followed; incorrect fixative; frozen
Department:	Molecular Diagnostics & Cytogenetics

Note: Currently outsourced in conjunction with multigene targeted disease panels. KRAS molecular testing is not indicated as a routine stand-alone assay as a sole determinant of targeted therapy.

Test Name:	BRAF V600E (cobas) - Melanoma
Methodology:	Polymerase Chain Reaction (PCR) (companion diagnostic assay for melanoma tissue as an aid for eligibility for vemurafenib)
Performed:	Monday-Friday
Reporting Time:	7-10 days from insurance approval
Specimen Collection Supplies:	Paraffin embedded tissue; 4 positively charged slides; paraffin embedded scrolls
Specimen Collection:	Universal precautions required
Handling:	Keep block cool, avoid excessive heat
Specimen Requirements:	Tumor in tissue; minimum of 4 slides
Transport:	Keep cool, place inside of biohazard bag
Suboptimal Specimen	No tumor present in tissue; tissue has been decalcified; labeling specifications not followed; incorrect fixative; frozen
Department:	Molecular Diagnostics & Cytogenetics

Note: Currently outsourced in conjunction with multigene targeted disease panels.

Test Name:	BRAF Mutation Analysis – Melanoma, Lung , Colon
Methodology:	Polymerase Chain Reaction (PCR)
Performed:	Monday-Friday
Reporting Time:	7-10 days from insurance approval
Specimen Collection Supplies:	Paraffin embedded tissue; 4 positively charged slides; paraffin embedded scrolls
Specimen Collection:	Universal precautions required
Handling:	Keep block cool, avoid excessive heat
Specimen Requirements:	Tumor in tissue; minimum of 4 slides
Transport:	Keep cool, place inside of biohazard bag
Suboptimal Specimen	No tumor present in tissue; tissue has been decalcified; labeling specifications not followed; incorrect fixative; frozen
Department:	Molecular Diagnostics & Cytogenetics

Note: Currently outsourced in conjunction with multigene targeted disease panels.

Test Name:	B-cell Clonality Assessment – Hematologic Disease
Methodology:	Polymerase Chain Reaction (PCR)
Performed:	Monday-Friday
Reporting Time:	7-10 days from insurance approval
Specimen Collection Supplies:	One purple EDTA peripheral blood; 2-3ml; EDTA bone marrow aspirate; FFPE
Specimen Collection:	Bone marrow aspirate; venous blood draw
Handling:	Whole blood - room temperature, on weekend store in refrigerator
Specimen Requirements:	Preferred: 3ml whole blood/bone marrow aspirate Minimum: 1ml whole blood/bone marrow aspirate
Transport:	Inside biohazard bag
Suboptimal Specimen	Frozen; wrong anticoagulant
Department:	Molecular Diagnostics and Cytogenetics

Note: Currently outsourced in conjunction with multigene targeted disease panels.

Test Name:	T-cell Clonality Assessment – Hematologic Disease
Methodology:	Polymerase Chain Reaction (PCR)
Performed:	Monday-Friday
Reporting Time:	7-10 days from insurance approval
Specimen Collection Supplies:	One purple EDTA peripheral blood; 2-3ml; EDTA bone marrow aspirate; FFPE
Specimen Collection:	Bone marrow aspirate; venous blood draw
Handling:	Whole blood - room temperature, on weekend store in refrigerator
Specimen Requirements:	Preferred: 3ml whole blood/bone marrow aspirate Minimum: 1ml whole blood/bone marrow aspirate
Transport:	Inside biohazard bag
Suboptimal Specimen	Frozen; wrong anticoagulant
Department:	Molecular Diagnostics and Cytogenetics

Note: Currently outsourced in conjunction with multigene targeted disease panels.

Test Name:	Next-Generation Sequencing (Various Disease Profiles)
Methodology:	Next-Generation Sequencing
Performed:	Monday-Friday
Reporting Time:	12-15 days from insurance approval
Specimen Collection Supplies:	Paraffin embedded tissue block or minimum of 4 slides; PB; BM
Specimen Collection:	Universal precautions required
Handling:	Keep block cool, avoid excessive heat; whole blood 2-8 degrees Celsius; refrigerate fresh tissue
Specimen Requirements:	Minimum 4 slides Preferred: 3ml whole blood/bone marrow aspirate Minimum: 1ml whole blood/bone marrow aspirate
Transport:	Ship with ice pack (only in hot weather); biohazard bag
Suboptimal Specimen	No tumor present in tissue; labeling specifications not followed; incorrect fixative; frozen
Department:	Molecular Diagnostics and Cytogenetics

***Delta Pathology has partnered with nationally recognized testing laboratories to offer a full range of molecular and FISH assay options if not performed at the local level. In lung cancer, multiplexed genetic sequencing panels are preferred over multiple single-gene test to identify other treatment options beyond EGFR, ALK, and ROS1.**

Specialty Testing/ Stains

- ❖ **Immunohistochemistry Stains**
- ❖ **Special Stains**
- ❖ **Flow Cytometry**
- ❖ **Cytogenetics**
- ❖ **FISH**
- ❖ **Molecular Microbiology**

IMMUNOHISTOCHEMISTRY STAINS

DAB CHROMAGEN

AAT-Alpha-antitrypsin	CK7
ACTH	CK8/18 (CAM5.2)
ADH5	CK19
AFP-Alpha Fetaprotein	CK20
ALK-Anaplastic Lymphoma Kinase	CK-PAN
Androgen IHC	CKA1
ARG-1	CKA3
B72-3 (Tag-72)	Cyclin D1
BCL-2	D2-40
BCL-6	Desmin
Ber-EP4 – Anti Human Epithelial Antigen	DOG-1
Beta-Catenin	EBV
CA52	E-Cadherin
CA125	EMA
CA9 or CA19.9	ER – Breast Panel
Calcitonin	ER – Diagnostic
Calponin	Factor 8
Calretinin	Factor 13
CD1A	GAST
CD3	Calectin-3
CD4	Gata-3
CD5	GCDFP-15
CD7	GFAP – Glial Fibrillary Acidic Protein
CD8	Glut-1
CD10	Glycophorin A
CD15	H. Pylori
CD20	HBME-1
CD23	HCG
CD30	HepPar 1
CD31	Her2Neu by IHC
CD34	HHV-8
CD44	HMB45
CD56	HMW-CK (34 beta E12)
CD57	HSV1
CD68	HSV2
CD79a	Inhibin
CD99	Kappa
CD117	Ki67
CD138	Ki67 – Breast Panel
CDH	Lambda
CDX2	LCA (CD45)
CEA	Mammoglobin
Chromogranin A	MelanA Red
CK5/6	MLH1
CK5/6-S100	MOC31

MSA – Muscle Specific Actin	PLAP
MSH2	PNEUMOC
MSH6	PR – Breast Panel
MUC1	PR – Diagnostic
MUC2	PNEUMOC
MUC5	PSA
MUM-1	PSAP
Myeloperoxidase	PSM2
Myosin	PSMA
Napsin A	PTS
Neurofilament	RCC
NSE	S100
NKX31	Smooth Muscle Actin
OCT3/4	SOX-10
P16	SOX-11
P40 (P)	STA6
P53	Synaptophysin
P57	SX1R
P63	TdT
P120	Thrombomodulin
P501s	Thyroglobulin
P504s	Treponema Pallidum (Spirochete)
PARV	Tryptase
PAX	TTF1
PAX2	Villin
PAX8	Vimentin
PD-L1	VZV
PHH3	WT-1
PIN4	

RED CHROMAGEN
Factor13
HMB45
HHV-8
Ki67
Melan A
S100
SOX 10
T Palladium

SPECIAL STAINS	
AFB/Fite	Helico
AFB Flo	Iron
Alcian Blue	Mast Cell
Colloidal Fe	Melanin Bleach
Congo Red	Mucicarmine
DIF (Direct Immunofluoresence)	Oil Red O
Elastic	PAS
Fontana Masson	PAS-Diastase
Giemsa	Reticulin
GMS-Pneumocystis	Trichrome
GMS-Fungus	Von Kossa
Gram	Warthin Starry

PANELS:
Breast In Situ
ER PR
Breast Invasive
ER, PR, Ki67, HER2 by FISH & IHC
Liver
Iron, Masson Trichrome, PASD
Granuloma
AFB-Fite, AFB-Flo, GMS-Fungus, PAS
Mismatch Repair
MLH1, MSH2, MSH6, PMS2

FLOW CYTOMETRY**CD4 Panel**

(Includes CD3, CD4 and CD8 per cent and absolute values)

Leukemia/Lymphoma Immunophenotyping

Blood

Bone Marrow

Body Fluid

Tissue/Lymph Node

CYTOGENETICS

Constitutional and Oncologic Chromosome Analysis

FLUORESCENT IN SITU HYBRIDIZATION (FISH)

HER2Neu for breast and gastric cancer

Oncologic FISH testing

MOLECULAR MICROBIOLOGY (Thin Prep Specimen)

HPV

HPV 16,18

GC/CT