University of Florida Pathology Laboratories (UF PathLabs) is a leading provider of surgical pathology and diagnostic laboratory services for physicians and medical facilities throughout the southeastern United States. Home to more than 30 nationally recognized pathologists with knowledge of all pathology subspecialties, UF PathLabs has the experience and expertise to diagnose your patient’s condition quickly, accurately and professionally. Consultative services, including accurate and meaningful test result interpretation, are provided by UF College of Medicine faculty members, whose daily involvement in clinical research and teaching keeps them abreast of new tests, methods and technologies. Additionally, UF PathLabs’ professional staff is committed to providing you and your patients with accurate diagnoses, as well as the personal service and quality of care you expect.

Contact us today to learn how UF PathLabs can work for you. At UF PathLabs, we are your pathologists, and we bring the power of research and academics into your practice.

Lab Credentials
UF PathLabs participates in the College of American Pathologists (CAP) Laboratory Accreditation Program and has Clinical Laboratory Improvement Amendments (CLIA) certification through the Centers of Medicare and Medicaid Services (CMS). We also maintain state of Florida and federal licensure and certification.
Message from the Medical Director:

The University of Florida Pathology Laboratories (UF PathLabs) has experienced significant growth in the services we offer. For many years, UF PathLabs has been a leading provider of diagnostic and prognostic tests to physicians in North Central Florida. Our faculty and staff were continuously recognized for providing high-quality, efficient and reliable service to our physicians and patients. From a high-quality regional reference laboratory we have expanded to become the largest academic outreach pathology laboratory in the state of Florida.

We provide comprehensive pathology services to hospitals and physician groups throughout the state of Florida. The services we offer are outlined in this test directory and encompass all aspects of anatomic pathology and specialized clinical pathology services. Our specialized anatomic pathology services include such areas as muscle and nerve pathology, renal pathology, autopsy pathology, oral and pediatric pathology and second opinion consultations. We also offer clinical pathology services in molecular pathology, cytogentic, coagulation, toxicology and a highly specialized endocrine autoantibody laboratory.

Despite our growth we continue to focus on providing the best care to our physicians and their patients. Our academic pathologists and dedicated staff will always be available to discuss any case and test with physicians and patients, to help provide a meaningful interpretation.

Sincerely,

Robert W. Allan, MD
Associate Professor
Medical Director
UF PathLabs
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Parentage Test
Pap Test: ThinPrep® with Reflex to Human Papillomavirus (HR-HPV) DNA Probe, High Risk
Pap Test: ThinPrep® with Reflex to Human Papillomavirus (HPV-HR) DNA Probe, High Risk
Parentage Test
Paroxysmal Nocturnal Hemoglobinuria (PNH) - CD55/59 Erythrocytes, FLAER Granulocytes/Monocytes
Pediatric Islet Autoantibody Panel (Islet Cell Cytoplasmic Autoantibodies (ICA), Glutamic Acid Decarboxylase Autoantibodies (GADA), Insulinoma-2 Associated Autoantibodies (IA-2A) and Insulin Autoantibodies (IAA))
Pediatric Pathology
Placental (Syncytrophoblast) Autoantibodies
Podiatry Pathology
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About UF PathLabs

The University of Florida Pathology Laboratories (UF PathLabs) is a leading provider of anatomic pathology and diagnostic laboratory services for the southeastern United States. Headquartered in Gainesville, Florida, UF PathLabs has been offering pathology services, including consultative second opinions and autopsies, for more than 20 years. We offer a range of diagnostic and prognostic tests that are supported by cutting-edge research findings and we serve all major markets across the state of Florida.

Research is the catalyst for the refinement of the assays performed at UF PathLabs, and we continually seek new knowledge while practicing state-of-the-art laboratory medicine. We are committed to making advanced diagnostic laboratory testing available through research and technological development. Our expert diagnostic services include:

Surgical pathology (all subspecialties) • Dermatopathology • Cytopathology
Cytogenetics • Hematopathology/Flow cytometry • Quantitative pathology for tumor analysis • Molecular diagnostics • Forensic toxicology
Parentage testing • Endocrine autoantibodies

These laboratory services have been consolidated within the College of Medicine’s Department of Pathology, Immunology, and Laboratory Medicine since 1988.

Meeting your surgical pathology and diagnostic laboratory needs is an important objective for UF PathLabs. We are committed to providing clients with high-quality, efficient and reliable service. This commitment is backed by a staff of expert pathologists who receive continuing education and ongoing training in their specialities. Our knowledgeable and experienced staff offers accurate interpretation of test results and guidance in decoding the technical aspects of assays. In many instances, our clients receive one-on-one consultative assistance from UF College of Medicine faculty members, whose daily involvement in clinical research and teaching keeps them abreast of new tests and technologies.

Our laboratories participate in continuous proficiency testing, comprehensive quality control and continued quality improvement. UF PathLabs maintains both state and federal licensure and certification; is accredited by the College of American Pathologists (CAP); and is certified to perform high-complexity testing. For additional information regarding specific services or testing, contact our Client Services Department by calling (888) 375-LABS (5227).
Credentials

State of Florida AHCA License Number: 800010089 and 800026083
CLIA Federal Identification Number: 10D0911006 and 10D2012101
CAP Accreditation Number: 1482312 and 7519083
Medicare Provider Number: L8486
Medicaid Provider Number: 0300489-000

Contact Information

Address: UF PathLabs
4800 SW 35th Drive
Gainesville, FL 32608
Phone: (352) 265-9900
Toll-Free: (888) 375-LABS (5227)
Fax: (352) 265-9901
Web: pathlabs.ufl.edu
(Clients can find new, updated information on the UF PathLabs website)

UF PathLabs Medical Team:
Medical Director: Robert W. Allan, M.D.

Unit Directors

Anatomical Pathology

Autopsy: Martha J. Burt, M.D.
Bone and Soft Tissue Pathology: John D. Reith, M.D.
Breast Pathology: Samer Z. Al-Quran, M.D.
Cardiovascular Pathology: Peter A. Drew, M.D.
Cytopathology: Larry J. Fowler, M.D.
Dermatopathology (Pathology): Frederick L. Glavin, M.D.
Ear, Nose and Throat Pathology: Peter A. Drew, M.D.
Endocrine Pathology: Larry J. Fowler, M.D.
Gastrointestinal and Liver Pathology: Chen Liu, M.D., Ph.D.
Genitourinary Pathology: Robert W. Allan, M.D.
Gynecological Pathology: Edward J. Wilkinson, M.D.
Hematopathology/Flow Cytometry: Ying Li, M.D., Ph.D.
Muscle and Nerve Pathology: Anthony T. Yachnis, M.D., M.S.
Neuropathology and Eye Pathology: Anthony T. Yachnis, M.D., M.S.

Oral & Maxillofacial Pathology: Donald Cohen D.M.D., MBA, M.S.
Pediatric Pathology: May R. Arroyo, M.D., Ph.D.
Pulmonary Pathology: Li Lu, M.D., Ph.D.
Renal Pathology: Byron P. Croker M.D., Ph.D.

Clinical Pathology

Chemistry: Neil S. Harris, M.D., M.B., Ch.B.
Special Coagulation: Neil S. Harris, M.D., M.B., Ch.B.
Endocrine Autoantibody: William E. Winter, M.D.
Toxicology: Bruce A. Goldberger, Ph.D., DABFT
Hematopathology: Ying Li, M.D., Ph.D.
Microbiology: Kenneth H. Rand, M.D.

Molecular/Genetic/Quantitative Pathology

Cytogenetics: Roberto T. Zori, M.D.
Molecular Pathology: Hui-Jia Dong, Ph.D.
Parentage Testing/HLA: Juan C. Scornik, M.D.
Quantitative Pathology: Edward J. Wilkinson, M.D.
Reporting

Reports are available via fax or through PathLabs 24/7, UF PathLabs’ online real-time ordering and reporting application. User-friendly and packed with convenient features—PathLabs 24/7 seamlessly integrates into users’ operational workflow, providing an intuitive, easy-to-use hub for ordering, tracking, resulting and managing pathology tests.

With PathLabs 24/7, test results can also be instantly transferred into patients’ electronic medical records at the click of a button. This time-saving application also includes an adjustable event-based engine to notify ordering physicians on critical test information, which allows for faster dissemination of test results and improved patient care.

For more details or to sign-up for PathLabs 24/7, call our Client Services Department at (352) 265-9900 or toll-free at (888) 375-LABS (5227).

Courier Services

UF PathLabs’ Client Services Department can arrange for couriers to retrieve specimens conveniently from your office. In some areas, specimen pick-up and report delivery may be available through independent contractors. Our Client Services Representatives can also set up FedEx transportation for overnight deliveries.

Supplies

Supplies for submitting specimens to UF PathLabs are available to our clients for no additional charge.

**UF PathLabs-provided supplies include:**

Preprinted test requisition forms.
Plastic specimen bags with side section for paperwork.
Specimen collection kits for:
- Histopathology
- Gynecologic cytology (ThinPrep™ and SurePath™ kits are available.)
- Prostate biopsies (6 or 12 specimens)
- Urology testing
- Hematopathology
- Fine-needle aspiration (FNA)

Tissue biopsy containers with appropriate fixatives are provided for the following needs:
- **Light Microscopy**: Formalin
- **Immunohistology**: Michel’s solution
- **Electron Microscopy**: Glutaraldehyde

**Note:** All of these solutions are colorless and should be stored at room temperature. If a color develops, such as a yellow tinge, they have spoiled and will damage specimens to the point that useful diagnosis cannot be rendered.

FedEx shipping supplies:
- Clinical Pac™, a leak-proof envelope that is required for shipping bodily fluids and allows for shipping multiple specimens at once.
- Preprinted air bills showing our shipping address and billing account number.

**Note:** By using these preprinted FedEx air bills, your specimens will be delivered to the correct destination, and we will be billed correctly for the delivery. Even though the air bills are premarked for next-afternoon delivery, all deliveries are made to UF PathLabs in the morning.
**Test Requisition Forms**

An appropriate and properly completed test requisition form must accompany all submitted specimens. A relevant clinical history and all applicable patient demographic data must be entered on each test requisition to facilitate the billing process.

Test requisition forms for general pathology and other specialty-specific tests, in addition to consultations, may be ordered by calling UF PathLabs’ Client Services Department at (352) 265-9900 or toll-free at (888) 375-LABS (5227). We also offer an online supply order form, which can be accessed on our website at:

http://pathlabs.ufl.edu/client-services/supply-ordering

**Hours of Operation**

<table>
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<tr>
<th>Days</th>
<th>Hours</th>
<th>After normal hours of operation, call (800) 633-2122 and ask to speak with the pathology resident on call. For hematopathology services, ask to speak with the hematopathology attending physician on call; the operator will have your call returned as soon as possible.</th>
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<td><strong>Monday - Friday</strong></td>
<td>8 a.m. - 5 p.m.</td>
<td>* UF PathLabs’ physicians are on-call 24 hours a day, every day, including on holidays.</td>
</tr>
<tr>
<td><strong>Saturday</strong></td>
<td>Open for prearranged hematopathology/cytogenetics specimens only</td>
<td></td>
</tr>
<tr>
<td><strong>Sunday</strong></td>
<td>Closed</td>
<td></td>
</tr>
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<td>Closed on New Year’s Day, Martin Luther King, Jr.’s birthday, Memorial Day, Independence Day, Labor Day, Veterans’ Day, Thanksgiving Day, the day after Thanksgiving Day and Christmas</td>
<td></td>
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**Test Additions**

If sufficient specimen volume remains after the initial tests are completed, additional tests may be requested by telephone. Before add-on tests can be processed, **test requests must be in writing and faxed** to UF PathLabs’ Client Services Department at (352) 265-9901.

**Billing**

UF PathLabs will bill third-party payers for any case sent to our laboratory. Client billing is also available upon request.

**Client Billing:** UF PathLabs offers monthly client billing services. Each month an invoice and a detailed list of the charges for tests on each patient will be sent to our clients. Include the remittance copy of the invoice with payment. If you have questions about UF PathLabs’ client billing services, call our Client Services Department at (352) 265-9900.

**Direct Patient Billing:** UF PathLabs offers a direct patient billing option. The patient’s (or responsible party’s) name, phone number, street address, city, state and zip code must be clearly indicated on the test request form. A discount of up to 64% is available to patients who do not have insurance.
Medicare/Medicaid Billing: UF PathLabs will bill Medicare for outpatients and state Medicaid programs, as indicated by law. The patient’s Medicare or Medicaid number, date of birth, address, sex, diagnosis, ordering physician’s name and Medicare provider number must be clearly indicated on the requisition form. Alternatively, both the front and back of the patient’s insurance card may be photocopied and stapled to the request. If the required information is not provided, the institution/ordering physician will be contacted to provide the information.

Third-Party Billing: UF PathLabs will bill third-party payers. The insurance company’s name, address and phone number, as well as the:

- Insured’s policy or identification number;
- Policy holder’s date of birth;
- Patient’s date of birth and diagnosis; and
- Ordering physician’s name must be indicated on the request form.

Alternatively, both the front and back of the insurance card may be photocopied and stapled to the request. If the required information is not provided, the ordering physician/institution will be contacted to provide the information.

Note: The billing for services provided by UF PathLabs is handled by the Florida Clinical Practice Association, Inc.; UF PathLabs’ taxpayer identification number is: 59-1680273

Delivery Address

During routine hours of operation, specimens can be delivered via courier service to:

University of Florida Pathology Laboratories
4800 SW 35th Drive
Gainesville, FL 32608

Federal Express (FedEx) Mailing Guidelines

FedEx regulations require fluid specimen packaging to include four layers of packaging:

1. **Primary Watertight Inner Receptacle**: Use watertight containers for liquid specimens with a positive closure, such as a screw-, snap- or push-on lid, taped for an additional seal. If you place multiple fragile primary receptacles in a single secondary receptacle, they must be individually wrapped or separated to prevent contact between them.

2. **Absorbent Material**: Place absorbent material between the primary and secondary receptacles, using enough material to absorb the entire contents of all primary receptacles. Acceptable absorbent materials include cellulose wadding, cotton balls, super-absorbent packets and paper towels.

3. **Secondary Watertight Inner Receptacle**: Use a watertight sealed plastic bag, plastic canister or screw-cap can.

4. **Sturdy Outer Packaging**: Use rigid outer packaging constructed of corrugated fiberboard, wood, metal or plastic, appropriately sized for the contents. Chipboard or paperboard boxes are unacceptable outer packaging.
Specimen Shipping

Specimen Labeling Requirements for All Specimens Submitted to UF PathLabs

The following information is required to be on the specimen label when submitting a sample for processing:

1. The patient’s full name*
2. The patient’s date of birth*
3. The collection date of the specimen
4. The type of specimen and/or site

*All pathology specimen containers submitted to UF PathLabs must include at least two unique patient identifiers, e.g. the patient’s full name and date of birth. This is a requirement for all College of American Pathologists (CAP)-certified laboratories.

Specimen Rejections

UF PathLabs will contact the ordering medical provider or facility if a requested test cannot be performed. Specimens may be rejected if they do not have proper identification or are received in a manner that does not allow testing (are received clotted, in the wrong preservative tube, etc.).

Acceptable Unique Patient Identifiers*

Slides and containers of all specimens submitted to UF PathLabs for testing must include at least two CAP/CLIA approved unique patient identifiers, including (but not limited to):

- Accession number
- Date of birth
- Hospital number
- Medical record number
- Outside case number
- Patient name
- Requisition number
- Social security number
- Unique number that corresponds to the container and requisition

Both patient identifiers must be legible and present on the submitted specimen container(s) and corresponding requisition.

Incorrectly Identified Specimens

If a specimen container is received without at least two unique patient identifiers, our Client Services Department will immediately:

- Contact the client;
- Repackaged the specimen in question; and
- Send the specimen back to the client with an enclosed problem sheet, explaining why it was returned.

Refrigerated Specimens

Place the specimen and cold pack in a sealed plastic bag. Care should be taken to buffer (e.g., a paper towel) the cold pack from the specimens. Label the outside of the packaging: “REFRIGERATED SPECIMEN – DO NOT FREEZE”
Frozen Specimens

Place five pounds of dry ice around the specimen(s). Use only plastic vials (not glass) and do not fill vials more than three-quarters full.

Shipping Bodily Fluids
(adapted from fedex.com)

Shipments of bodily fluids (blood, plasma, semen, urine, tissue, excrement, etc.), either human or animal, must be packaged in shipper-provided containers that can withstand leakage of contents, shocks, pressure changes and other conditions incidental to ordinary handling in transportation.

A. Outer packaging must contain sufficient absorbent materials to absorb the entire content of the inner packaging (specimens) in the event of any leakage.

B. Federal Express (FedEx) reserves the right to refuse any bodily fluid shipment not packaged as stated above, which in turn is not tendered in a FedEx Clinical Pac™ container. Exceptions include specimens with packaging dimensions too large to fit entirely within a Clinical Pac™, allowing for proper closure of the container. These may be shipped in shipper provided packaging alone but the packaging must bear a FedEx Clinical Pac™ label to be acceptable for transport by FedEx.

Notice

The special lab pack label for large shipper-prepared packages can be obtained by calling (800) 463-3339 or by contacting your local FedEx courier. It is unnecessary to label packages containing dry ice for preservation of clinical materials as "hazardous" and should be avoided. Instead, FedEx guidelines indicate that the following information must be printed on the outside of a specimen package containing dry ice:
The CPT Codes provided in this document are based on AMA guidelines and are for informational purposes only. CPT coding is the sole responsibility of the billing party. Please direct any questions regarding coding to the payor being billed.
1p/19q, d(1;19) Deletion by FISH

**Methodology:** Fluorescence in-situ hybridization (FISH)

**Frequency Performed:** Weekly

** Routinely Reported:** Within 9 days

**Use:** This test is used to support a diagnosis of oligodendrogloma.

**Specimen Requirements:**

**Collection:** Tumor tissue

**Storage/Transport Temperature:** Specimens should be formalin-fixed, paraffin-embedded and stored between 20° - 25° C; paraffin blocks should be protected from excessive heat. Specimens should be shipped in a cooled container during summer months. A surgical pathology report should be included with all shipped specimens.

**Unacceptable Conditions:**
- Tissue without tumor cells
- Frozen specimens
- Specimens processed in any fixative other than formalin

**Stability (collection to initiation of testing):**
- **Ambient:** Indefinitely
- **Frozen:** Unacceptable

**Reference Values:** Non-deleted; interpretive report

**CPT Code(s):** 88365 x 4
Adrenocortical Autoantibodies

**Methodology:** Indirect immunofluorescence

**Frequency Performed:** Weekly

**Routinely Reported:** 1 - 7 business days

**Use:**
- **Diagnosis of Addison’s Disease:** Adrenocortical cytoplasmic autoantibodies detected in the presence of biochemically defined primary adrenocortical insufficiency identify an autoimmune etiology as the cause of the subject’s Addison’s disease (e.g., autoimmune Addison’s disease).

- **Prediction of Addison’s Disease:** Adrenocortical cytoplasmic autoantibodies detected in an asymptomatic individual indicate an increased risk for the subsequent development of clinical Addison’s disease.

**Specimen Requirements:**
Collect blood in a 1-5 mL serum separator tube. Centrifuge, separate and transfer the serum to a plastic vial. Ship specimens with a frozen cold pack for overnight delivery.

**Stability (collection to shipping of the sample):**
- **Ambient:** 24 hours
- **Refrigerated:** 24 hours
- **Frozen:** 1 year (Avoid repeated freeze/thaw cycles.)

**Reference Values:** Negative interpretive report

**CPT Code(s):** 88347
**Adult Islet Autoantibody Panel**

(Islet Cell Cytoplasmic Autoantibodies (ICA), Glutamic Acid Decarboxylase Autoantibodies (GADA) and Insulinoma-2 Associated Autoantibodies (IA-2A))

**Methodology:** Indirect immunofluorescence (ICA), radioimmunoassay (GADA, IA-2A)

**Performed:** Weekly

**Routinely Reported:** 10 - 20 business days

**Use:**

**Diagnosis of Type 1 Diabetes:** The presence of autoantibodies against the cytoplasm of ICA, GADA and/or IA-2A with diabetes mellitus indicates the presence of autoimmune, type 1 diabetes (aka type 1A diabetes). It is advised that blood for IAA testing be drawn before insulin therapy is initiated. For the IAA result to be valid, the patient must not be insulin treated for more than one week.

**Prediction of Type 1 Diabetes:** Autoantibodies against the cytoplasm of ICA, GADA and/or IA-2A in an asymptomatic individual places the subject at increased risk for the development of type 1 diabetes.

**Specimen Requirements:** Collect blood in a 5 mL serum separator tube. Centrifuge, separate and transfer the serum to a plastic vial. Ship specimens with a frozen cold pack for overnight delivery.

**Stability (collection to shipping of the sample):**
- **Ambient:** 24 hours
- **Refrigerated:** 24 hours
- **Frozen:** 1 year (Avoid repeated freeze/thaw cycles.)

**Reference Values:**

**ICA:**
- **Negative (quantitative results reported in JDF units):** < 10 JDF units
- **Positive:** ≥ 10 JDF units

**GADA:**
- **Negative:** < 1.1
- **Positive:** ≥ 1.1 U/mL

**IA-2A:**
- **Negative:** < 0.76
- **Positive:** ≥ 0.76

**CPT Code(s):**
- **ICA:** 86337, 88347
- **GADA:** 86341
- **IA-2A:** 86341
Amniotic Fluid: Acetylcholinesterase (AChE)

Methodology: Arranged for send-out for concurrently submitted prenatal cytogenetic studies only

Frequency Performed: Monday - Saturday

 Routinely Reported: 10 - 14 days (subject to a broad range of variables)

Use: The presence AChE detected in amniotic fluid samples may reflect the presence of fetal open neural tube defects, such as spina bifida. This test is applicable to late gestational age specimens, where AFP values are not applicable.

Specimen Requirements: Amniotic Fluid: Aseptically collect 1 - 2 cc of amniotic fluid. The initial 1 - 2 cc collected for prenatal chromosome studies may be utilized for AchE testing.

Do not freeze or fix samples in any manner contrary to the maintenance of cell viability. Maintain sample sterility; keep all specimens at room temperature; and deliver samples to the laboratory within 24 - 48 hours. Ship specimens at room temperature for overnight delivery.

Unacceptable Conditions:
• Frozen specimens

Stability (collection to initiation of testing):
• Ambient: 48 hours
• Frozen: Unacceptable

Contact the laboratory prior to submission (approved by consultation).

CPT Code(s): 88285
Amniotic Fluid: Alpha-Feto Protein (AFP)

Methodology: Arranged for send-out for concurrently submitted prenatal cytogenetic studies only

Frequency Performed: Monday - Saturday

Routinely Reported: 10 - 14 days (subject to a broad range of variables)

Use: This screening test is used to detect the presence of elevated levels of alpha-fetoprotein detected in amniotic fluid samples collected during the second trimester of pregnancy (15w0d-22w6d), which may reflect the presence of fetal open neural tube defects, such as spina bifida.

Specimen Requirements:

Amniotic Fluid: Aseptically collect 1 - 2 cc of amniotic fluid. The initial 1-2 cc collected for prenatal chromosome studies may be utilized for AChE testing.

Do not freeze or fix samples in any manner contrary to the maintenance of cell viability. Maintain sample sterility; keep all specimens at room temperature; and deliver samples to the laboratory within 24 - 48 hours. Ship specimens at room temperature for overnight delivery.

Unacceptable Conditions:

• Frozen
• Specimens greater than 48 hours old*

Stability (collection to initiation of testing):

• Ambient: 24 - 48 hours*
• Frozen: Unacceptable

* Cell viability of specimens requiring cell culture may be compromised in specimens greater than 48 hours of age upon receipt. Refrigeration at 2° - 8° C may assist when a delay is not preventable (Do not freeze or place specimens directly on ice.).

Contact the laboratory prior to submission (approved by consultation).

CPT Code(s): 88269
Amniotic Fluid Chromosome Study

Methodology: Classic cytogenetic G-band analysis (karyotyping); requires cell culture*

Frequency Performed: Monday - Saturday

 Routinely Reported: 10 - 14 days

Use: This test is used to detect fetal chromosome abnormalities.

Specimen Requirements:

- **Amniotic Fluid:** Aseptically collect approximately 1 cc of amniotic fluid of per week of gestational age in two sterile 15 mL conical centrifuge tubes and sequentially label the tubes. The initial 1 - 2 cc should not be included for chromosome studies (but may be utilized for AFP testing).

Do not freeze or fix samples in any manner contrary to the maintenance of cell viability. Maintain sample sterility; keep all specimens at room temperature; and deliver samples to the laboratory within 24 - 48 hours. Ship specimens at room temperature for overnight delivery.

Unacceptable Conditions:
- Frozen specimens
- Specimens greater than 48 hours old*

Stability (collection to initiation of testing):
- **Ambient:** 24 - 48 hours*
- **Frozen:** Unacceptable

* Cell viability of specimens requiring cell culture may be compromised in specimens older than 48 hours upon receipt. Refrigeration at 2° - 8° C may assist when a delay is not preventable. Do not freeze or place specimens directly on ice.

Result: Interpretive report

CPT Code(s): 88235, 88269, 88285, 88280, 88291

Note: Adjustments and/or additional CPT codes and/or modifiers may be warranted.
Anti-Beta-2 Glycoprotein 1 Antibodies, IgG & IgM

**Methodology:** Enzyme-linked immunosorbent assay (ELISA), INOVA Diagnostics, Inc.

**Frequency Performed:** Monday - Friday

**Routinely Reported:** Within 10 days

**Use:** This assay is used in the diagnosis of antiphospholipid syndrome.

**Vascular Thrombosis:** One or more clinical episodes of arterial, venous or small-vessel thrombosis in any tissue or organ.

**Pregnancy Morbidity:**
- One or more unexplained deaths of a morphologically normal fetus at or beyond the tenth week of gestation, with normal fetal morphology documented by ultrasound.
- One or more premature births of a morphologically normal neonate before the 34th week of gestation because of (a) eclampsia or severe preeclampsia divined according to standard definitions or (b) recognized features of placental insufficiency.
- Three or more unexplained consecutive spontaneous abortions before the tenth week of gestation, with maternal anatomic or hormonal abnormalities and paternal and maternal chromosomal causes excluded.

**Laboratory criteria for the antiphospholipid syndrome include:**
- Anti-β2 glycoprotein-I antibody of IgG and/or IgM isotype in serum or plasma (in titer > the 99th percentile)

**Specimen Requirements:** One 4 mL light-blue-cap tube (3.2% sodium citrate)

**Unacceptable Conditions:**
- Ambient
- Frozen
- Specimens greater than 24 hours old

**Stability (collection to initiation of testing):**
- Ambient: Unacceptable
- Refrigerated: 24 hours
- Frozen: Unacceptable

**Reference Values:**

**Normal:**
- $\beta_2$ GPI IgG ≤ 20 SGU U/mL
- $\beta_2$ GPI IgM ≤ 20 SMU U/mL

**Positive:**
- $\beta_2$ GPI IgG > 20 SGU U/mL
- $\beta_2$ GPI IgM > 20 SMU U/mL

**CPT Code(s):** 86146 x 2
Anti-Cardiolipin Antibodies, IgG & IgM

**Methodology:** Enzyme-linked immunosorbent assay (ELISA)

**Frequency Performed:** Monday - Friday

**Routinely Reported:** Within 10 days

**Use:** This test is used to diagnose antiphospholipid syndrome.

**Vascular Thrombosis:** One or more clinical episodes of arterial, venous or small-vessel thrombosis in any tissue or organ.

**Pregnancy Morbidity:**
- One or more unexplained deaths of a morphologically normal fetus at or beyond the tenth week of gestation, with normal fetal morphology documented by ultrasound.
- One or more premature births of a morphologically normal neonate before the 34th week of gestation because of (a) eclampsia or severe preeclampsia divined according to standard definitions or (b) recognized features of placental insufficiency.
- Three or more unexplained consecutive spontaneous abortions before the tenth week of gestation, with maternal anatomic or hormonal abnormalities and paternal and maternal chromosomal causes excluded.

**Specimen Requirements:** One 4 mL light-blue-cap tube (3.2% sodium citrate)

**Unacceptable Conditions:**
- Ambient
- Frozen
- Specimens greater than 24 hours old

**Stability (collection to initiation of testing):**
- Ambient: Unacceptable
- Refrigerated: 24 hours
- Frozen: Unacceptable

**Reference Values:**

- **Normal:**
  - IgG < 15 GPL U/mL
  - IgM < 12.5 MPL U/mL

- **Indeterminate:**
  - IgG = 15 – 20 GPL U/mL
  - IgM = 12.5 – 20 MPL U/mL

- **Positive:**
  - IgG > 20 GPL U/mL
  - IgM > 20 MPL U/mL

GPL = IgG phospholipid units; MPL = IgM phospholipid units

**CPT Code(s):** 86147 x 2
B-Cell Clonality Analysis

(IgH Gene Rearrangements)

Methodology: Polymerase chain reaction/fluorescent DNA fragment analysis

Frequency Performed: Monday - Friday

Routinely Reported: 5 - 10 days

Use: Clonality analysis of B-cell populations can aid in the diagnosis of lymphoproliferative disorders. This test is used to support or refute the diagnosis of B-cell lymphomas/leukemias.

Specimen Requirements:
- Paraffin-embedded tissue; send one tissue block or 4 unstained slides. Ship the specimen at 20° - 25° C. Tissues that are fixed in formalin substitute are unacceptable. Tissue that does not contain lymphocytes is not accepted. Ship all tissue specimens with a cold pack in summer months.
- Blood or bone marrow in an EDTA or ACD tube; one 3 mL tube of blood or 1 mL tube of bone marrow shipped at 4° C is acceptable. Severely hemolyzed whole blood and/or clotted or frozen whole blood/bone marrow specimens are not accepted.
- Fresh tissue that is at least a 5 mm cube, shipped frozen or on ice in RPMI 1640, is accepted.
- Cell pellets, at least 10^6-cells shipped at 4° C, are acceptable.

Reference Values: Negative; interpretative report

Interpretation Data:

<table>
<thead>
<tr>
<th>B-Cell Clonality</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Positive:</strong> A monoclonal B-cell population is detected.</td>
</tr>
<tr>
<td><strong>Negative:</strong> A monoclonal B-cell population is not detected.</td>
</tr>
<tr>
<td><strong>Indeterminate:</strong> Refer to the interpretation notes.</td>
</tr>
<tr>
<td><strong>QNS:</strong> There is not sufficient material to perform the test.</td>
</tr>
</tbody>
</table>

Note: The test is performed by using Invivoscribe Technologies’ Gene Rearrangement Assay, which targets the joining region and all three of the conserved framework regions (FR 1 – 3) within the IGH gene. False negatives may be due to somatic mutations in the IgH gene at or near the primer binding sites. In N-region diversity, the clonal
population is lower than detection limitation, and may also be due to the poor sample quality of paraffin-embedded tissue. Thus, the presence of a clonal B-cell population in the specimen cannot be entirely excluded by the negative PCR results. Correlation with morphology and immunophenotype is recommended.

**CPT Code(s):**

- 83907 lysis
- 83891 DNA extraction
- 83898 x 6 amplification
- 83894 x 6 capillary gel electrophoresis
- 83912 interpretation
BCL2/JH, t(14;18) Translocation

Methodology: Polymerase chain reaction/southern blot hybridization

Frequency Performed: Monday - Friday

 Routinely Reported: 5 - 10 business days

Use: The BCL-2 PCR gene rearrangement test is used to detect follicular lymphomas. More than 80% of follicular lymphomas carry a t(14;18) translocation; of which, more than 60% involve the JH locus of the immunoglobulin heavy chain gene on chromosome 14, as well as the major breakpoint region and minor cluster region of the BCL-2 gene from chromosome 18. The test is performed by using PCR primers spanning the major and minor breakpoint regions and six J segments of the immunoglobulin-heavy chain gene for the translocation detection. Therefore, the assay is able to detect the majority of breakpoints that occur; however, some breakpoints that were out of the primer coverage will not be detected by this method. In addition, the poor quantity of DNA (caused by inadequate amount of tissue) or poor quality of DNA could also cause absence of t(14;18) translocation amplification. Thus, a negative result does not necessarily exclude the presence of t(14;18) translocation.

Specimen Requirements: • Paraffin-embedded tissue; send one tissue block or 4 unstained slides. Ship the specimen at 20° - 25° C. Tissues that are fixed in formalin substitute are unacceptable. Tissue that does not contain sufficient tumor is not accepted.

• Blood or bone marrow in an EDTA or ACD tube; one 3 mL of blood or 1 mL of bone marrow shipped at 4° C is acceptable. Severely hemolyzed whole blood or clotted/ frozen whole blood/bone marrow specimen is unacceptable.

• Tissue with a minimum size of 5 mm cube shipped frozen or on ice in RPMI 1640 is accepted.

• Cell pellets with at least 1 million cells, shipped at 4° C, are accepted.

Reference Values: Negative
**Interpretation Data:**

<table>
<thead>
<tr>
<th>t(14;18) Translocation</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Positive:</strong> A t(14;18) translocation cell population is detected.</td>
</tr>
<tr>
<td><strong>Negative:</strong> A t(14;18) translocation cell population is not detected.</td>
</tr>
<tr>
<td><strong>Indeterminate:</strong> Refer to the interpretation notes.</td>
</tr>
<tr>
<td><strong>QNS:</strong> There is not sufficient material to perform the test.</td>
</tr>
</tbody>
</table>

**CPT Code(s):** 83907 lysis, 83891 DNA extraction, 83898 x 3 amplification, 83894 x 2 gel electrophoresis, 83896 x 3 nucleic acid probes, 83912 interpretation
Methodology: Microscopic exam

Frequency Performed: Monday - Friday

Routinely Reported: 1 - 3 days

Result: Interpretive report

Specimen Requirements: Tissue must be fixed in 10% formalin. A copy of all radiological findings should be submitted with all tumor cases to avoid delay.

Storage/Transport Temperature: Submit specimens according to Biological Substance, Category B, shipping guidelines.

Unacceptable Conditions:
- Frozen specimens
- Specimens not in appropriate fixative

Stability (collection to initiation of testing):
- Ambient: Indefinitely
- Refrigerated: Indefinitely
- Frozen: Unacceptable

CPT Code(s): 88302, 88304, 88305, 88307 or 88309, depending on the case complexity, 88311 for decalcification, 88312 and 88313 if special stains are used, 88342 if immunoperoxidase stains are utilized
**BRAF V600E Mutation Detection**

**Methodology:** Polymerase chain reaction/DNA pyrosequencing

**Frequency Performed:** Monday - Friday

**Routinely Reported:** 5 - 10 business days

**Use:** BRAF mutation can be utilized as an independent predictor for colorectal cancer patients’ responsiveness to anti-epidermal growth factor receptor therapy. In addition to being used in MSI-high patients as an exclusion factor of HNPCC, the test can also guide therapy for melanoma patients (anti-BRAF).

**Specimen Requirements:** Paraffin-embedded, formalin-fixed tissue block; in case the blocks are not available, 5 unstained slides are accepted. Ship the specimen at 20° - 25° C. Tissues fixed in formalin substitute are unacceptable. Fine-needle biopsy, shipped in frozen condition or on ice with RPMI-1640.

**Reference Values:** No mutation detected; interpretative report

**Interpretation Data:**

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Interpretation Text</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mutation Detected</td>
<td>A mutation was detected in BRAF codon 600 (c. 1799 T &gt; A).</td>
</tr>
<tr>
<td>No Mutation Detected</td>
<td>No BRAF mutation was identified in the provided specimen of the patient codon 600 (c. 1799 T &gt; A).</td>
</tr>
<tr>
<td>QNS</td>
<td>Due to an inadequate specimen or less than 50% tumor cells present in the tissue.</td>
</tr>
</tbody>
</table>

**CPT Code(s):** Microdissection, 83907 lysis, 83891 DNA extraction, 83898 amplification, 83904 sequencing, 83912 interpretation
Breast Pathology

**Methodology:** Microscopic exam

**Frequency Performed:** Monday - Friday

**Routinely Reported:** 1 - 3 days

**Result:** Interpretive report

**Specimen Requirements:** Tissue must be fixed in 10% formalin. Tissue for prognostic marker testing should be processed according to CAP/ASCO guidelines.

**Storage/Transport Temperature:** Submit specimens according to Biological Substance, Category B, shipping guidelines.

**Unacceptable Conditions:**
- Frozen specimens
- Specimens not in appropriate fixative

**Stability (collection to initiation of testing):**
- **Ambient:** Indefinitely
- **Refrigerated:** Indefinitely
- **Frozen:** Unacceptable

**CPT Code(s):** 88302, 88304, 88305, 88307 or 88309, depending on the case complexity, 88312 and 88313 if special stains are used, 88342 if immunoperoxidase stains are utilized
Cardiovascular Pathology

**Methodology:** Microscopic exam

**Frequency Performed:** Monday - Friday

**Routinely Reported:** 1 - 3 days

**Result:** Interpretive report

**Specimen Requirements:** Tissue must be fixed in 10% formalin.

*Storage/Transport Temperature:* Submit specimens according to Biological Substance, Category B, shipping guidelines.

**Unacceptable Conditions:**
- Frozen specimens
- Specimens not in appropriate fixative

**Stability (collection to initiation of testing):**
- **Ambient:** Indefinitely
- **Refrigerated:** Indefinitely
- **Frozen:** Unacceptable

**CPT Code(s):** 88302, 88304, 88305, 88307 or 88309, depending on the case complexity, 88312 and 88313 if special stains are used, 88342 if immunoperoxidase stains are utilized
Cell Culture: Solid Tissue Only

**Methodology:** Cell culture for cell-line buildup only; for reference lab send-out

**Frequency Performed:** Monday - Saturday

**Routinely Reported:** 14 - 21 days

**Use:** This test is used for esoteric send-out testing, which may require a given quantity of cells or living tissue cultures (e.g., specific enzyme test for metabolic disorders, etc.).

**Specimen Requirements:**

**Skin Biopsy:** In an aseptic manner, obtain an approximately 2 mm x 2 mm specimen, which is deep enough to ensure that the dermal layer is included. Deposit the specimen in a sterile container that contains the tissue culture medium with antibiotics, which has been brought to room temperature prior to collection. Alternate solid tissue samples include autopsy specimens (e.g., lung, cartilage, etc.).

Do not freeze or fix samples in any manner contrary to the maintenance of cell viability. Maintain sample sterility; keep all specimens at room temperature; and deliver samples to the laboratory within 24 - 48 hours. Ship specimens at room temperature for overnight delivery.

**Reference Values:** By report; interpretive

**CPT Code(s):** 88233 per routine test
Chlamydia Trachomatis and Neisseria Gonorrhoeae (CT/NG)

Methodology: Nucleic Acid Probe (by Amplified Detection Method (APTIMA Combo 2))

Frequency Performed: Monday - Friday
Routinely Reported: 4 days
Use: This test is used to detect sexually transmitted diseases, specifically Chlamydia trachomatis and Neisseria gonorrhoeae.

Specimen Requirements:
Sample Types:
• Female endocervical or male urethral swabs (Aptima Specimen Collection Swab)
• Female vaginal swabs (Aptima Specimen Collection Swab)
• Gynecologic samples processed with the Cytyc ThinPrep® 2000 System or SurePath™
• 2 mL Urine (Aptima Urine Transport Tube)

Collection: ThinPrep® or SurePath™ samples may be shipped at room temperature. Unpreserved urine samples must be received within 24 hours. Samples may be shipped at 2° - 30° C.

Unacceptable Conditions:
• Frozen specimens
• Aptima Urine Transport Tube > 60 days old
• Aptima Specimen Collection Swab > 60 days old

Stability (collection to initiation of testing):
• Ambient: < 60 days old (swab); 3 weeks old (ThinPrep®); 4 weeks (SurePath™)
• Refrigerated: < 60 days old; 3 weeks old (ThinPrep®); 4 weeks (SurePath™)
• Frozen: Unacceptable

Reference Values: Negative (interpretative report provided)

Interpretation Data:

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Interpretation Text</th>
</tr>
</thead>
<tbody>
<tr>
<td>Detected</td>
<td>Presence of Chlamydia trachomatis DNA and/or N. gonorrhoeae DNA by nucleic acid probe.</td>
</tr>
<tr>
<td>Not Detected</td>
<td>Absence of Chlamydia trachomatis DNA and N. gonorrhoeae DNA by nucleic acid probe.</td>
</tr>
<tr>
<td>QNS</td>
<td>Due to inadequate specimen, resubmission of samples is suggested.</td>
</tr>
</tbody>
</table>

CPT Code(s): 87801, 87491, 87591
Chromosome Study: Chorionic Villi

**Methodology:** Classic cytogenetic G-band analysis (karyotyping); requires cell culture

**Frequency Performed:** Monday - Saturday

**Routinely Reported:** 10 - 14 days

**Use:** This test is used to detect fetal chromosome abnormalities at 11 - 15 weeks of gestation.

**Specimen Requirements:**
- **Chorionic Villi:** Collect 10 - 30 mg of chorionic villi, utilizing aspiration medium, containing sodium heparin. After assessment of the appropriate amount and quality of villi, transfer it to a sterile centrifuge tube with a transportation medium.

Do not freeze or fix samples in any manner contrary to the maintenance of cell viability. Maintain sample sterility; keep all specimens at room temperature; and deliver samples to the laboratory within 24 - 48 hours. Ship specimens at room temperature for overnight delivery.

**Unacceptable Conditions:**
- Frozen specimens
- Specimens greater than 48 hours old*

**Stability (collection to initiation of testing):**
- **Ambient:** 24 - 48 hours old*
- **Frozen:** Unacceptable

*Cell viability of specimens requiring cell culture may be compromised in specimens greater than 48 hours old upon receipt. Refrigeration at 2° - 8° C may assist when a delay in delivery is unpreventable. Do not freeze or place specimens directly on ice.

**Results:** By report; interpretive

**CPT Code(s):** 88235, 88267, 88285, 88280, 88291
Chromosome Study: Neoplastic Lymphatic Tissue

Methodology: Classic cytogenetic G-band analysis (karyotyping); requires cell culture

Frequency Performed: Monday - Saturday

 Routinely Reported: 7 - 21 days

Use: This test is used to identify clonal chromosome changes by conventional karyotyping methods associated with various lymphoma subtypes.

Specimen Requirements: Lymph Node/Spleen/Other: Aseptically obtain a sample of approximately 2 mm x 2 mm x 2 mm and deposit it in RPMI tissue culture medium.*

Fine-Needle Aspirates: Deliver the contents in RPMI or sterile tissue culture medium in a 15 mL conical tube.*

Unacceptable Conditions:  
• Frozen specimens  
• Specimens greater than 48 hours old*

Stability (collection to initiation of testing):  
• Ambient: 24 - 48 hours old*  
• Frozen: Unacceptable

* Cell viability of specimens requiring cell culture may be compromised in specimens greater than 48 hours old upon receipt. Refrigeration at 2° - 8°C may assist when a delay in delivery is unpreventable. Do not freeze or place specimens directly on ice.

No formalin-, alcohol- or paraffin-preserved specimens. Do not freeze or fix samples in any manner contrary to the maintenance of cell viability. Maintain sample sterility; keep all specimens at room temperature; and deliver samples to the laboratory within 24 - 48 hours. Ship specimens at room temperature for overnight delivery.

Reference Values: By report; interpretive

CPT Code(s): 88239, 88262, 88291
Chromosome Study: Neoplastic Marrow/Blood

**Methodology:** Classic cytogenetic G-band analysis (karyotyping); requires cell culture

**Frequency Performed:** Monday - Saturday

**Routinely Reported:** 7 - 14 days

**Use:** This test is used to identify clonal chromosome changes by conventional karyotyping methods for the diagnosis and classification of various hematological disorders.

**Specimen Requirements:**
- **Bone Marrow Aspirate:** Obtain 1 - 2 cc of aspirate in a green-top sodium heparin tube and immediately rotate it thoroughly to ensure adequate mixing with the anticoagulant.
- **Bone Marrow Core Biopsy:** Deposit the sample in a sterile container containing RPMI or tissue culture medium with antibiotics, which has been brought to room temperature prior to collection.*
- **Peripheral Blood Specimens:** These may be submitted in certain clinical conditions (e.g., circulating blasts) and/or circumstances where warranted.

**Unacceptable Conditions:**
- Frozen specimens
- Specimens greater than 48 hours old*

**Stability (collection to initiation of testing):**
- **Ambient:** 24 - 48 hours old*
- **Frozen:** Unacceptable

* Cell viability of specimens requiring cell culture may be compromised in specimens greater than 48 hours old upon receipt. Refrigeration at 2° - 8° C may assist when a delay in delivery is unpreventable. Do not freeze or place specimens directly on ice.

**No formalin-, alcohol- or paraffin-preserved specimens.**
Do not freeze or fix samples in any manner contrary to the maintenance of cell viability. Maintain sample sterility; keep all specimens at room temperature; and deliver samples to the laboratory within 24 - 48 hours. Ship specimens at room temperature for overnight delivery.

**Reference Values:** By report; interpretive

**CPT Code(s):** 88237, 88262, 88291
# Chromosome Study: Neoplastic Solid Tumor

**Methodology:** Classic cytogenetic G-band analysis (karyotyping); requires cell culture

**Frequency Performed:** Monday - Saturday

** Routinely Reported:** 7 - 21 days

**Use:** This test is used to detect clonal cytogenetic changes in solid tumor tissue specimens which may provide classification and prognostic information.

**Specimen Requirements:**

**Solid Tumor Tissue:** Aseptically obtain a sample (approximately 2 mm x 2 mm x 2 mm) and deposit it in RPMI or tissue culture medium.*

Do not freeze or fix samples in any manner contrary to the maintenance of cell viability. Maintain sample sterility; keep all specimens at room temperature; and deliver samples to the laboratory within 24 - 48 hours. Ship specimens at room temperature for overnight delivery.

**Unacceptable Conditions:**
- Frozen specimens
- Formalin, alcohol, or paraffin-preserved specimens

**Stability (collection to initiation of testing):**
- **Ambient:** 24 - 48 hours old*
- **Frozen:** Unacceptable

* Cell viability of specimens requiring cell culture may be compromised in specimens greater than 48 hours old upon receipt. Refrigeration at 2° - 8° C may assist when a delay in delivery is unpreventable. Do not freeze or place specimens directly on ice.

**Reference Values:** By report; interpretive

**CPT Code(s):** 88239, 88262, 88291
## Chromosome Study: Products of Conception

**Methodology:** Classic cytogenetic G-band analysis (karyotyping); requires cell culture

**Frequency Performed:** Monday - Saturday

**Routinely Reported:** 10 - 28 days

**Use:** This test is used to detect chromosome abnormalities in fetal tissues post demise (e.g. spontaneous fetal abortion), which may assist in determining cause and recurrence risks.

**Specimen Requirements:**

**Fetal Tissue Samples:** As aseptically as possible, obtain a sample approximately 2 mm x 2 mm x 2 mm in size. Recommended tissues for abortus materials include recognizable fetal components, such as skin, lung and cartilage, and extra-embryonic tissues, like chorionic villi.

Transfer each sample to a separate sterile container (15 mL conical centrifuge tube) containing RPMI or tissue culture medium, which has been brought to room temperature prior to collection.* Do not place the sample in cold or hot medium. To enhance the possibility of a successful cytogenetic study, we recommend that at least two tissue types be sent in separate containers.

Do not freeze or fix samples in any manner contrary to the maintenance of cell viability. Maintain sample sterility; keep all specimens at room temperature; and deliver samples to the laboratory within 24 - 48 hours. Ship specimens at room temperature for overnight delivery.

**Unacceptable Conditions:**
- Frozen specimens
- Specimens greater than 48 hours old*

**Stability (collection to initiation of testing):**
- **Ambient:** 24 - 48 hours old*
- **Frozen:** Unacceptable

*Cell viability of specimens requiring cell culture may be compromised in specimens greater than 48 hours old upon receipt. Refrigeration at 2° - 8°C may assist when a delay in delivery is unpreventable. Do not freeze or place specimens directly on ice.

**Reference Values:** By report; interpretive

**CPT Code(s):** 88233, 88262, 88291
Chromosome Study: Routine Peripheral Blood

Methodology: Classic cytogenetic G-band analysis (karyotyping); requires cell culture

Frequency Performed: Monday - Saturday

Routinely Reported: 14 - 21 days

Use: This test is used to assess the karyotypic status in individuals with phenotypic abnormalities who are suspected to have congenital chromosome abnormality (e.g., down syndrome or trisomy 21) and/or be a carrier of a chromosome abnormality by clinical or family history.

Specimen Requirements: Peripheral Blood: Peripheral blood must be collected aseptically in sodium heparin tubes (usually green-top tubes) and immediately rotated thoroughly to prevent clotting; for infants, obtain approximately 2 cc, and obtain 5 - 7 cc for children and adults.

Note: A separate blood sample is required if concurrent CGH microarray study is desired.

Do not freeze or fix samples in any manner contrary to the maintenance of cell viability. Maintain sample sterility; keep all specimens at room temperature; and deliver samples to the laboratory within 24 - 48 hours. Ship specimens at room temperature for overnight delivery.

Unacceptable Conditions:  
- Frozen specimens  
- Specimens greater than 48 hours old*

Stability (collection to initiation of testing):  
- Ambient: 24 - 48 hours old*  
- Frozen: Unacceptable

* Cell viability of specimens requiring cell culture may be compromised in specimens greater than 48 hours old upon receipt. Refrigeration at 2° - 8° C may assist when a delay in delivery is unpreventable. Do not freeze or place specimens directly on ice.

Reference Values: By report; interpretive

CPT Code(s): 88230, 88262, 88291
Chromosome Study: Solid Tissue
(for Constitutional Congenital Studies)

**Methodology:** Classic cytogenetic G-band analysis (karyotyping); requires cell culture

**Frequency Performed:** Monday - Saturday

**Routinely Reported:** 14 - 21 days

**Use:** This test is used to assess the karyotypic status in individuals suspected to have a congenital or constitutional chromosome abnormality, which is not expected to be detected in peripheral blood (e.g., Pallister-Killian syndrome, trisomy 8, low-level mosaicsisms, etc.) or where peripheral blood is not available (e.g., autopsy specimens).

**Specimen Requirements:** Skin (or Other Tissues) Biopsy: In an aseptic manner, obtain a specimen (approximately 2 mm x 2 mm), which is deep enough to ensure that the dermal layer is included. Deposit the specimen in a sterile container containing tissue culture medium with antibiotics, which has been brought to room temperature prior to collection.* Alternate solid tissue samples include autopsy specimens (e.g., lung, cartilage, etc.). Do not freeze or fix samples in any manner contrary to the maintenance of cell viability. Maintain sample sterility; keep all specimens at room temperature; and deliver samples to the laboratory within 24 - 48 hours. Ship specimens at room temperature for overnight delivery.

**Unacceptable Conditions:**
- Frozen specimens
- Specimens greater than 48 hours old*

**Stability (collection to initiation of testing):**
- Ambient: 24 - 48 hours old*
- Frozen: Unacceptable

* Cell viability of specimens requiring cell culture may be compromised in specimens greater than 48 hours old upon receipt. Refrigeration at 2° - 8° C may assist when a delay in delivery is unpreventable. Do not freeze or place specimens directly on ice.

**Reference Values:** By report; interpretive

**CPT Code(s):** 88233, 88262, 88291
Consultation

(All Pathology Subspecialties)

Methodology: Microscopic exam
Performed: Monday - Friday
Routinely Reported: 1 - 3 days
Result: Interpretive report
Use: This service is offered to provide patients with another opinion on an existing diagnosis.

Specimen Requirements:
• Any relevant paraffin-embedded blocks (or at least five unstained immunohistochemistry slides)
• Hematoxylin, eosin and all special-stain slides (if any)
• The patient’s clinical history, along with an explanatory note and copies of the pathology report and all radiological findings

For more information, contact the UF PathLabs Client Services Department at (888) 375-LABS (5227).

Storage/Transport Temperature: Submit specimens according to Biological Substance, Category B, shipping guidelines.

CPT Code(s): 88321 Basic, consultation and report on referred material (or); 88323 Moderate, consultation and report on referred material requiring slide preparation (or); 88325 Complex, consultation, with review of records and/or radiographs, as well as report on referred material

Additional billing may apply if special studies are indicated.
### Culture: Anaerobe (Includes Gram Stain)

**Methodology:** Anaerobic culture

**Frequency Performed:** Monday - Friday

**Routinely Reported:** 2 - 7 days
- **Preliminary Report:** Available when the test is negative after one day of growth
- ** Routinely Reported:** Available when the test is positive at 1 - 4 days or negative at 4 days

**Use:** This test is used to identify anaerobic pathogenic organisms from a specified site.

**Specimen Requirements:**

- **Collection:** Specimens, such as pus, fluids, tissues or material collected from a wound, abscess or aspirate, must be collected in an anaerobic transport tube. We recommend collecting 0.5 mL of specimen from the aspirated site in an anaerobic transport tube.

- **Storage/Transport Temperature:** Store samples in an anaerobe transport container at 20° - 25° C. Submit specimens according to Biological Substance, Category B, shipping guidelines.

- **Unacceptable Conditions:**
  - Refrigerated specimens
  - Specimens from the site with normal anaerobic flora
  - Non-sterile or leaking containers
  - Non-anaerobic containers
  - Delayed transport to lab

- **Stability (collection to initiation of testing):**
  - **Ambient:** 24 - 72 hours
  - **Refrigerated:** Unacceptable
  - **Frozen:** Unacceptable

**Reference Values:** Negative for anaerobes

**CPT Code(s):** 87075 culture; gram stain CPT codes may vary.
**Culture: Biopsy/Tissue**

**Methodology:** Anaerobic culture

**Frequency Performed:** Monday - Friday

**Routinely Reported:** 2 - 7 days
- **Preliminary Report:** Available when the test is negative after one day of growth
- ** Routinely Reported:** Available when the test is positive at 1 - 4 days or negative at 4 days

**Use:** This test is used to identify anaerobic pathogenic organisms from a specified bone or tissue site.

**Specimen Requirements:**
- **Collection:** Bone or tissue; please indicate the source of the specimen.

**Storage/Transport Temperature:** Store the bone sample in a sterile container at 20° - 25° C and send it immediately to UF PathLabs. Submit the specimen according to Biological Substance, Category B, shipping guidelines. Specimens should be kept moist at all times; place sterile, saline-soaked gauze in the container.

**Unacceptable Conditions:**
- Specimens in formalin
- Dry specimens
- Specimens in a non-sterile container

**Stability (collection to initiation of testing):**
- **Ambient:** 24 hours
- **Refrigerated:** Unacceptable
- **Frozen:** Unacceptable

**Reference Values:** Negative or non-growth

**CPT Code(s):** 87070
Culture: Body Fluid (Includes Gram Stain)

Methodology: Anaerobic culture

Frequency Performed: Monday - Friday

Routinely Reported: 2 - 7 days

- **Preliminary Report**: Available when the test is negative after one day of growth
- **Routinely Reported**: Available when the test is positive at 1 - 4 days or negative at 4 days

Use: This test is used to identify anaerobic pathogenic organisms from body fluid.

Specimen Requirements:

Collection: Specimens, such as pus, fluids, tissues or material collected from a wound, abscess or aspirate, must be collected in an anaerobic transport tube. We recommend collecting 0.5 mL from the aspirated site in an anaerobic transport tube.

Storage/Transport Temperature: Store samples in an anaerobe transport container at 20° - 25° C. Submit specimens according to Biological Substance, Category B, shipping guidelines.

Unacceptable Conditions:

- Refrigerated specimens
- Specimens from the site with normal anaerobic flora
- Non-sterile or leaking containers
- Non-anaerobic containers
- Delayed transport to lab

Stability (collection to initiation of testing):

- Ambient: 24 - 72 hours
- Refrigerated: Unacceptable
- Frozen: Unacceptable

Reference Values: Negative for anaerobes

CPT Code(s): 87070/87075 culture; gram stain CPT codes may vary.
**Culture: Fungal, Skin, Hair or Nails**

**Methodology:** Culture  
**Frequency Performed:** Monday - Friday  
**Routinely Reported:** Culture:  
- **Preliminary negative:** 1 week (or as found positive)  
- **Final negative:** 4 weeks  
**Use:** Indicate all suspected fungal organisms. Media is available for direct inoculation.  

**Specimen Requirements:**  
**Collection:** Collect cuttings, scrapings, swabs of aspirate, biopsies, body fluid, hair, nails, sinus specimens, skin, sputum, stool or urine in a sterile container. Indicate the source of the specimen.  
- **Tissue:** 2 mL  
- **Body Fluid:** 50 mL  
- **Aspirates:** 2 - 5 mL  

**Storage/Transport Temperature:** Material must be stored in a sterile container at 2° - 8° C for body fluids or clippings. Use bacterial swab transport tubes for all other. Include an additional swab for gram stains. Submit specimens according to Biological Substance, Category B, shipping guidelines.  

**Unacceptable Conditions:** Frozen samples; skin that is fixed in formalin, alcohol or saline; specimens greater than 72 hours old.  

**Stability (collection to initiation of testing):**  
- **Ambient:** 72 hours  
- **Refrigerated:** 72 hours  
- **Frozen:** Unacceptable  

**Reference Values:** Negative for fungus  
**CPT Code(s):** 87101
**Culture: Wound**

**Methodology:** Anaerobic culture

**Frequency Performed:** Monday - Friday

**Routinely Reported:** 2 - 7 days

- **Preliminary:** No growth at 2 days; positive within 2 days.
- **Final:** Negative result 5 days; if actinomyces is being ruled out, allow for up to 10 days

**Use:** This test is used to identify anaerobic pathogenic organisms from a specified site.

**Specimen Requirements:**

- **Collection:** Specimens, such as pus, fluids, tissues or material collected from a wound, abscess or aspirate, must be collected in an anaerobic transport tube. We recommend collecting 0.5 mL from the aspirated site in an anaerobic transport tube.

- **Storage/Transport Temperature:** Store samples in an anaerobe transport container at 20° - 25° C. Submit specimens according to Biological Substance, Category B, shipping guidelines.

- **Unacceptable Conditions:**
  - Refrigerated specimens
  - Specimens from the site with normal anaerobic flora
  - Non-sterile or leaking containers
  - Non-anaerobic containers
  - Delayed transport to lab

- **Stability (collection to initiation of testing):**
  - **Ambient:** 24 - 72 hours
  - **Refrigerated:** Unacceptable
  - **Frozen:** Unacceptable

**Reference Values:** Negative for anaerobes

**CPT Code(s):** 87075 culture; gram stain CPT codes may vary.
Cytopathology

Methodology: Cytopathology
Frequency Performed: Monday - Friday
Routinely Reported: 1 - 3 days
Interpretation Data: Interpretative report provided

Use: Cytopathology is routinely performed on any collectable specimen containing cells. Its general function is to evaluate exfoliated cells in any collectable specimen for abnormalities. These abnormalities include:

- Presence of cancer;
- Precancerous conditions; and
- Infection due to fungus, virus, parasites or bacteria, etc.

Specimen Requirements:
- Direct smears;
- Cytocentrifuge specimens;
- ThinPrep® or SurePath™; and
- Cell blocks, special stains and immunohistochemistry (when appropriate)

Stability (collection to initiation of testing):
Ambient:
- Sterile Container: 2 Hours
- ThinPrep®: 3 Weeks
- SurePath™: 4 Weeks

Refrigerated: 24 hours

CPT Code(s): For codes, contact the UF PathLabs Client Services Department at (888) 375-LABS (5227).
Cytopathology: Anal

Methodology: Cytopathology
Frequency Performed: Monday - Friday
Routinely Reported: 1 - 3 days
Result: Interpretive report
Use: This test is used to diagnose anal intraepithelial neoplasia (AIN).

Specimen Requirements:
- A glass microscope slide for fixed smears; or
- Samples collected in SurePath™ or PreservCyt® collection fluid (preferred)

Collection: For collection instructions, see collection guidelines for SurePath™ or PreservCyt®. Collection fluid can be ordered through UF PathLabs Client Services Department at (888) 375-LABS (5227).

Storage/Transport Temperature: If collected in SurePath™, ThinPrep® or PreservCyt® at 15° - 30° C, submit specimens according to Biological Substance, Category B, shipping guidelines.

Stability (collection to initiation of testing):
- Ambient: SurePath™; 4 weeks at 15° - 30° C.
- Ambient: ThinPrep® or PreservCyt®; 3 weeks at 15° - 30° C.
- Frozen: Unacceptable

CPT Code(s): Depending on collection method:
- 88112 Selective cellular enhancement with interpretation; or
- 88160 Smear with interpretation

Additional CPT codes may apply if special studies are required.
Cytopathology: Body Cavity Fluid

Methodology: Cytopathology

Frequency Performed: Monday - Friday

Routinely Reported: 1 - 2 days

Result: Interpretive report

Use: This test is primarily used to evaluate the presence of malignant cells. Body fluid specimens may include the following:
- Peritoneal fluid (paracentesis)
- Body cavity washings
- Pleural fluid (thoracentesis)
- Pericardial fluid (pericardiocentesis)
- Synovial fluid
- Cyst fluid

Specimen Requirements: Collection: Effusions/Washings

Collect a specimen and place it in a sterile container if it can be delivered immediately to the lab. If immediate delivery is not available, then it is recommended to place 30 mL of the specimen in ThinPrep® or SurePath™ medium or place the specimen in a sterile container with 3 units of heparin and refrigerate it.

We do not recommend storing joint fluids in alcohol.

Storage/Transport Temperature: Submit specimens according to Biological Substance, Category B, shipping guidelines.

Unacceptable Conditions: Frozen, sterile container > 2 hours old without heparin

Stability (collection to initiation of testing):
- Ambient:
  - Sterile Container: 2 hours
  - ThinPrep®: 3 weeks
  - SurePath™: 4 weeks
- Refrigerated: Add 3 units of heparin (48 hours)

CPT Code(s): 88108, 88106, 88305 (if cell block performed)

Additional CPT codes may apply if special studies are required.
**Cytopathology: Breast Nipple Secretion**

**Methodology:** Cytopathology

**Frequency Performed:** Monday - Friday

** Routinely Reported:** 1 - 2 days

**Result:** Interpretive report

**Use:** This test is used to aid in the diagnosis of breast malignancy.

**Specimen Requirements:**

**Supplies:** You will need two clean glass slides (single-end frosted), fixative (95% ethanol) and a request form. Collect cells in nipple discharge. Collect 1 - 2 drops only on the center on one of the labeled slides. Place the other labeled slide face down on the other and let the specimen slowly spread out between the two slides. Working quickly, separate the two slides like opening a book, resulting in a mirrored-image specimen. Do not press the two slides together. Immediately fix one slide in 95% ETOH.

**Storage/Transport Temperature:** Submit specimens according to Biological Substance, Category B, shipping guidelines.

**Unacceptable Conditions:** Frozen, sterile container > 2 hours old without heparin

**Stability (collection to initiation of testing):**
- **Fixed slides:** Indefinitely
- **Ambient:** Indefinitely
- **Frozen:** Unacceptable

**CPT Code(s):** 88104
Cytopathology: Bronchoalveolar Lavage (BAL)

Methodology: Cytopathology

Frequency Performed: Monday - Friday

Routinely Reported: 1 - 2 days

Result: Interpretive report

Use: This test is used to diagnose pulmonary disease, including infections and cancer.

Specimen Requirements:

Collection: BAL

We recommend for specimens to be transported to the lab immediately. If immediate transportation is unavailable, place 30 mL of BAL into ThinPrep® or SurePath™ medium. If CytoLyt is unavailable, place the specimen into a sterile container with 3 units of heparin and refrigerate it.

Storage/Transport Temperature: Submit specimens according to Biological Substance, Category B, shipping guidelines.

Unacceptable Conditions: Frozen, sterile container > 2 hours old without heparin

Stability (collection to initiation of testing):
- Ambient:
- Sterile Container: 2 hours
- ThinPrep®: 3 weeks
- SurePath™: 4 weeks
- Refrigerated: Add 3 units of heparin (48 hours)

CPT Code(s): 88108, 88112, 88106

Additional CPT codes may apply if special studies are required.
### Cytopathology: Cerebrospinal Fluid (CSF)

<table>
<thead>
<tr>
<th>Methodology:</th>
<th>Cytopathology</th>
</tr>
</thead>
<tbody>
<tr>
<td>Frequency Performed:</td>
<td>Monday - Friday</td>
</tr>
<tr>
<td>Routinely Reported:</td>
<td>1 - 3 days</td>
</tr>
<tr>
<td>Result:</td>
<td>Interpretive report</td>
</tr>
<tr>
<td>Use:</td>
<td>This test is primarily used to detect and characterize malignant cells, including lymphoma/leukemia, in the central nervous system.</td>
</tr>
</tbody>
</table>

**Specimen Requirements:**
Collect a minimum of 3 mL of CSF. If flow cytometry for lymphoma/leukemia is required, provide as much specimen as possible (CSF for flow cytometry must be submitted fresh).

Collect and transport specimens according to Biological Substance, Category B, and shipping guidelines.

**Stability (collection to initiation of testing):**

- **Ambient:**
  - ThinPrep®: 3 weeks
  - SurePath™: 4 weeks

- **Refrigerated:** Sterile container (24 hours)

**CPT Code(s):**
88108, 88112, 88106; additional CPT codes may apply if special studies are required.
**Cytopathology: Corneal or Conjunctival Scraping**

**Methodology:** Cytopathology

**Frequency Performed:** Monday - Friday

**Routinely Reported:** 1 - 3 days

**Result:** Interpretive report

**Use:** This test is primarily used to detect, identify, and diagnose any infections of the conjunctiva. It can also be used to identify inflammatory conditions.

**Specimen Requirements:** A direct smear of material collected from the conjunctival surface is required. You will need two clean glass slides (single-end frosted), fixative (95% ethanol) and a request form. Collect 1 - 2 drops of fluid or scrapings only on the center on one of the labeled slides. Place the other labeled slide face down on the other and let the specimen slowly spread out between the two slides. Working quickly, separate the two slides like opening a book, resulting in a mirrored-image specimen. Do not press the two slides together. Fix the slides immediately in 95% ETOH.

If only one air-dried slide is received, it will be stained with GMS for fungi and acanthamoeba.

Fluid samples from the eye should be transported immediately to UF PathLabs for processing or, if delayed, refrigerated and, if shipped long distance, should be placed in ThinPrep® or SurePath™ preservative, similar to fine-needle aspirations.

**Storage/Transport Temperature:** Submit specimens according to Biological Substance, Category B, shipping guidelines.

**Unacceptable Conditions:**
- **Frozen:** Unacceptable
- **Stability (collection to initiation of testing):**
  - **Fixed Slides:** Indefinitely
  - **Ambient:** 2 hours
  - **ThinPrep®:** 3 weeks
  - **SurePath™:** 4 weeks
  - **Refrigerated:** Sterile container (24 hours)

**CPT Code(s):** 88160
**Cytopathology: Fine Needle Aspiration (FNA)**

**Methodology:** Cytopathology

**Frequency Performed:** Monday - Friday

**Routinely Reported:** 1 - 3 days

**Result:** Interpretive report

**Use:** Fine needle aspiration (FNA) is used as a diagnostic tool. This procedure entails inserting a small-gauge needle, usually a 21- to 25-gauge needle, into a mass to remove a cellular sample for microscopic evaluation. The procedure should be performed by using a sewing machine-like motion, while applying minimal negative pressure (No more than 0.5 cc of suction is needed.).

**Specimen Requirements:**

**Collection:** FNA kits (#0099) may be obtained by calling UF PathLabs’ Client Services Department at (888) 375-LABS (5227).

**FNA Procedure:**
A. Sterile technique must be used on all patients. Gloves should always be worn for personal safety.
B. FNA specimens may be submitted as smeared slides or fluid specimens made by rinsing the needle and syringe in PreservCyt® or SurePath™ fluid.
C. While maintaining aseptic conditions, the contents of the syringe and needle are partially expelled onto a glass slide, which is appropriately labeled with the patient’s name and the number of the pass on its frosted side. Working quickly, the specimen should be gently smeared between two slides by lightly sandwiching them together (do not compress) and then separating them as if opening a book.
D. Immediately fix one Superfrost Plus slide in 95% ETOH with 2% acetic acid for each pass. All specimens must be fixed for at least 15 minutes before staining to preserve cellular morphology.
E. All other slides (plain slides) are air dried and immediately stained by the modified Giemsa (e.g.: Diff-Quik) method and may be screened by the aspirator for immediate assessment.
F. The remaining material in the needle should be rinsed in a preservative fluid.
G. If fixed smears are received, these are usually stained with Pap stain unless there is a request for special stains.
H. If a fluid specimen is received, one Pap (plus) and one Diff-Quik (plain) slide should be prepared from each fluid specimen unless special stains are required.
I. Discuss requests for special stains with a pathologist.
J. Specimens from different sites should never be combined.
K. Specimens must be in clean containers to avoid contamination.
L. Collection errors or problems may compromise the results by obscuring cellular morphology.

Storage/Transport Temperature:
Unacceptable Conditions:
- Air drying
- Excessively thick smears
- Excessively bloody samples

Stability (collection to initiation of testing):
Ambient:
- Slides: Indefinitely
- CytoLyt®: 3 weeks
- ThinPrep®: 3 weeks
- SurePath™: 4 weeks

Acceptable specimens include:
1. Smeared slides fixed in 95% ethyl alcohol + 2% acetic acid on Superfrost Plus slides (preferred);
2. Smeared slides fixed in methanol (preferred);
3. Smeared slides fixed with a spray fixative, such as Profix;
4. Air-dried smears for Diff-Quik stain on plain slides;
5. Cystic masses may be drained and the cyst content submitted for cytologic evaluation; or
6. Material in PreservCyt® or SurePath™ fixatives or other special study preservative.

Adequacy Procedure:
UF PathLabs prefers to receive specimens as prepared slides; however, if the clinician performing the adequacy procedure lacks the proper supplies, a needle rinse must be rushed to the lab and should be refrigerated unless it is in CytoLyt®.

If supplies are needed, UF PathLabs can be contacted to provide these prior to scheduling the FNA. Specimens should be submitted as paired slides (air-dried and alcohol-fixed). If specimens are submitted as needle rinse only, the sensitivity/specificity of the test may be impaired.
If alcohol-fixed smears are received, they are typically stained with Pap stain, unless there is a request for special stains. If they are air-dried, a modified Giemsa stain will be used. If you have any questions about this procedure, check with UF PathLabs before staining. Document any requests for special stains on the requisition form. Specimens from different mass sites should never be combined.

**Slide Preparation for Adequacy:**

1. Following the FNA, gently remove the needle from the syringe while holding the needle above the slide in case of accidental spillage of the specimen.

2. Draw air into the syringe and replace the needle onto the syringe.

3. Squirt only 1 - 2 drops to the center of one of the labeled slides.

4. Place the labeled slide face down on the other slide and let the specimen slowly spread out between the two slides. **Do not press the two slides together.** Place the needle and syringe into the CytoLyt® needle rinse tube or RPMI and draw in some fluid.

5. Quickly separate the two slides like opening a book. The result will be a mirror-image of the specimen on each slide.

6. Immediately fix one slide in 95% ETOH (ethanol; the green-top slide holder). Allow the other slide to air-dry. Return to the syringe and needle and gently flush the needle in the solution 2 - 3 times. Then, place the needle in an appropriate sharps disposal container.

7. The other air-dried slide should now be stained by immediately using the Diff-Quick staining method, so it can be reviewed for adequacy. The Diff-Quick staining method should be performed as follows:

   - **Greenish-Blue QuickLink III Fixative (Methanol):** Dip the slide in the greenish-blue methanol fixative 20 times.
   - **Dark Orange QuickLink III Solution I (Sodium Azide):** Dip the slide in the dark orange sodium azide solution 20 times.
   - **Dark Blue QuickLink III Solution II (Hematoxylin):** Dip the slide in the dark blue hematoxylin solution 20 times.
   - **Water:** Dip the slide in the water 20 times to rinse it.
   - Use a towel to carefully wipe the excess water off the edge of the slide.
   - Let the stained slide dry for 30 - 40 seconds.
8. After the slide has been stained and air-dried, view the slide with a microscope. If the stained slide is adequate (cellular material of target organ present), it is ready to be packaged and returned to UF PathLabs. **If the slide is inadequate (blood or fat only), you must repeat this entire procedure, beginning with step 1 of the FNA Procedure.**

9. Repeat the adequacy process for each FNA pass on the same mass extraction site as needed (Remember to begin with a new kit, if moving to a different site, and use a separate requisition for each site.).

10. Following meticulous adequacy reviews, place all slides and the properly labeled container into the biohazard bags and kit box with the completed requisition. Kit boxes will be retrieved by UF PathLabs’ courier, and the results will usually be available in 1 - 2 days.

11. All used needles should be placed in appropriate sharps disposal containers following the preparation of the slides and rinses. Unsatisfactorily used slides are also placed in sharps containers. Other contaminated materials are placed in their proper containers respectively.

12. Collection errors or problems may compromise the results by obscuring cellular morphology. These include:
   1. Air-drying of the slides placed in alcohol
   2. Excessively thick or crushed smears
   3. Excessively bloody samples

   **Note:** Liquid specimens (cyst contents) must be in clean containers to avoid contamination.

   **CPT Code(s):** 88173; this CPT code may also be reported in conjunction with aspiration of the specimen (10021) and/or immediate on-site evaluation of the specimen (88172). Additional CPT codes, such as 88106, 88108 and/or 88305, may be reported, depending on the preparation methods.
## Cytopathology: Gastrointestinal

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<thead>
<tr>
<th>Methodology</th>
<th>Cytopathology</th>
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<tr>
<td>Routinely Reported</td>
<td>1 - 3 days</td>
</tr>
<tr>
<td>Result</td>
<td>Interpretive report</td>
</tr>
<tr>
<td>Use</td>
<td>This test is used to detect GI tract malignancy and abnormalities.</td>
</tr>
<tr>
<td>Specimen Requirements</td>
<td>For FNA specimen requirements and collection instructions, refer to <em>Cytopathology, Fine Needle Aspiration (FNA)</em> in this directory.</td>
</tr>
</tbody>
</table>
| Unacceptable Conditions: | 1. Air-dried specimens  
                              2. Excessively thick smears  
                              3. Excessively bloody samples |
| Stability (collection to initiation of testing): |  
  • Ambient:  
  • Slides: Indefinitely  
  • ThinPrep®: 3 weeks  
  • SurePath™: 4 weeks |
| CPT Code(s)          | 88173; this CPT code may also be reported in conjunction with aspiration of the specimen (10021) and/or immediate on-site evaluation of the specimen (88172). Additional CPT codes, such as 88106, 88108 and/or 88305, may be reported, depending on the preparation methods. |
Cytopathology: Oral

Methodology: Routine cytopathologic evaluation

Frequency Performed: Monday - Friday

Routinely Reported: 1 - 3 days

Result: Interpretive report

Use: This test is used as an important adjunct in the assessment of the patient with a potentially cancerous oral lesion.

Specimen Requirements: For FNA specimen requirements and collection instructions, refer to Cytopathology, Fine Needle Aspiration (FNA) in this directory.

We recommend for specimens to be transported to the lab immediately. If immediate transportation is unavailable, place 30 mL of effusions/washings into ThinPrep® or SurePath™ medium. If CytoLyt is unavailable, place the specimen into a sterile container with 3 units of heparin and refrigerate it.

Storage/Transport Temperature: Submit specimens according to Biological Substance, Category B, shipping guidelines.

Unacceptable Conditions: Frozen, sterile container > 2 hours old without heparin

Stability (collection to initiation of testing):
Ambient:
• Slides: Indefinitely
• ThinPrep®: 3 weeks
• SurePath™: 4 weeks

CPT Code(s): Depending on the Collection Method: 88108, 88112, 88106; additional CPT codes may apply if special studies are required.
# Cytopathology: Pulmonary

**Methodology:** Cytopathology  
**Frequency Performed:** Monday - Friday  
**Routinely Reported:** 1 - 3 days  
**Result:** Interpretive report  
**Use:** This test is used in the diagnosis and treatment of respiratory conditions, including lung cancer.

**Specimen Requirements:**
A direct smear of material may be provided. Two clean glass slides (single-end frosted), fixative (95% ethanol) and a request form are required for this procedure. Collect only 1 - 2 drops of specimen fluid or scrapings on the center of one of the labeled slides. Place the clean labeled slide face down on the slide with the specimen on it and let the specimen slowly spread out between the two slides. Working quickly, separate the two slides like opening a book, which will result in a mirror-image specimen. Do not press the two slides together. Immediately fix the slides in 95% ETOH.

Body fluid specimens may include the following:
- Sputum;  
- Brushings and washings;  
- Transbronchial FNA;  
- Percutaneous FNA; and  
- Pleural fluid.

We recommend for specimens to be transported to the lab immediately. If immediate transportation is unavailable, place 30 mL of effusions/washings into ThinPrep® or SurePath™ medium. If CytoLyt is unavailable, place the specimen into a sterile container with 3 units of heparin and refrigerate it.

**Storage/Transport Temperature:** Submit specimens according to Biological Substance, Category B, shipping guidelines.

**Unacceptable Conditions:** Frozen, sterile container > 2 hours without heparin

**Stability (collection to initiation of testing):**

**Ambient:**
- **Slides:** Indefinitely  
- **Sterile Container:** 2 Hours  
- **ThinPrep®:** 3 Weeks  
- **SurePath™:** 4 Weeks

**Refrigerated:** 24 hours

**CPT Code(s):** 88112, 88108, 88104, 88106
Additional codes may apply if special studies are required.
Cytopathology: Skin Scraping

Methodology: Cytopathology
Frequency Performed: Monday - Friday
Routinely Reported: 1 - 3 days
Result: Interpretive report
Use: This test is used as a substitute for Tzanck smear to detect and characterize inflammatory/infectious processes of the skin, especially herpetic infections.

Specimen Requirements: A direct smear of material collected from the epidermal surface is required. Two clean glass slides (single-end frosted), fixative (95% ethanol) and a request form are required for this procedure. Collect only 1 - 2 drops of specimen fluid or scrapings on the center of one of the labeled slides. Place the clean labeled slide face down on the slide with the specimen on it and let the specimen slowly spread out between the two slides. Working quickly, separate the two slides like opening a book, which will result in a mirror-image specimen. Do not press the two slides together. Immediately fix the slides in 95% ETOH.

If only one air-dried slide is received, it will be stained with GMS for fungi and acanthamoeba.

Storage/Transport Temperature: Submit specimens according to Biological Substance, Category B, shipping guidelines.

Unacceptable Conditions: Frozen; formalin

Stability (collection to initiation of testing):
- Fixed Slides: Indefinitely
- Ambient: 2 hours
- ThinPrep®: 3 weeks
- SurePath™: 4 weeks
- Refrigerated (Sterile Container): 24 hours

CPT Code(s): 88160
Cytopathology: Sputum

Methodology: Cytopathology

Frequency Performed: Monday - Friday

 Routinely Reported: 1 - 3 days

Result: Interpretive report

Use: Aids in the diagnosis of infections and neoplasia.

Specimen Requirements: Collect specimen and place in a sterile container if it can be delivered immediately to the lab. If immediate delivery is not available, then it is recommended to place 30 mL in ThinPrep® or SurePath™ medium or place 3 units of heparin in a sterile container and then refrigerate.

Storage/Transport Temperature: Submit specimens according to Biological Substance, Category B, shipping guidelines.

Unacceptable Conditions: Frozen, sterile container > 2 hours old without heparin

Stability (collection to initiation of testing):
Ambient:
• Sterile Container: 2 hours
• ThinPrep®: 3 weeks
• SurePath™: 4 weeks
• Refrigerated: Add 3 units of heparin (48 hours)

CPT Code(s): 88108, 88112, 88106

Additional CPT codes may apply if special studies are required.
Cytopathology: Urine and Bladder Washes and Brushings

Methodology: Cytopathology
Frequency Performed: Monday - Friday
 Routinely Reported: 1 - 3 days
Result: Interpretive report
Use: Urine cytology is commonly performed to detect urologic malignancies. The method of specimen collection, as well as time of collection, will affect the cytologic evaluation in many instances.

Specimen Requirements: Collection: Send fresh, refrigerated specimens directly for best results. If the specimen is to be sent a long distance in ambient temperatures, spin the specimen down (50 cc) and add it to ThinPrep® or SurePath™ preservative containers for liquid-based processing. See below for specific urological collection methods.

We recommend for specimens to be transported to the lab immediately. If immediate transportation is unavailable, place 30 mL of the specimen into ThinPrep® or SurePath™ medium. If CytoLyt is unavailable, place the specimen into a sterile container with 3 units of heparin and refrigerate it.

Storage/Transport Temperature: Submit specimens according to Biological Substance, Category B, shipping guidelines.

Unacceptable Conditions: Frozen, sterile container >2 hours without heparin

Stability (collection to initiation of testing): Ambient:
• Sterile Container: 2 Hours
• ThinPrep®: 3 Weeks
• SurePath™: 4 Weeks

Refrigerated: 24 hours

CPT Code(s): 88108, 88112, 88106

Additional CPT codes may apply if special studies are required. See UroVysion - FISH in this directory for further CPT codes.
Cytopathology: Vitreous Fluid

Methodology: Cytopathology

Frequency Performed: Monday - Friday

Routinely Reported: 1 - 3 days

Result: Interpretive report

Use: This test is used to detect cancer or the presence of malignant cells in the eye.

Specimen Requirements: We recommend for specimens to be immediately transported to the lab and kept cool. If immediate transportation is unavailable, place the specimen into a sterile container and refrigerate it.

Storage/Transport Temperature: Submit specimens according to Biological Substance, Category B, shipping guidelines.

Unacceptable Conditions: Frozen specimens greater than 72 hours old

Stability (collection to initiation of testing):
Ambient:
• Sterile Container: 24 hours
• Refrigerated: 72 hours

CPT Code(s): 88108, 88112, 88106

Additional CPT codes may apply if special studies are required.
### Dermatopathology

**Methodology:** Microscopic exam  
**Frequency Performed:** Monday - Friday  
**Routinely Reported:** 1 - 3 days  
**Result:** Interpretive report  
**Specimen Requirements:** Skin tissue must be fixed in formalin. If immunobullous disease is suspected, submit half of the tissue in Michel's fixative for a direct immunofluorescence study. See *Immunofluorescence - Direct, Skin* in this directory for specimen requirements.

For dermatology kits (#103), fixative and more information, contact the UF PathLabs Client Services Department at **(888) 375-LABS (5227)**.

**Storage/Transport Temperature:** Submit specimens according to Biological Substance, Category B, shipping guidelines.

**Unacceptable Conditions:**  
- Frozen specimens  
- Specimens not in appropriate fixative

**Stability (collection to initiation of testing):**  
- Ambient: Indefinitely  
- Refrigerated: Indefinitely  
- Frozen: Unacceptable

**CPT Code(s):** 88302, 88304, 88305, 88307 or 88309, depending on the case complexity, 88312 and 88313 if special stains are used, 88342 if immunoperoxidase stains are utilized
**Methodology:** Microscopic exam

**Frequency Performed:** Monday - Friday

**Routinely Reported:** 1 - 3 days

**Result:** Interpretive report

**Specimen Requirements:**
- Tissue must be fixed in formalin. A copy of all radiological findings is recommended to be submitted with the case.

For fixative and more information, contact the UF PathLabs Client Services Department at (888) 375-LABS (5227).

**Storage/Transport Temperature:** Submit specimens according to Biological Substance, Category B, shipping guidelines.

**Unacceptable Conditions:**
- Frozen specimens
- Specimens not in appropriate fixative

**Stability (collection to initiation of testing):**
- **Ambient:** Indefinitely
- **Refrigerated:** Indefinitely
- **Frozen:** Unacceptable

**CPT Code(s):** 88302, 88304, 88305, 88307 or 88309, depending on the case complexity, 88311 for decalcification, 88312 and 88313 if special stains are used, 88342 if immunoperoxidase stains are utilized
**Endocrine Autoantibodies**

**Methodology:** Indirect immunofluorescence, radioimmunoassay

**Frequency Performed:** Weekly

**Routinely Reported:** 1 - 7 business days

**Use:**
- **Diagnosis of an Autoimmune Endocrine Disorder:** In the presence of clinical endocrine disease, an autoantibody directed against the affected gland indicates an autoimmune etiology for the glandular dysfunction.

- **Prediction of an Autoimmune Endocrine Disorder:** Endocrine autoantibodies detected in an asymptomatic individual indicate an increased risk for the subsequent development of clinical endocrine disease.

**Specimen Requirements:**
- Collect blood in a 1 - 5 mL serum separator tube.
- Centrifuge, separate and transfer the serum to a plastic vial. Ship specimens with a frozen cold pack for overnight delivery.

**Stability (collection to shipping of the sample):**
- Ambient: 24 hours
- Refrigerated: 24 hours
- Frozen: 1 year (Avoid repeated freeze/thaw cycles.)

**Reference Values:**
- Negative (interpretive report provided)

**CPT Code(s):** 88347 x 6, 86376, 86800

**Note:** This panel includes adrenocortical, gastric parietal cell, islet cell, steroidal (ovarian, placental and testicular), thyroglobulin and thyroid microsomal. If insulin autoantibodies are requested, a preliminary report will be issued whenever the insulin autoantibodies, which have an in-house turnaround time of 20 working days, are not completed with the other tests. A final report will be issued upon completion.
Endocrine Pathology

Methodology: Microscopic exam
Frequency Performed: Monday - Friday
Routinely Reported: 1 - 3 days
Result: Interpretive report
Specimen Requirements: Tissue must be fixed 10% formalin. For thyroid FNA collection and specimen requirement specifications, see Cytopathology, Fine Needle Aspiration (FNA) in this directory.

For fixative and more information, contact the UF PathLabs Client Services Department at (888) 375-LABS (5227).

Storage/Transport Temperature: Submit specimens according to Biological Substance, Category B, shipping guidelines.

Unacceptable Conditions:
• Frozen specimens
• Specimens not in appropriate fixative

Stability (collection to initiation of testing):
• Ambient: Indefinitely
• Refrigerated: Indefinitely
• Frozen: Unacceptable

CPT Code(s): 88302, 88304, 88305, 88307 or 88309, depending on the case complexity, 88312 and 88313 if special stains are used, 88342 if immunoperoxidase stains are utilized
Epidermal Growth Factor Receptor Mutation Analysis (EGFR Mutation)

**Methodology:** Real-time polymerase reaction

**Performed:** Weekly

**Routinely Reported:** Within 10 business days

**Use:** This test is used to detect EGFR somatic mutations in exons 18, 19, 20 and 21. EGFR mutation is significantly associated with response to gefitinib and erlotinib and prolonged survival in non-small-cell lung carcinoma patients.

**Specimen Requirements:** At least 7 unstained formalin-fixed paraffin-embedded slides with adequate amounts of tumor to be analyzed with the areas of tumor marked.

**Storage/Transport:** Ship specimens at 20° - 25° C for overnight delivery and protect them from excessive heat. Include a surgical pathology report.

**Unacceptable Specimens:**
- Specimens that do not contain tumor
- Specimens in fixatives other than 10% formalin
- Frozen specimens

**Stability (collection to initiation of testing):**
- Ambient: Indefinitely
- Refrigerated: Acceptable
- Frozen: Unacceptable

**CPT Codes:** 88381, 83891, 83898 x 8, 83907, 83912, 83914 x 29
**ER/PR (Estrogen/Progesterone Receptor Image Analysis)**

**Methodology:** Immunohistochemistry with image quantitation

**Frequency Performed:** Weekly

**Routinely Reported:** 7 days

**Use:** This test is used in the diagnosis of patients with in-situ and invasive breast cancer. Positive results aid in choosing appropriate treatment therapies.

**Specimen Requirements:** At least five unstained slides or a paraffin block containing representative breast tumor

**Storage/Transport:** Ship at 20° - 25° C to protect specimens from excessive heat. Include a surgical pathology report.

**Reference Values:**

<table>
<thead>
<tr>
<th>Antibody</th>
<th>% Nuclear Area</th>
<th>Interpretation</th>
</tr>
</thead>
<tbody>
<tr>
<td>ER</td>
<td>&lt; 1%</td>
<td>Negative</td>
</tr>
<tr>
<td></td>
<td>&gt; 1%</td>
<td>Positive</td>
</tr>
<tr>
<td>PR</td>
<td>&lt; 1%</td>
<td>Negative</td>
</tr>
<tr>
<td></td>
<td>&gt; 1%</td>
<td>Positive</td>
</tr>
</tbody>
</table>

**CPT Code(s):** 88361 x 2
Eye Pathology

Methodology: Microscopic exam
Frequency Performed: Monday - Friday
Routinely Reported: 1 - 3 days
Result: Interpretive report
Specimen Requirements: Tissue must be fixed in 10% formalin.

For fixative and more information, contact the UF PathLabs Client Services Department at (888) 375-LABS (5227).

Storage/Transport Temperature: Submit specimens according to Biological Substance, Category B, shipping guidelines.

Unacceptable Conditions:
- Frozen specimens
- Specimens not in appropriate fixative

Stability (collection to initiation of testing):
- Ambient: Indefinitely
- Refrigerated: Indefinitely
- Frozen: Unacceptable

CPT Code(s): 88302, 88304, 88305, 88307 or 88309, depending on the case complexity, 88312 and 88313 if special stains are used, 88342 if immunoperoxidase stains are utilized
Factor V Leiden Mutation

Methodology: Polymerase chain reaction with sequence specific primers (PCR-SSP) combined with agarose gel electrophoresis

Frequency Performed: Monday - Friday

Routinely Reported: Within 10 days

Use: This test is used to detect factor V Leiden mutation, which is a risk factor for thrombosis.

Specimen Requirements: 4 mL of blood in a lavender (purple-top) tube (EDTA)

Stability (collection to initiation of testing):
- Ambient: 3 days
- Refrigerated: 7 days

Unacceptable Conditions: Frozen specimens

Reference Values: Negative for the Factor V Leiden R506Q mutation

The “mutation” is actually a common polymorphism in the Factor V gene that replaces a critical arginine with a glutamine at position 506 of the protein (FV R506Q). This removes a cleavage site for activated protein C. Approximately 5% of Caucasians is heterozygous for the R506Q polymorphism. Heterozygous FV R506Q carriers have a 4-fold risk increase for venous thromboembolism. Homozygotes have an 80-fold increased risk.

CPT Code(s): 83891, 83894 x 2, 83898 x 2, 83912
**FISH Study: Prenatal Chromosome Identification**

**Methodology:** Metaphase fluorescence in-situ hybridization analysis (FISH) for characterization of de novo chromosomal findings; requires concurrent classic cytogenetic analysis; **not for standalone use**

**Frequency Performed:** Monday - Saturday

**Routinely Reported:** 10 - 21 days

**Use:** This test is used further characterize chromosome abnormalities as previously identified by conventional G-banding techniques in prenatal studies (e.g., marker chromosome identification, derivative chromosome content, breakpoint analysis, etc.).

**Specimen Requirements:**

- **Amniotic Fluid:** Aseptically collect approximately 1 cc of per week of gestational age in two sterile 15 mL conical centrifuge tubes and sequentially label the tubes. The initial 1 - 2 cc should not be included for chromosome studies (but may be utilized for AFP testing).

- **Chorionic Villi:** Collect 10 - 30 mg of utilizing aspiration medium containing sodium heparin.* After assessment of the appropriate amount and quality of villi, transfer to a sterile centrifuge tube with transportation medium.

Do not freeze or fix samples in any manner contrary to the maintenance of cell viability. Maintain sample sterility; keep all specimens at room temperature; and deliver samples to the laboratory within 24 - 48 hours. Ship specimens at room temperature for overnight delivery.

**Unacceptable Conditions:**
- Frozen specimens
- Specimens greater than 48 hours old*

**Stability (collection to initiation of testing):**
- **Ambient:** 24 - 48 hours*
- **Frozen:** Unacceptable

*Cell viability of specimens requiring cell culture may be compromised in specimens older than 48 hours upon receipt. Refrigeration at 2° - 8° C may assist when a delay is not preventable. Do not freeze or place specimens directly on ice.

Contact UF PathLabs prior to submission (approved by consultation).

**Reference Values:** By report; interpretive

**CPT Code(s):** 88271, 88273, 88291
FISH Study: Prenatal X/Y

Methodology: Interphase nuclei fluorescence in-situ hybridization (FISH) analysis for sex chromosome constitution; requires concurrent classic cytogenetic analysis; not for standalone use

Frequency Performed: Monday - Saturday

Routinely Reported: 2 - 4 days

Use: This screening test is only used to detect fetal sex in cases with an established history of sex-linked disorders.

Specimen Requirements: Amniotic Fluid: Aseptically collect approximately 1 cc of per week of gestational age in two sterile 15 mL conical centrifuge tubes and sequentially label the tubes. The initial 1 - 2 cc should not be included for chromosome studies (but may be utilized for AFP testing).

Chorionic Villi: Collect 10 - 30 mg of utilizing aspiration medium containing sodium heparin.* After assessment of the appropriate amount and quality of villi, transfer to a sterile centrifuge tube with transportation medium.

Do not freeze or fix samples in any manner contrary to the maintenance of cell viability. Maintain sample sterility; keep all specimens at room temperature; and deliver samples to the laboratory within 24 - 48 hours. Ship specimens at room temperature for overnight delivery.

Unacceptable Conditions:
- Frozen specimens
- Specimens greater than 48 hours old*

Stability (collection to initiation of testing):
- Ambient: 24 - 48 hours*
- Frozen: Unacceptable

* Cell viability of specimens requiring cell culture may be compromised in specimens older than 48 hours upon receipt. Refrigeration at 2° - 8° C may assist when a delay is not preventable. Do not freeze or place specimens directly on ice.

Contact the UFPath Labs prior to submission (approved by consultation).

Reference Values: By report; interpretive

CPT Code(s): 88271 x 2, 88274, 88291
**FISH Study: Chromosome Identification (for Constitutional Congenital Studies)**

**Methodology:** Metaphase fluorescence in-situ hybridization (FISH) analysis for characterization of de novo chromosomal findings; requires concurrent classic cytogenetic analysis; **not for standalone use** (prior chromosome study required)

**Frequency Performed:** Monday - Saturday

**Routinely Reported:** 10 - 21 days

**Use:** This test is used to further characterize chromosome abnormalities, as previously identified by conventional karyotyping techniques (e.g., marker chromosome identification, derivative chromosome content, breakpoint analysis, etc.).

**Specimen Requirements:**
- **Peripheral Blood:** Peripheral blood must be collected aseptically in sodium heparin tubes (usually green top tubes) and immediately rotated thoroughly to prevent clotting. For infants, obtain approximately 2 cc and for children and adults obtain 5 - 7 cc.
- **Skin Biopsy or Other Tissues:** In an aseptic manner, obtain approximately 2 mm x 2 mm, which is deep enough to ensure that the dermal layer is included. Deposit the specimen in a sterile container containing tissue culture medium with antibiotics (RPMI) which has been brought to room temperature prior to collection.* Alternate solid tissue samples include autopsy specimens (e.g., lung, cartilage, etc.).

**Note:** A separate blood sample is required if a concurrent CGH microarray study is desired. Do not freeze or fix samples in any manner contrary to the maintenance of cell viability. Maintain sample sterility; keep all specimens at room temperature; and deliver samples to the laboratory within 24 - 48 hours. Ship specimens at room temperature for overnight delivery.

* Cell viability of specimens requiring cell culture may be compromised in specimens older than 48 hours upon receipt. Refrigeration at 2° - 8° C may assist when a delay is not preventable. Do not freeze or place specimens directly on ice.

**Reference Values:** By report; interpretive

**CPT Code(s):** 88271, 88273, 88291
FISH Study: Microdeletion Metaphase - 1p36 Deletion Syndrome

Methodology: Metaphase/chromosome fluorescence in situ hybridization (FISH) analyses; requires cell culture and a concurrent or previous routine karyotyping

Frequency Performed: Monday - Saturday
Routinely Reported: 10 - 28 days

Use: This test is used to detect distal chromosome 1 short-arm deletions most frequently associated with a genetic condition commonly referred to as the Microdeletion 1p syndrome.

Specimen Requirements: Peripheral Blood: Peripheral blood must be collected aseptically in sodium heparin tubes (usually green-top tubes) and immediately rotated thoroughly to prevent clotting. For infants, obtain approximately 2 cc. Obtain 5 - 7 cc for children and adults.

Note: A separate blood sample is required if a concurrent CGH microarray study is desired. Do not freeze or fix samples in any manner contrary to the maintenance of cell viability. Maintain sample sterility; keep all specimens at room temperature; and deliver samples to the laboratory within 24 - 48 hours. Ship specimens at room temperature for overnight delivery.

Unacceptable Conditions:
- Frozen specimens
- Specimens greater than 48 hours*

Stability (collection to initiation of testing):
- Ambient: 24 - 48 hours*
- Frozen: Unacceptable

* Cell viability of specimens requiring cell culture may be compromised in specimens older than 48 hours upon receipt. Refrigeration at 2° - 8° C may assist when a delay is not preventable. Do not freeze or place specimens directly on ice.

Reference Values: By report; interpretive
CPT Code(s): 88271, 88273, 88291
FISH Study: Microdeletion Metaphase - Angelman Syndrome (15q11.2)

Methodology: Metaphase/chromosome fluorescence in-situ hybridization (FISH) analyses; requires cell culture and a concurrent or previous routine karyotyping.

Frequency Performed: Monday - Saturday

Routinely Reported: 10 - 28 days

Use: This test is used to detect proximal chromosome 15 long-arm deletions most frequently associated with the genetic condition commonly referred to as the Angelman Syndrome. It does not detect other mechanisms that may result in the Angelman Syndrome, such as PUD, gene defects, etc.

Specimen Requirements: Peripheral Blood: Peripheral blood must be collected aseptically in sodium heparin tubes (usually green-top tubes) and immediately rotated thoroughly to prevent clotting. For infants, obtain approximately 2 cc. Obtain 5 - 7 cc for children and adults.

Note: A separate blood sample is required if a concurrent CGH microarray study is desired. Do not freeze or fix samples in any manner contrary to the maintenance of cell viability. Maintain sample sterility; keep all specimens at room temperature; and deliver samples to the laboratory within 24 - 48 hours. Ship specimens at room temperature for overnight delivery.

Unacceptable Conditions:
- Frozen specimens
- Specimens greater than 48 hours*

Stability (collection to initiation of testing):
- Ambient: 24 - 48 hours*
- Frozen: Unacceptable

* Cell viability of specimens requiring cell culture may be compromised in specimens older than 48 hours upon receipt. Refrigeration at 2° - 8° C may assist when a delay is not preventable. Do not freeze or place specimens directly on ice.

Reference Values: By report; interpretive

CPT Code(s): 88271, 88273, 88291
**FISH Study: Microdeletion Metaphase - Cri-du-Chat Syndrome (5p15.3)**

**Methodology:** Metaphase/chromosome fluorescence in-situ hybridization (FISH) analyses; requires cell culture and a concurrent or previous routine karyotyping.

**Frequency Performed:** Monday - Saturday

**Routinely Reported:** 10 - 28 days

**Use:** This test detects cryptic distal chromosome 5 short-arm deletions most frequently associated with a genetic condition commonly referred to as the Cri-du-Chat Syndrome.

**Specimen Requirements:** **Peripheral Blood:** Peripheral blood must be collected aseptically in sodium heparin tubes (usually green-top tubes) and immediately rotated thoroughly to prevent clotting. For infants, obtain approximately 2 cc. Obtain 5 - 7 cc for children and adults.

*Note:* A separate blood sample is required if a concurrent CGH microarray study is desired. Do not freeze or fix samples in any manner contrary to the maintenance of cell viability. Maintain sample sterility; keep all specimens at room temperature; and deliver samples to the laboratory within 24 - 48 hours. Ship specimens at room temperature for overnight delivery.

**Unacceptable Conditions:**
- Frozen specimens
- Specimens greater than 48 hours old*

**Stability (collection to initiation of testing):**
- **Ambient:** 24 - 48 hours*
- **Frozen:** Unacceptable

*Cell viability of specimens requiring cell culture may be compromised in specimens older than 48 hours upon receipt. Refrigeration at 2° - 8° C may assist when a delay is not preventable. Do not freeze or place specimens directly on ice.

**Reference Values:** By report; interpretive

**CPT Code(s):** 88271, 88273, 88291
# FISH Study: Microdeletion Metaphase - DiGeorge Syndrome (22q11.2)

**Methodology:** Metaphase/chromosome fluorescence in-situ hybridization (FISH) analyses; requires cell culture and a concurrent or previous routine karyotyping

**Frequency Performed:** Monday - Saturday

**Routinely Reported:** 10 - 28 days

**Use:** This test is used to detect chromosome 22 long-arm deletions associated with multiple genetic conditions, including DiGeorge Syndrome, but have also been described with 22q11.2 deletion syndrome, CATCH-22, velo-cardio facial syndrome, Shprintzen syndrome and others.

**Specimen Requirements:**

**Peripheral Blood:** Collected aseptically in sodium heparin tubes (usually green top tubes) and immediately rotated thoroughly to prevent clotting. For infants obtain approximately 2 cc and for children and adults obtain 5 - 7 cc.

**Note:** A separate blood sample is required if a concurrent CGH microarray study is desired. Do not freeze or fix samples in any manner contrary to the maintenance of cell viability. Maintain sample sterility; keep all specimens at room temperature; and deliver samples to the laboratory within 24 - 48 hours. Ship specimens at room temperature for overnight delivery.

**Unacceptable Conditions:**
- Frozen specimens
- Specimens greater than 48 hours old*

**Stability (collection to initiation of testing):**
- **Ambient:** 24 - 48 hours*
- **Frozen:** Unacceptable

* Cell viability of specimens requiring cell culture may be compromised in specimens older than 48 hours upon receipt. Refrigeration at 2° - 8° C may assist when a delay is not preventable. Do not freeze or place specimens directly on ice.

**Reference Values:** By report; interpretive

**CPT Code(s):** 88271, 88273, 88291
FISH Study: Microdeletion Metaphase - Kallmann Syndrome (Xp22.3)

Methodology: Metaphase/chromosome fluorescence in-situ hybridization (FISH) analyses; requires cell culture and a concurrent or previous routine karyotyping.

Frequency Performed: Monday - Saturday
Routinely Reported: 10 - 28 days

Use: This test is used to detect microdeletions in the distal short-arm region of the X chromosome that include the KAL1 gene locus and have been reported in some patients with Kallmann syndrome.

Specimen Requirements: Peripheral Blood: Peripheral blood must be collected aseptically in sodium heparin tubes (usually green-top tubes) and immediately rotated thoroughly to prevent clotting. For infants, obtain approximately 2 cc. Obtain 5 - 7 cc for children and adults.

Note: A separate blood sample is required if a concurrent CGH microarray study is desired. Do not freeze or fix samples in any manner contrary to the maintenance of cell viability. Maintain sample sterility; keep all specimens at room temperature; and deliver samples to the laboratory within 24 - 48 hours. Ship specimens at room temperature for overnight delivery.

Unacceptable Conditions:
- Frozen specimens
- Specimens greater than 48 hours old*

Stability (collection to initiation of testing):
- Ambient: 24 - 48 hours*
- Frozen: Unacceptable

* Cell viability of specimens requiring cell culture may be compromised in specimens older than 48 hours upon receipt. Refrigeration at 2° - 8° C may assist when a delay is not preventable. Do not freeze or place specimens directly on ice.

Reference Values: By report; interpretive
CPT Code(s): 88271, 88273, 88291
FISH Study: Microdeletion Metaphase - Miller-Dieker Syndrome (17p13.3)

Methodology: Metaphase/chromosome fluorescence in-situ hybridization (FISH) analyses; requires cell culture and a concurrent or previous routine karyotyping

Frequency Performed: Monday - Saturday
Routinely Reported: 10 - 28 days

Use: This test is used to detect microdeletions in the distal short-arm region of chromosome 17, which include the PAFAH1B1 (LIS1) gene locus and are reported in patients with the Miller-Dieker Lissencephaly Syndrome (MDLS).

Specimen Requirements: Peripheral Blood: Peripheral blood must be collected aseptically in sodium heparin tubes (usually green-top tubes) and immediately rotated thoroughly to prevent clotting. For infants, obtain approximately 2 cc. Obtain 5 - 7 cc for children and adults.

Note: A separate blood sample is required if a concurrent CGH microarray study is desired. Do not freeze or fix samples in any manner contrary to the maintenance of cell viability. Maintain sample sterility; keep all specimens at room temperature; and deliver samples to the laboratory within 24 - 48 hours. Ship specimens at room temperature for overnight delivery.

Unacceptable Conditions:
- Frozen specimens
- Specimens greater than 48 hours old*

Stability (collection to initiation of testing):
- Ambient: 24 - 48 hours*
- Frozen: Unacceptable

* Cell viability of specimens requiring cell culture may be compromised in specimens older than 48 hours upon receipt. Refrigeration at 2° - 8° C may assist when a delay is not preventable. Do not freeze or place specimens directly on ice.

Reference Values: By report; interpretive

CPT Code(s): 88271, 88273, 88291
## FISH Study: Microdeletion Metaphase - Prader-Willi Syndrome (15q11.2)

**Methodology:** Metaphase/chromosome fluorescence in-situ hybridization (FISH) analyses; requires cell culture and a concurrent or previous routine karyotyping

**Frequency Performed:** Monday - Saturday

**Routinely Reported:** 10 - 28 days

**Use:** This test is used to detect proximal chromosome 15 long-arm deletions most frequently associated with a genetic condition commonly referred to as the Prader-Willi Syndrome. It does not detect other mechanisms that may result in the Prader-Willi syndrome, such as PUD, gene defects, etc.

**Specimen Requirements:**

**Peripheral Blood:** Peripheral blood must be collected aseptically in sodium heparin tubes (usually green-top tubes) and immediately rotated thoroughly to prevent clotting. For infants, obtain approximately 2 cc. Obtain 5 - 7 cc for children and adults.

*Note:* A separate blood sample is required if a concurrent CGH microarray study is desired.

*Do not freeze or fix samples in any manner contrary to the maintenance of cell viability. Maintain sample sterility; keep all specimens at room temperature; and deliver samples to the laboratory within 24 - 48 hours. Ship specimens at room temperature for overnight delivery.*

**Unacceptable Conditions:**
- Frozen specimens
- Specimens greater than 48 hours old*

**Stability (collection to initiation of testing):**
- **Ambient:** 24 - 48 hours*
- **Frozen:** Unacceptable

* Cell viability of specimens requiring cell culture may be compromised in specimens older than 48 hours upon receipt. Refrigeration at 2° - 8° C may assist when a delay is not preventable. Do not freeze or place specimens directly on ice.

**Reference Values:** By report; interpretive

**CPT Code(s):** 88271, 88273, 88291
FISH Study: Microdeletion Metaphase - Smith-Magenis Syndrome (17p11.2)

Methodology: Metaphase/chromosome fluorescence in-situ hybridization (FISH) analyses; requires cell culture and a concurrent or previous routine karyotyping.

Frequency Performed: Monday - Saturday

Routinely Reported: 10 - 28 days

Use: This test is used to detect microdeletions in the proximal short-arm region of chromosome 17, which include the RAI1 gene locus and are reported in patients with the Smith-Magenis Syndrome.

Specimen Requirements: Peripheral Blood: Peripheral blood must be collected aseptically in sodium heparin tubes (usually green-top tubes) and immediately rotated thoroughly to prevent clotting. For infants, obtain approximately 2 cc. Obtain 5 - 7 cc for children and adults.

Note: A separate blood sample is required if a concurrent CGH microarray study is desired. Do not freeze or fix samples in any manner contrary to the maintenance of cell viability. Maintain sample sterility; keep all specimens at room temperature; and deliver samples to the laboratory within 24 - 48 hours. Ship specimens at room temperature for overnight delivery.

Unacceptable Conditions:
- Frozen specimens
- Specimens greater than 48 hours old*

Stability (collection to initiation of testing):
- Ambient: 24 - 48 hours*
- Frozen: Unacceptable

* Cell viability of specimens requiring cell culture may be compromised in specimens older than 48 hours upon receipt. Refrigeration at 2° - 8° C may assist when a delay is not preventable. Do not freeze or place specimens directly on ice.

Reference Values: By report; interpretive

CPT Code(s): 88271, 88273, 88291
**FISH Study: Microdeletion Metaphase - SRY Sex Determination (Yp11.3)**

**Methodology:** Metaphase/chromosome fluorescence in-situ hybridization (FISH) analyses; requires cell culture and a concurrent or previous routine karyotyping

**Frequency Performed:** Monday - Saturday

**Routinely Reported:** 10 - 28 days

**Use:** This test is used to detect microdeletions or rearrangements involving the distal short-arm region of the Y chromosome, which includes the SRY (sex-determining region) gene locus, and may result in sexual phenotype abnormalities (e.g., XY females, Swyer syndrome, etc.).

**Specimen Requirements:**

**Peripheral Blood:** Peripheral blood must be collected aseptically in sodium heparin tubes (usually green-top tubes) and immediately rotated thoroughly to prevent clotting. For infants, obtain approximately 2 cc. Obtain 5 - 7 cc for children and adults.

*Note: A separate blood sample is required if a concurrent CGH microarray study is desired. Do not freeze or fix samples in any manner contrary to the maintenance of cell viability. Maintain sample sterility; keep all specimens at room temperature; and deliver samples to the laboratory within 24 - 48 hours. Ship specimens at room temperature for overnight delivery.*

**Unacceptable Conditions:**
- Frozen specimens
- Specimens greater than 48 hours old*

**Stability (collection to initiation of testing):**
- **Ambient:** 24 - 48 hours*
- **Frozen:** Unacceptable

*Cell viability of specimens requiring cell culture may be compromised in specimens older than 48 hours upon receipt. Refrigeration at 2° - 8°C may assist when a delay is not preventable. Do not freeze or place specimens directly on ice.*

**Reference Values:** By report; interpretive

**CPT Code(s):** 88271, 88273, 88291
**FISH Study: Microdeletion Metaphase - Steroid Sulfatase Deficiency (Xp22.3)**

**Methodology:** Metaphase/chromosome fluorescence in-situ hybridization (FISH) analyses; requires cell culture and a concurrent or previous routine karyotyping.

**Frequency Performed:** Monday - Saturday

**Routinely Reported:** 10 - 28 days

**Use:** This test is used to detect microdeletions in the distal short-arm region of the X chromosome, which includes the STS gene locus, and have been reported in some patients with the X-linked ichthyosis.

**Specimen Requirements:**

**Peripheral Blood:** Peripheral blood must be collected aseptically in sodium heparin tubes (usually green-top tubes) and immediately rotated thoroughly to prevent clotting. For infants, obtain approximately 2 cc. Obtain 5 - 7 cc for children and adults.

**Note:** A separate blood sample is required if a concurrent CGH microarray study is desired. Do not freeze or fix samples in any manner contrary to the maintenance of cell viability. Maintain sample sterility; keep all specimens at room temperature; and deliver samples to the laboratory within 24 - 48 hours. *Ship specimens at room temperature for overnight delivery.*

**Unacceptable Conditions:**
- Frozen specimens
- Specimens greater than 48 hours old*

**Stability (collection to initiation of testing):**
- **Ambient:** 24 - 48 hours*
- **Frozen:** Unacceptable

* Cell viability of specimens requiring cell culture may be compromised in specimens older than 48 hours upon receipt. Refrigeration at 2° - 8° C may assist when a delay is not preventable. Do not freeze or place specimens directly on ice.

**Reference Values:** By report; interpretive

**CPT Code(s):** 88271, 88273, 88291
### FISH Study: Microdeletion Metaphase - VCF Syndrome (22q11.2)

**Methodology:** Metaphase/chromosome fluorescence in-situ hybridization (FISH) analyses; requires cell culture and a concurrent or previous routine karyotyping.

**Frequency Performed:** Monday - Saturday

**Routinely Reported:** 10 - 28 days

**Use:** This test is used to detect chromosome 22 long-arm deletions associated with multiple genetic conditions, which includes velo-cardio-facial syndrome, but have also been described with 22q11.2 deletion syndrome, CATCH-22, DiGeorge syndrome velo-cardio facial syndrome, Shprintzen syndrome and others.

**Specimen Requirements:**

**Peripheral Blood:** Peripheral blood must be collected aseptically in sodium heparin tubes (usually green-top tubes) and immediately rotated thoroughly to prevent clotting. For infants, obtain approximately 2 cc. Obtain 5 - 7 cc for children and adults.

*Note: A separate blood sample is required if a concurrent CGH microarray study is desired. Do not freeze or fix samples in any manner contrary to the maintenance of cell viability. Maintain sample sterility; keep all specimens at room temperature; and deliver samples to the laboratory within 24 - 48 hours. Ship specimens at room temperature for overnight delivery.*

**Unacceptable Conditions:**
- Frozen specimens
- Specimens greater than 48 hours old*

**Stability (collection to initiation of testing):**
- Ambient: 24 - 48 hours*
- Frozen: Unacceptable

* Cell viability of specimens requiring cell culture may be compromised in specimens older than 48 hours upon receipt. Refrigeration at 2° - 8° C may assist when a delay is not preventable. Do not freeze or place specimens directly on ice.

**Reference Values:** By report; interpretive

**CPT Code(s):** 88271, 88273, 88291
FISH Study: Microdeletion Metaphase - Williams Syndrome (7q11.23)

Methodology: Metaphase/chromosome fluorescence in-situ hybridization (FISH) analyses; requires cell culture and a concurrent or previous routine karyotyping

Frequency Performed: Monday - Saturday

Routinely Reported: 10 - 28 days

Use: This test is used to detect microdeletions in the proximal long-arm region of chromosome 7, which includes the ELN, LIMK1, GTF2I gene loci, and is associated with Williams’ syndrome (aka Williams-Beuren syndrome).

Specimen Requirements: Peripheral Blood: Peripheral blood must be collected aseptically in sodium heparin tubes (usually green-top tubes) and immediately rotated thoroughly to prevent clotting. For infants, obtain approximately 2 cc. Obtain 5 - 7 cc for children and adults.

Note: A separate blood sample is required if a concurrent CGH microarray study is desired. Do not freeze or fix samples in any manner contrary to the maintenance of cell viability. Maintain sample sterility; keep all specimens at room temperature; and deliver samples to the laboratory within 24 - 48 hours. Ship specimens at room temperature for overnight delivery.

Unacceptable Conditions:
- Frozen specimens
- Specimens greater than 48 hours old*

Stability (collection to initiation of testing):
- Ambient: 24 - 48 hours*
- Frozen: Unacceptable

* Cell viability of specimens requiring cell culture may be compromised in specimens older than 48 hours upon receipt. Refrigeration at 2° - 8° C may assist when a delay is not preventable. Do not freeze or place specimens directly on ice.

Reference Values: By report; interpretive

CPT Code(s): 88271, 88273, 88291
FISH Study: Microdeletion Metaphase - Wolf-Hirschhorn Syndrome (4p16.3)

Methodology: Metaphase/chromosome fluorescence in-situ hybridization (FISH) analyses; requires cell culture and a concurrent or previous routine karyotyping

Frequency Performed: Monday - Saturday

 Routinely Reported: 10 - 28 days

Use: This test is used to detect cryptic distal chromosome 4 short-arm deletions most frequently associated with a genetic condition commonly referred to as the Wolf-Hirschhorn syndrome.

Specimen Requirements: Peripheral Blood: Peripheral blood must be collected aseptically in sodium heparin tubes (usually green-top tubes) and immediately rotated thoroughly to prevent clotting. For infants, obtain approximately 2 cc. Obtain 5 - 7 cc for children and adults.

Note: A separate blood sample is required if a concurrent CGH microarray study is desired. Do not freeze or fix samples in any manner contrary to the maintenance of cell viability. Maintain sample sterility; keep all specimens at room temperature; and deliver samples to the laboratory within 24 - 48 hours. Ship specimens at room temperature for overnight delivery.

Unacceptable Conditions:
• Frozen specimens
• Specimens greater than 48 hours old*

Stability (collection to initiation of testing):
• Ambient: 24 - 48 hours*
• Frozen: Unacceptable

* Cell viability of specimens requiring cell culture may be compromised in specimens older than 48 hours upon receipt. Refrigeration at 2° - 8° C may assist when a delay is not preventable. Do not freeze or place specimens directly on ice.

Reference Values: By report; interpretive

CPT Code(s): 88271, 88273, 88291
**FISH Study: Neoplastic Interphase ALK**

**Methodology:** Interphase nuclei fluorescence in-situ hybridization (FISH) break-apart rearrangement analyses; a concurrent or previous conventional cytogenetic workup is required/recommended (where possible).

**Frequency Performed:** Monday - Saturday

**Routinely Reported:** 5 - 12 days

**Use:** This test is used to detect rearrangements involving the ALK gene locus (2p23), which are most commonly associated with anaplastic large cell lymphomas.

**Specimen Requirements:**

**Lymphatic Tissues:** Aseptically obtain a sample of approximately 2mm x 2mm x 2mm and deposit it in tissue culture medium.

**Bone Marrow Aspirate:** Obtain 1 - 2 cc of aspirate in a green-top sodium heparin tube and immediately rotate it thoroughly to ensure adequate mixing with the anticoagulant.

**Bone Marrow Core Biopsy:** Deposit samples in a sterile container containing tissue culture medium with antibiotics (RPMI) that have been brought to room temperature before collection.*

**Peripheral Blood Specimens:** Peripheral blood specimens may be submitted in certain clinical conditions (e.g. circulating lymphoma cells).

Do not freeze or fix samples in any manner contrary to the maintenance of cell viability. Maintain sample sterility; keep all specimens at room temperature; and deliver samples to the laboratory within 24 - 48 hours. Ship specimens at room temperature for overnight delivery.

**Unacceptable Conditions:**
- Frozen specimens
- Specimens for FISH study only > one week old
- Specimens for concurrent FISH and cytogenetic studies > 48 hours old*
- Formalin, alcohol or paraffin-preserved specimens

**Stability (collection to initiation of testing):**
- **Ambient:** 24 - 48 hours*
- **Frozen:** Unacceptable
* Cell viability of specimens requiring cell culture may be compromised in specimens older than 48 hours upon receipt. Refrigeration at 2° - 8°C may assist when a delay is not preventable. Do not freeze or place specimens directly on ice.

Reference Values:  By report; interpretive
CPT Code(s):  88271, 88275, 88291
FISH Study: Neoplastic Interphase ATM (deletion 11q22.3)

Methodology: Interphase nuclei fluorescence in-situ hybridization (FISH) fusion rearrangement analyses

Frequency Performed: Monday - Saturday

Routinely Reported: 5 - 12 days (subject to a broad range of variables)

Use: This test is used to detect deletions of the long-arm of chromosome 11, which include the ATM gene locus which are commonly associated with CLL/SLL.

Specimen Requirements: Bone Marrow Aspirate: Obtain 1 - 2 cc of in a green-top sodium heparin tube and immediately rotate it thoroughly to ensure adequate mixing with the anticoagulant.

Bone Marrow Core Biopsy: Deposit samples in a sterile container containing tissue culture medium with antibiotics (RPMI) which has been brought to room temperature prior to collection.*

Peripheral Blood Specimens: Peripheral blood specimens may be submitted in certain clinical conditions (e.g. circulating lymphoma cells).

Do not freeze or fix samples in any manner contrary to the maintenance of cell viability. Maintain sample sterility; keep all specimens at room temperature; and deliver samples to the laboratory within 24 - 48 hours. Ship specimens at room temperature for overnight delivery.

Unacceptable Conditions: • Frozen specimens • Specimens for FISH study only > one week old • Specimens for concurrent FISH and cytogenetic studies > 48 hours old* • Formalin, alcohol or paraffin-preserved specimens

Stability (collection to initiation of testing): • Ambient: 24 - 48 hours* • Frozen: Unacceptable

* Cell viability of specimens requiring cell culture may be compromised in specimens older than 48 hours upon receipt. Refrigeration at 2° - 8° C may assist when a delay is not preventable. Do not freeze or place specimens directly on ice.

Reference Values: By report; interpretive

CPT Code(s): 88271, 88275, 88291
**Methodology:**
Interphase nuclei fluorescence in-situ hybridization (FISH) break-apart rearrangement analyses

**Use:**
This test is used to detect rearrangements involving the BCL2 gene locus (18q21), which are most commonly associated with B-cell NHL (follicular lymphoma and diffuse large B-cell lymphoma).

**Specimen Requirements:**

- **Lymphatic Tissues:** Aseptically obtain a sample of approximately 2mm x 2mm x 2mm and deposit it in tissue culture medium.*
- **Bone Marrow Aspirate:** Obtain 1 - 2 cc of in a green-top sodium heparin tube and immediately rotate it thoroughly to ensure adequate mixing with the anticoagulant.
- **Bone Marrow Core Biopsy:** Deposit samples in a sterile container containing tissue culture medium with antibiotics (RPMI) that have been brought to room temperature before collection.*
- **Peripheral Blood Specimens:** Peripheral blood specimens may be submitted in certain clinical conditions (e.g. circulating lymphoma cells).

- Do not freeze or fix samples in any manner contrary to the maintenance of cell viability. Maintain sample sterility; keep all specimens at room temperature; and deliver samples to the laboratory within 24 - 48 hours. Ship specimens at room temperature for overnight delivery.

**Unacceptable Conditions:**
- Frozen specimens
- Specimens for FISH study only > one week old
- Specimens for concurrent FISH and cytogenetic studies > 48 hours old*
- Formalin, alcohol or paraffin-preserved specimens

**Stability (collection to initiation of testing):**
- **Ambient:** 24 - 48 hours*
- **Frozen:** Unacceptable

* Cell viability of specimens requiring cell culture may be compromised in specimens older than 48 hours upon receipt. Refrigeration at 2° - 8° C may assist when a delay is not preventable. Do not freeze or place specimens directly on ice.

**Reference Values:**
By report; interpretive

**CPT Code(s):**
88271, 88275, 88291
FISH Study: Neoplastic Interphase BCL6

Methodology: Interphase nuclei fluorescence in-situ hybridization (FISH) break-apart rearrangement analyses; a concurrent or previous conventional cytogenetic workup is required/ recommended (where possible).

Frequency Performed: Monday - Saturday

Routinely Reported: 5 - 12 days

Use: This test is used to detect rearrangements involving the BCL6 gene locus (3q27), which are most commonly associated with B-cell NHL (follicular lymphoma, diffuse large B-cell lymphoma. These rearrangements are also seen in nodular lymphocyte predominant Hodgkin lymphomas.

Specimen Requirements:

Lymphatic Tissues: Aseptically obtain a sample of approximately 2mm x 2mm x 2mm and deposit in tissue culture medium*.

Bone Marrow Aspirate: Obtain 1 - 2 cc of in a green-top sodium heparin tube and immediately rotate it thoroughly to ensure adequate mixing with the anticoagulant.

Bone Marrow Core Biopsy: Deposit samples in a sterile container containing tissue culture medium with antibiotics (RPMI) that have been brought to room temperature before collection.*

Peripheral Blood Specimens: Peripheral blood specimens may be submitted in certain clinical conditions (e.g. circulating lymphoma cells).

Do not freeze or fix samples in any manner contrary to the maintenance of cell viability. Maintain sample sterility; keep all specimens at room temperature; and deliver samples to the laboratory within 24 - 48 hours. Ship specimens at room temperature for overnight delivery.

Unacceptable Conditions:
- Frozen specimens
- Specimens for FISH study only > one week old
- Specimens for concurrent FISH and cytogenetic studies > 48 hours old*
- Formalin, alcohol or paraffin-preserved specimens
Stability (collection to initiation of testing):
- Ambient: 24 - 48 hours*
- Frozen: Unacceptable

* Cell viability of specimens requiring cell culture may be compromised in specimens older than 48 hours upon receipt. Refrigeration at 2° - 8° C may assist when a delay is not preventable. Do not freeze or place specimens directly on ice.

Reference Values: By report; interpretive
CPT Code(s): 88271, 88275, 88291
FISH Study: Neoplastic Interphase BCR/ABL1

Methodology: Interphase nuclei fluorescence in-situ hybridization (FISH) fusion rearrangement analyses

Frequency Performed: Monday - Saturday

Routinely Reported: 5 - 12 days

Use: This test is used to detect the presence of BCR/ABL1 fusions, which are most commonly the result of a 9/22 translocation (Philadelphia chromosome formation), and may be seen in CML, ALL and AML.

Specimen Requirements:

Bone Marrow Aspirate: Obtain 1 - 2 cc of in a green-top sodium heparin tube and immediately rotate it thoroughly to ensure adequate mixing with the anticoagulant.

Bone Marrow Core Biopsy: Deposit samples in a sterile container containing tissue culture medium with antibiotics (RPMI) that have been brought to room temperature before collection.*

Peripheral Blood Specimens: Peripheral blood specimens may be submitted in certain clinical conditions (e.g. circulating blasts).

Do not freeze or fix samples in any manner contrary to the maintenance of cell viability. Maintain sample sterility; keep all specimens at room temperature; and deliver samples to the laboratory within 24 - 48 hours. Ship specimens at room temperature for overnight delivery.

Unacceptable Conditions:

- Frozen specimens
- Specimens for FISH study only > one week old
- Specimens for concurrent FISH and cytogenetic studies > 48 hours old*
- Formalin, alcohol or paraffin-preserved specimens

Stability (collection to initiation of testing):

- Ambient: 24 - 48 hours*
- Frozen: Unacceptable

* Cell viability of specimens requiring cell culture may be compromised in specimens older than 48 hours upon receipt. Refrigeration at 2° - 8°C may assist when a delay is not preventable. Do not freeze or place specimens directly on ice.

Reference Values: By report; interpretive

CPT Code(s): 88271, 88275, 88291
FISH Study: Neoplastic Interphase CBFB

Methodology: Interphase nuclei fluorescence in-situ hybridization (FISH) break-apart rearrangement analyses

Frequency Performed: Monday - Saturday

 Routinely Reported: 5 - 12 days (subject to a broad range of variables)

 Use: This test is used to detect rearrangements involving the CBFB gene locus (16q22), which are most commonly associated with chromosome 16 rearrangements and the AML subtype M4eo.

Specimen Requirements: Bone Marrow Aspirate: Obtain 1 - 2 cc of in a green-top sodium heparin tube and immediately rotate it thoroughly to ensure adequate mixing with the anticoagulant.

Bone Marrow Core Biopsy: Deposit samples in a sterile container containing tissue culture medium with antibiotics (RPMI) that have been brought to room temperature before collection.*

Peripheral Blood Specimens: Peripheral blood specimens may be submitted in certain clinical conditions (e.g. circulating blasts).

Unacceptable Conditions:
• Frozen specimens
• Specimens for FISH study only > one week old
• Specimens for concurrent FISH and cytogenetic studies > 48 hours old*
• Formalin, alcohol or paraffin-preserved specimens

Stability (collection to initiation of testing):
• Ambient: 24 - 48 hours*
• Frozen: Unacceptable

* Cell viability of specimens requiring cell culture may be compromised in specimens older than 48 hours upon receipt. Refrigeration at 2° - 8° C may assist when a delay is not preventable. Do not freeze or place specimens directly on ice.

Do not freeze or fix samples in any manner contrary to the maintenance of cell viability. Maintain sample sterility; keep all specimens at room temperature; and deliver samples to the laboratory within 24 - 48 hours. Ship specimens at room temperature for overnight delivery.

Reference Values: By report; interpretive

CPT Code(s): 88271, 88275, 88291
FISH Study: Neoplastic Interphase D10Z1 (Trisomy 10)

Methodology: Interphase nuclei fluorescence in-situ hybridization (FISH) copy number analyses

Frequency Performed: Monday - Saturday

Routinely Reported: 5 - 12 days

Use: This test is used to detect the presence of chromosome 10 copy number changes (e.g., trisomy) which are commonly observed in childhood B-ALL and have prognostic value.

Specimen Requirements:

**Bone Marrow Aspirate:** Obtain 1 - 2 cc of in a green-top sodium heparin tube and immediately rotate it thoroughly to ensure adequate mixing with the anticoagulant.

**Bone Marrow Core Biopsy:** Deposit samples in a sterile container containing tissue culture medium with antibiotics (RPMI) that have been brought to room temperature before collection.*

**Peripheral Blood Specimens:** Peripheral blood specimens may be submitted in certain clinical conditions (e.g. circulating blasts).

Unacceptable Conditions:

- Frozen specimens
- Specimens for FISH study only > one week old
- Specimens for concurrent FISH and cytogenetic studies > 48 hours old*
- Formalin, alcohol or paraffin-preserved specimens

Stability (collection to initiation of testing):

- **Ambient:** 24 - 48 hours*
- **Frozen:** Unacceptable

* Cell viability of specimens requiring cell culture may be compromised in specimens older than 48 hours upon receipt. Refrigeration at 2° - 8° C may assist when a delay is not preventable. Do not freeze or place specimens directly on ice.

Do not freeze or fix samples in any manner contrary to the maintenance of cell viability. Maintain sample sterility; keep all specimens at room temperature; and deliver samples to the laboratory within 24 - 48 hours. Ship specimens at room temperature for overnight delivery.

Reference Values: By report; interpretive

CPT Code(s): 88271, 88275, 88291
# FISH Study: Neoplastic Interphase D12Z3 (Trisomy 12)

**Methodology:** Interphase nuclei fluorescence in-situ hybridization (FISH) copy number analyses

**Frequency Performed:** Monday - Saturday

**Routinely Reported:** 5 - 12 days

**Use:** This test is primarily used to detect the presence of trisomy for chromosome 12, which is commonly observed in CLL/SLL.

**Specimen Requirements:**

- **Bone Marrow Aspirate:** Obtain 1 - 2 cc of in a green-top sodium heparin tube and immediately rotate it thoroughly to ensure adequate mixing with the anticoagulant.

- **Bone Marrow Core Biopsy:** Deposit samples in a sterile container containing tissue culture medium with antibiotics (RPMI) that have been brought to room temperature before collection.*

- **Peripheral Blood Specimens:** Peripheral blood specimens may be submitted in certain clinical conditions (e.g. circulating lymphoma cells).

**Unacceptable Conditions:**

- Frozen specimens
- Specimens for FISH study only > one week old
- Specimens for concurrent FISH and cytogenetic studies > 48 hours old*
- Formalin, alcohol or paraffin-preserved specimens

**Stability (collection to initiation of testing):**

- **Ambient:** 24 - 48 hours*
- **Frozen:** Unacceptable

*Cell viability of specimens requiring cell culture may be compromised in specimens older than 48 hours upon receipt. Refrigeration at 2° - 8° C may assist when a delay is not preventable. Do not freeze or place specimens directly on ice.

Do not freeze or fix samples in any manner contrary to the maintenance of cell viability. Maintain sample sterility; keep all specimens at room temperature; and deliver samples to the laboratory within 24 - 48 hours. Ship specimens at room temperature for overnight delivery.

**Reference Values:** By report; interpretive

**CPT Code(s):** 88271, 88275, 88291
**FISH Study: Neoplastic Interphase D13S319 with LAMP1 (Deletion 13q)**

**Methodology:** Interphase nuclei fluorescence in-situ hybridization (FISH) copy number analyses

**Frequency Performed:** Monday - Saturday

**Routinely Reported:** 5 - 12 days

**Use:** This test is used to detect the presence of chromosome 13 long-arm deletions and monosomy 13, which are commonly observed in CLL/SLL and plasma cell disorders.

**Specimen Requirements:**
- **Bone Marrow Aspirate:** Obtain 1 - 2 cc of in a green-top sodium heparin tube and immediately rotate it thoroughly to ensure adequate mixing with the anticoagulant.
- **Bone Marrow Core Biopsy:** Deposit samples in a sterile container containing tissue culture medium with antibiotics (RPMI) that have been brought to room temperature before collection.*
- **Peripheral Blood Specimens:** Peripheral blood specimens may be submitted in certain clinical conditions (e.g. circulating tumor cells).

**Unacceptable Conditions:**
- Frozen specimens
- Specimens for FISH study only > one week old
- Specimens for concurrent FISH and cytogenetic studies > 48 hours old*
- Formalin, alcohol or paraffin-preserved specimens

**Stability (collection to initiation of testing):**
- **Ambient:** 24 - 48 hours*
- **Frozen:** Unacceptable

* Cell viability of specimens requiring cell culture may be compromised in specimens older than 48 hours upon receipt. Refrigeration at 2° - 8°C may assist when a delay is not preventable. Do not freeze or place specimens directly on ice.

Do not freeze or fix samples in any manner contrary to the maintenance of cell viability. Maintain sample sterility; keep all specimens at room temperature; and deliver samples to the laboratory within 24 - 48 hours. Ship specimens at room temperature for overnight delivery.

**Reference Values:** By report; interpretive

**CPT Code(s):** 88271, 88275, 88291
**FISH Study: Neoplastic Interphase D17Z1 (Trisomy 17)**

**Methodology:** Interphase nuclei fluorescence in-situ hybridization (FISH) copy number analyses

**Frequency Performed:** Monday - Saturday

**Routinely Reported:** 5 - 12 days

**Use:** This test is used to detect the presence of chromosome 17 copy number changes (e.g., trisomy), which are commonly observed in childhood B-ALL and have prognostic value.

**Specimen Requirements:**
- **Bone Marrow Aspirate:** Obtain 1 - 2 cc of in a green-top sodium heparin tube and immediately rotate it thoroughly to ensure adequate mixing with the anticoagulant.
- **Bone Marrow Core Biopsy:** Deposit samples in a sterile container containing tissue culture medium with antibiotics (RPMI) that have been brought to room temperature before collection.*
- **Peripheral Blood Specimens:** Peripheral blood specimens may be submitted in certain clinical conditions (e.g. circulating blasts)

**Unacceptable Conditions:**
- Frozen specimens
- Specimens for FISH study only > one week old
- Specimens for concurrent FISH and cytogenetic studies > 48 hours old*
- Formalin, alcohol or paraffin-preserved specimens

**Stability (collection to initiation of testing):**
- **Ambient:** 24 - 48 hours*
- **Frozen:** Unacceptable

*Cell viability of specimens requiring cell culture may be compromised in specimens older than 48 hours upon receipt. Refrigeration at 2° - 8° C may assist when a delay is not preventable. Do not freeze or place specimens directly on ice.

Do not freeze or fix samples in any manner contrary to the maintenance of cell viability. Maintain sample sterility; keep all specimens at room temperature; and deliver samples to the laboratory within 24 - 48 hours. Ship specimens at room temperature for overnight delivery.

**Reference Values:** By report; interpretive

**CPT Code(s):** 88271, 88275, 88291
**FISH Study: Neoplastic Interphase D20S108 (Deletion 20q)**

**Methodology:** Interphase nuclei fluorescence in-situ hybridization (FISH) copy number analyses

**Frequency Performed:** Monday - Saturday

**Routinely Reported:** 5 - 12 days

**Use:** This test is used to detect the presence of chromosome 20 long-arm deletions, which are observed in broad-range hematological malignancies as MDS, AML, polycythemia vera and chronic neutrophilic leukemia

**Specimen Requirements:**
- **Bone Marrow Aspirate:** Obtain 1 - 2 cc of in a green-top sodium heparin tube and immediately rotate it thoroughly to ensure adequate mixing with the anticoagulant.
- **Bone Marrow Core Biopsy:** Deposit samples in a sterile container containing tissue culture medium with antibiotics (RPMI) that have been brought to room temperature before collection.*
- **Peripheral Blood Specimens:** Peripheral blood specimens may be submitted in certain clinical conditions (e.g. circulating blasts).

**Unacceptable Conditions:**
- Frozen specimens
- Specimens for FISH study only > one week old
- Specimens for concurrent FISH and cytogenetic studies > 48 hours old*
- Formalin, alcohol or paraffin-preserved specimens

**Stability (collection to initiation of testing):**
- **Ambient:** 24 - 48 hours*
- **Frozen:** Unacceptable

* Cell viability of specimens requiring cell culture may be compromised in specimens older than 48 hours upon receipt. Refrigeration at 2° - 8° C may assist when a delay is not preventable. Do not freeze or place specimens directly on ice.

Do not freeze or fix samples in any manner contrary to the maintenance of cell viability. Maintain sample sterility; keep all specimens at room temperature; and deliver samples to the laboratory within 24 - 48 hours. Ship specimens at room temperature for overnight delivery.

**Reference Values:** By report; interpretive

**CPT Code(s):** 88271, 88275, 88291
Methodology: Interphase nuclei fluorescence in-situ hybridization (FISH) copy number analyses

Frequency Performed: Monday - Saturday

Routinely Reported: 5 - 12 days

Use: This test is used to detect the presence of chromosome 4 copy number changes (e.g., trisomy), which are commonly observed in childhood B-ALL and have prognostic value.

Specimen Requirements:

Bone Marrow Aspirate: Obtain 1 - 2 cc of in a green-top sodium heparin tube and immediately rotate it thoroughly to ensure adequate mixing with the anticoagulant.

Bone Marrow Core Biopsy: Deposit samples in a sterile container containing tissue culture medium with antibiotics (RPMI) that have been brought to room temperature before collection.*

Peripheral Blood Specimens: Peripheral blood specimens may be submitted in certain clinical conditions (e.g. circulating blasts).

Unacceptable Conditions:
- Frozen specimens
- Specimens for FISH study only > one week old
- Specimens for concurrent FISH and cytogenetic studies > 48 hours old*
- Formalin, alcohol or paraffin-preserved specimens

Stability (collection to initiation of testing):
- Ambient: 24 - 48 hours*
- Frozen: Unacceptable

* Cell viability of specimens requiring cell culture may be compromised in specimens older than 48 hours upon receipt. Refrigeration at 2° - 8°C may assist when a delay is not preventable. Do not freeze or place specimens directly on ice.

Do not freeze or fix samples in any manner contrary to the maintenance of cell viability. Maintain sample sterility; keep all specimens at room temperature; and deliver samples to the laboratory within 24 - 48 hours. Ship specimens at room temperature for overnight delivery.

Reference Values: By report; interpretive

CPT Code(s): 88271, 88275, 88291
**FISH Study: Neoplastic Interphase D7S522 with D7Z1 (Deletion 7q)**

**Methodology:** Interphase nuclei fluorescence in-situ hybridization (FISH) copy number analyses; a concurrent or previous conventional cytogenetic workup is required/recommended (where possible)

**Frequency Performed:** Monday - Saturday

**Routinely Reported:** 5 - 12 days

**Use:** This test is used to detect the presence of chromosome 7 long-arm deletions and monosomy 7, which are common clonal aberrations observed both primary and secondary MDS and AML.

**Specimen Requirements:**

- **Bone Marrow Aspirate:** Obtain 1 - 2 cc of in a green-top sodium heparin tube and immediately rotate it thoroughly to ensure adequate mixing with the anticoagulant.

- **Bone Marrow Core Biopsy:** Deposit samples in a sterile container containing tissue culture medium with antibiotics (RPMI) that have been brought to room temperature before collection.*

- **Peripheral Blood Specimens:** Peripheral blood specimens may be submitted in certain clinical conditions (e.g. circulating blasts).

**Unacceptable Conditions:**

- Frozen specimens
- Specimens for FISH study only > one week old
- Specimens for concurrent FISH and cytogenetic studies > 48 hours old*
- Formalin, alcohol or paraffin-preserved specimens

**Stability (collection to initiation of testing):**

- **Ambient:** 24 - 48 hours*
- **Frozen:** Unacceptable

*Cell viability of specimens requiring cell culture may be compromised in specimens older than 48 hours upon receipt. Refrigeration at 2° - 8°C may assist when a delay is not preventable. Do not freeze or place specimens directly on ice.

Do not freeze or fix samples in any manner contrary to the maintenance of cell viability. Maintain sample sterility; keep all specimens at room temperature; and deliver samples to the laboratory within 24 - 48 hours. Ship specimens at room temperature for overnight delivery.

**Reference Values:** By report; interpretive

**CPT Code(s):** 88271, 88275, 88291
FISH Study: Neoplastic Interphase D8Z2 (Trisomy 8)

Methodology: Interphase nuclei fluorescence in-situ hybridization (FISH) copy number analyses; a concurrent or previous conventional cytogenetic workup is required/recommended (where possible)

Frequency Performed: Monday - Saturday

Routinely Reported: 5 - 12 days

Use: This test is used to detect trisomy for chromosome 8, which is one of the most common chromosome abnormalities in myeloid disorders.

Specimen Requirements:
- Bone Marrow Aspirate: Obtain 1 - 2 cc of in a green-top sodium heparin tube and immediately rotate it thoroughly to ensure adequate mixing with the anticoagulant.
- Bone Marrow Core Biopsy: Deposit samples in a sterile container containing tissue culture medium with antibiotics (RPMI) that have been brought to room temperature before collection.*
- Peripheral Blood Specimens: Peripheral blood specimens may be submitted in certain clinical conditions (e.g. circulating blasts).

Unacceptable Conditions:
- Frozen specimens
- Specimens for FISH study only > one week old
- Specimens for concurrent FISH and cytogenetic studies > 48 hours old*
- Formalin, alcohol or paraffin-preserved specimens

Stability (collection to initiation of testing):
- Ambient: 24 - 48 hours*
- Frozen: Unacceptable

* Cell viability of specimens requiring cell culture may be compromised in specimens older than 48 hours upon receipt. Refrigeration at 2° - 8° C may assist when a delay is not preventable. Do not freeze or place specimens directly on ice.

Reference Values: By report; interpretive

CPT Code(s): 88271, 88275, 88291
**FISH Study: Neoplastic Interphase D9Z1 (Trisomy 9)**

**Methodology:** Interphase nuclei fluorescence in-situ hybridization (FISH) copy number analyses; a concurrent or previous conventional cytogenetic workup is required/recommended (where possible)

**Frequency Performed:** Monday - Saturday

**Routinely Reported:** 5 - 12 days

**Use:** This test is used to detect trisomy for chromosome 9, which is a relatively common finding in plasma cell disorders.

**Specimen Requirements:**

- **Bone Marrow Aspirate:** Obtain 1 - 2 cc of in a green-top sodium heparin tube and immediately rotate it thoroughly to ensure adequate mixing with the anticoagulant.

- **Bone Marrow Core Biopsy:** Deposit samples in a sterile container containing tissue culture medium with antibiotics (RPMI) that have been brought to room temperature before collection.*

- **Peripheral Blood Specimens:** Peripheral blood specimens may be submitted in certain clinical conditions (e.g. circulating tumor cells).

**Unacceptable Conditions:**

- Frozen specimens
- Specimens for FISH study only > one week old
- Specimens for concurrent FISH and cytogenetic studies > 48 hours old*
- Formalin, alcohol or paraffin-preserved specimens

**Stability (collection to initiation of testing):**

- **Ambient:** 24 - 48 hours*
- **Frozen:** Unacceptable

* Cell viability of specimens requiring cell culture may be compromised in specimens older than 48 hours upon receipt. Refrigeration at 2° - 8° C may assist when a delay is not preventable. Do not freeze or place specimens directly on ice.

**Reference Values:** By report; interpretive

**CPT Code(s):** 88271, 88275, 88291
# FISH Study: Neoplastic Interphase DDIT3 (12q13.3)
(For Formalin-Fixed Paraffin-Embedded Tissue) (FFPE)

**Methodology:** Interphase nuclei fluorescence in-situ hybridization (FISH) break-apart analyses; previous or concurrent conventional cytogenetic workup recommended (where possible)

**Frequency Performed:** Monday - Saturday

**Routinely Reported:** 5 - 14 days

**Use:** This test is used to diagnose myxoid/round cell liposarcoma by detecting a neoplastic association with gene rearrangement.

**Specimen Requirements:**
- Formalin-fixed, paraffin-embedded tissues
- FFPE-isolated nuclei
- De-paraffinated, four-micron, slide-mounted tissue sections

The identification of tissues/cells to be targeted and DNA probe selection is the responsibility of the requesting or submitting parties.

Tissue sections and tissues utilized to obtain nuclei isolated from paraffin blocks submitted for interphase FISH analysis must include concurrent evaluation by qualified individuals utilizing additional non-FISH morphometric features to ensure that the requested FISH tests are applied to the appropriate tissues/cells.

**Reference Values:** By report; interpretive

**CPT Code(s):** 88367x 2 (computer-assisted), 88368 x 2 (manual)
**FISH Study: Neoplastic Interphase EGR1 with D5S23, DS721 (Deletion 5q)**

**Methodology:** Interphase nuclei fluorescence in-situ hybridization (FISH) copy number analyses; a concurrent or previous conventional cytogenetic workup is required/recommended (where possible)

**Frequency Performed:** Monday - Saturday

**Routinely Reported:** 5 - 12 days

**Use:** This test is used to detect del(5q) in a broad variety of myeloid neoplasms and is specifically useful for MDS/AML.

**Specimen Requirements:**

**Bone Marrow Aspirate:** Obtain 1 - 2 cc of in a green-top sodium heparin tube and immediately rotate it thoroughly to ensure adequate mixing with the anticoagulant.

**Bone Marrow Core Biopsy:** Deposit samples in a sterile container containing tissue culture medium with antibiotics (RPMI) that have been brought to room temperature before collection.*

**Peripheral Blood Specimens:** Peripheral blood specimens may be submitted in certain clinical conditions (e.g. circulating blasts).

**Unacceptable Conditions:**
- Frozen specimens
- Specimens for FISH study only > one week old
- Specimens for concurrent FISH and cytogenetic studies > 48 hours old*
- Formalin, alcohol or paraffin-preserved specimens

**Stability (collection to initiation of testing):**
- **Ambient:** 24 - 48 hours*
- **Frozen:** Unacceptable

* Cell viability of specimens requiring cell culture may be compromised in specimens older than 48 hours upon receipt. Refrigeration at 2° - 8° C may assist when a delay is not preventable. Do not freeze or place specimens directly on ice.

**Reference Values:** By report; interpretive

**CPT Code(s):** 88271, 88275, 88291
**FISH Study: Neoplastic Interphase ETV6**

**Methodology:** Interphase nuclei fluorescence in-situ hybridization (FISH) break-apart rearrangement analyses; a concurrent or previous conventional cytogenetic workup is required/recommended (where possible)

**Frequency Performed:** Monday - Saturday

**Routinely Reported:** 5 - 12 days

**Use:** This test is used to detect cryptic rearrangements involving the ETV6 gene locus, which have been implicated in a broad range of hematological conditions including acute leukemias and MDS.

**Specimen Requirements:**

- **Bone Marrow Aspirate:** Obtain 1 - 2 cc of in a green-top sodium heparin tube and immediately rotate it thoroughly to ensure adequate mixing with the anticoagulant.

- **Bone Marrow Core Biopsy:** Deposit samples in a sterile container containing tissue culture medium with antibiotics (RPMI) that have been brought to room temperature before collection.*

- **Peripheral Blood Specimens:** Peripheral blood specimens may be submitted in certain clinical conditions (e.g. circulating blasts).

**Unacceptable Conditions:**
- Frozen specimens
- Specimens for FISH study only > one week old
- Specimens for concurrent FISH and cytogenetic studies > 48 hours old*
- Formalin, alcohol or paraffin-preserved specimens

**Stability (collection to initiation of testing):**
- Ambient: 24 - 48 hours*
- Frozen: Unacceptable

*Cell viability of specimens requiring cell culture may be compromised in specimens older than 48 hours upon receipt. Refrigeration at 2° - 8° C may assist when a delay is not preventable. Do not freeze or place specimens directly on ice.*

**Reference Values:** By report; interpretive

**CPT Code(s):** 88271, 88275, 88291
**FISH Study: Neoplastic Interphase ETV6/RUNX1**

**Methodology:** Interphase nuclei fluorescence in-situ hybridization (FISH) fusion rearrangement analyses; a concurrent or previous conventional cytogenetic workup is required/recommended (where possible)

**Frequency Performed:** Monday - Saturday

**Routinely Reported:** 5 - 12 days

**Use:** This test is used to detect a cryptic translocation involving chromosomes 12 and 21, which results in the formation of an ETV6/RUNX1 fusion gene hybrid that is commonly seen in childhood B-ALL.

**Specimen Requirements:**

- **Bone Marrow Aspirate:** Obtain 1 - 2 cc of in a green-top sodium heparin tube and immediately rotate it thoroughly to ensure adequate mixing with the anticoagulant.

- **Bone Marrow Core Biopsy:** Deposit samples in a sterile container containing tissue culture medium with antibiotics (RPMI) that have been brought to room temperature before collection.*

- **Peripheral Blood Specimens:** Peripheral blood specimens may be submitted in certain clinical conditions (e.g. circulating blasts)

**Unacceptable Conditions:**
- Frozen specimens
- Specimens for FISH study only > one week old
- Specimens for concurrent FISH and cytogenetic studies > 48 hours old*
- Formalin, alcohol or paraffin-preserved specimens

**Stability (collection to initiation of testing):**
- **Ambient:** 24 - 48 hours*
- **Frozen:** Unacceptable

* Cell viability of specimens requiring cell culture may be compromised in specimens older than 48 hours upon receipt. Refrigeration at 2° - 8° C may assist when a delay is not preventable. Do not freeze or place specimens directly on ice.

**Reference Values:** By report; interpretive

**CPT Code(s):** 88271, 88275, 88291
**FISH Study: Neoplastic Interphase EWSR1**

**Methodology:** Interphase nuclei fluorescence in-situ hybridization (FISH) fusion rearrangement analyses; a concurrent or previous conventional cytogenetic workup is required/recommended (where possible)

**Frequency Performed:** Monday - Saturday

**Routinely Reported:** 5 - 12 days

**Use:** This test is used to detect the presence of rearrangements involving the EWSR1 gene locus at 22q11.2 in non-preserved/fixed tissue specimens, which have been described in several types of soft tissue neoplasms, including Ewing sarcoma, PNET, clear cell sarcoma and extraskeletal myxoid chondrosarcoma.

**Specimen Requirements:**

- **Bone Marrow Aspirate:** Obtain 1 - 2 cc of in a green-top sodium heparin tube and immediately rotate it thoroughly to ensure adequate mixing with the anticoagulant.

- **Bone Marrow Core Biopsy:** Deposit samples in a sterile container containing tissue culture medium with antibiotics (RPMI) that have been brought to room temperature before collection.*

- **Peripheral Blood Specimens:** Peripheral blood specimens may be submitted in certain clinical conditions (e.g. circulating blasts) and/or circumstances (where warranted).

**Unacceptable Conditions:**
- Frozen specimens
- Specimens for FISH study only > one week old
- Specimens for concurrent FISH and cytogenetic studies > 48 hours old*
- Formalin, alcohol or paraffin-preserved specimens

**Stability (collection to initiation of testing):**
- **Ambient:** 24 - 48 hours*
- **Frozen:** Unacceptable

* Cell viability of specimens requiring cell culture may be compromised in specimens older than 48 hours upon receipt. Refrigeration at 2° - 8° C may assist when a delay is not preventable. Do not freeze or place specimens directly on ice.

**Reference Values:** By report; interpretive

**CPT Code(s):** 88271, 88275, 88291
FISH Study: Neoplastic Interphase EWSR1 (22q12) (For Formalin-Fixed Paraffin-Embedded Tissue) (FFPE)

Methodology: Interphase nuclei fluorescence in-situ hybridization (FISH) break-apart analyses; previous or concurrent conventional cytogenetic workup recommended (where possible)

Frequency Performed: Monday - Saturday

Routinely Reported: 5 - 14 days (subject to a broad range of variables)

Use: This test is used to detect Ewing’s sarcoma/primitive neuroectodermal tumor and other small round cell tumors sharing EWS rearrangement.

Specimen Requirements:
- Formalin-fixed, paraffin-embedded tissues
- FFPE-isolated nuclei
- De-paraffinated, four-micron, slide-mounted tissue sections

The identification of tissues/cells to be targeted and DNA probe selection is the responsibility of the requesting or submitting parties.

Tissue sections and tissues utilized to obtain nuclei isolated from paraffin blocks submitted for interphase FISH analysis must include concurrent evaluation by qualified individuals utilizing additional non-FISH morphometric features to ensure that the requested FISH test(s) are applied to the appropriate tissues/cells.

Reference Values: By report; interpretive

CPT Code(s): 88367 x 2 (computer-assisted), 88368 x 2 (manual)
FISH Study: Neoplastic Interphase FOXO1

Methodology: Interphase nuclei fluorescence in-situ hybridization (FISH) fusion rearrangement analyses; a concurrent or previous conventional cytogenetic workup is required/recommended (where possible)

Frequency Performed: Monday - Saturday
Routinely Reported: 5 - 12 days
Use: This test is used to diagnose alveolar rhabdomyosarcoma (ARMS).

Specimen Requirements: Bone Marrow Aspirate: Obtain 1 - 2 cc of in a green-top sodium heparin tube and immediately rotate it thoroughly to ensure adequate mixing with the anticoagulant.

Bone Marrow Core Biopsy: Deposit samples in a sterile container containing tissue culture medium with antibiotics (RPMI) that have been brought to room temperature before collection.*

Peripheral Blood Specimens: Peripheral blood specimens may be submitted in certain clinical conditions (e.g. significant circulating tumor cells).

Unacceptable Conditions:
• Frozen specimens
• Specimens for FISH study only > one week old
• Specimens for concurrent FISH and cytogenetic studies > 48 hours old*
• Formalin, alcohol or paraffin-preserved specimens

Stability (collection to initiation of testing):
• Ambient: 24 - 48 hours*
• Frozen: Unacceptable

* Cell viability of specimens requiring cell culture may be compromised in specimens older than 48 hours upon receipt. Refrigeration at 2°C - 8°C may assist when a delay is not preventable. Do not freeze or place specimens directly on ice.

Reference Values: By report; interpretive
CPT Code(s): 88271, 88275, 88291
FISH Study: Neoplastic Interphase FOXO1 (13q14.11) (For Formalin-Fixed Paraffin-Embedded Tissue) (FFPE)

**Methodology:** Interphase nuclei fluorescence in-situ hybridization (FISH) break-apart analyses; previous or concurrent conventional cytogenetic workup recommended (where possible)

**Frequency Performed:** Monday - Saturday

**Routiney Reported:** 5 - 14 days

**Use:** This test is used to diagnose alveolar rhabdomyosarcoma (ARMS).

**Specimen Requirements:**
- Formalin-fixed, paraffin-embedded tissues
- FFPE-isolated nuclei
- De-paraffinated, four-micron, slide-mounted tissue sections

The identification of tissues/cells to be targeted and DNA probe selection is the responsibility of the requesting or submitting parties.

Tissue sections and tissues utilized to obtain nuclei isolated from paraffin blocks submitted for interphase FISH analysis must include concurrent evaluation by qualified individuals utilizing additional non-FISH morphometric features to ensure that the requested FISH test(s) are applied to the appropriate tissues/cells.

**Reference Values:** By report; interpretive

**CPT Code(s):** 88367 x 2 (computer-assisted), 88368 x 2 (manual)
**FISH Study: Neoplastic Interphase FUS (16q11.2)
(For Formalin-Fixed Paraffin-Embedded Tissue) (FFPE)**

**Methodology:**
Interphase nuclei fluorescence in-situ hybridization (FISH) break-apart analyses; previous or concurrent conventional cytogenetic workup recommended (where possible)

**Frequency Performed:**
Monday - Saturday

**Routinely Reported:**
5 - 14 days

**Use:**
This test is used in the diagnosis and management of soft tissue tumors such as myxoid liposarcoma and low-grade fibromyxoid sarcoma.

**Specimen Requirements:**
- Formalin-fixed, paraffin-embedded tissues
- FFPE-isolated nuclei
- De-paraffinated, four-micron, slide-mounted tissue sections

The identification of tissues/cells to be targeted and DNA probe selection is the responsibility of the requesting or submitting parties.

Tissue sections and tissues utilized to obtain nuclei isolated from paraffin blocks submitted for interphase FISH analysis must include concurrent evaluation by qualified individuals utilizing additional non-FISH morphometric features to ensure that the requested FISH test(s) are applied to the appropriate tissues/cells.

**Reference Values:**
By report; interpretive

**CPT Code(s):**
88367 x 2 (computer-assisted), 88368 x 2 (manual)
FISH Study: Neoplastic Interphase IGH (14q32)

Methodology: Interphase nuclei fluorescence in-situ hybridization (FISH) break-apart rearrangement analyses; a concurrent or previous conventional cytogenetic workup is required/recommended (where possible).

Frequency Performed: Monday - Saturday
Routinely Reported: 5 - 12 days

Use: This test is used to detect BCL2 chromosome rearrangements in patients with plasma-cell myeloma or lymphoma (It does not identify a rearrangement partner).

Specimen Requirements:

Bone Marrow Aspirate: Obtain 1 - 2 cc of in a green-top sodium heparin tube and immediately rotate it thoroughly to ensure adequate mixing with the anticoagulant.

Bone Marrow Core Biopsy: Deposit samples in a sterile container containing tissue culture medium with antibiotics (RPMI) that have been brought to room temperature before collection.*

Peripheral Blood Specimens: Peripheral blood specimens may be submitted in certain clinical conditions (e.g. circulating blasts) and/or circumstances (where warranted).

Unacceptable Conditions:
- Frozen specimens
- Specimens for FISH study only > one week old
- Specimens for concurrent FISH and cytogenetic studies > 48 hours old*

Formalin, alcohol or paraffin-preserved specimens

Stability (collection to initiation of testing):
- Ambient: 24 - 48 hours*
- Frozen: Unacceptable

* Cell viability of specimens requiring cell culture may be compromised in specimens older than 48 hours upon receipt. Refrigeration at 2° - 8° C may assist when a delay is not preventable. Do not freeze or place specimens directly on ice.

Reference Values: By report; interpretive

CPT Code(s): 88271, 88275, 88291
FISH Study: Neoplastic Interphase IGH/BCL2

Methodology: Interphase nuclei fluorescence in-situ hybridization (FISH) fusion rearrangement analyses; a concurrent or previous conventional cytogenetic workup is required/recommended (where possible)

Frequency Performed: Monday - Saturday

Routiney Reported: 5 - 12 days

Use: This test is used to detect IGH/ BCL2 fusion gene rearrangements, which are most commonly associated with B-cell NHL (follicular lymphoma and diffuse large B-cell lymphoma).

Specimen Requirements: Bone Marrow Aspirate: Obtain 1 - 2 cc of in a green-top sodium heparin tube and immediately rotate it thoroughly to ensure adequate mixing with the anticoagulant.

Bone Marrow Core Biopsy: Deposit samples in a sterile container containing tissue culture medium with antibiotics (RPMI) that have been brought to room temperature before collection.*

Peripheral Blood Specimens: Peripheral blood specimens may be submitted in certain clinical conditions (e.g. circulating lymphoma cells).

Unacceptable Conditions:
- Frozen specimens
- Specimens for FISH study only > one week old
- Specimens for concurrent FISH and cytogenetic studies > 48 hours old*
- Formalin, alcohol or paraffin-preserved specimens

Stability (collection to initiation of testing):
- Ambient: 24 - 48 hours*
- Frozen: Unacceptable

Reference Values: By report; interpretive

CPT Code(s): 88271, 88275, 88291
FISH Study: Neoplastic Interphase IGH/CCND1

Methodology:
Interphase nuclei fluorescence in-situ hybridization (FISH) fusion rearrangement analyses; a concurrent or previous conventional cytogenetic workup is required/recommended (where possible)

Frequency Performed:
Monday - Saturday

Routinely Reported:
5 - 12 days

Use:
This test can be used to identify plasma-cell myeloma and mantle-cell lymphoma. This probe is for recurrent genetic abnormalities that can be detected by the most frequent chromosomal fusion translocations involving the immunoglobulin heavy locus.

Specimen Requirements:
Bone Marrow Aspirate: Obtain 1 - 2 cc of in a green-top sodium heparin tube and immediately rotate it thoroughly to ensure adequate mixing with the anticoagulant.

Bone Marrow Core Biopsy: Deposit samples in a sterile container containing tissue culture medium with antibiotics (RPMI) that have been brought to room temperature before collection.*

Peripheral Blood Specimens: Peripheral blood specimens may be submitted in certain clinical conditions (e.g. circulating lymphoma cells).

Unacceptable Conditions:
• Frozen specimens
• Specimens for FISH study only > one week old
• Specimens for concurrent FISH and cytogenetic studies > 48 hours old*
• Formalin, alcohol or paraffin-preserved specimens

Stability (collection to initiation of testing):
• Ambient: 24 - 48 hours*
• Frozen: Unacceptable

* Cell viability of specimens requiring cell culture may be compromised in specimens older than 48 hours upon receipt. Refrigeration at 2° - 8° C may assist when a delay is not preventable. Do not freeze or place specimens directly on ice.

Reference Values:
By report; interpretive

CPT Code(s):
88271, 88275, 88291
**FISH Study: Neoplastic Interphase IGH/FGFR3**

**Methodology:** Interphase nuclei fluorescence in-situ hybridization (FISH) fusion rearrangement analyses; a concurrent or previous conventional cytogenetic workup is required/recommended (where possible)

**Frequency Performed:** Monday - Saturday

**Routiney Reported:** 5 - 12 days

**Use:** This test is used to detect IGH/FGFR3 fusion gene rearrangements, which are most commonly associated with plasma cell disorders.

**Specimen Requirements:**

- **Bone Marrow Aspirate:** Obtain 1-2 cc of in a green-top sodium heparin tube and immediately rotate it thoroughly to ensure adequate mixing with the anticoagulant.

- **Bone Marrow Core Biopsy:** Deposit samples in a sterile container containing tissue culture medium with antibiotics (RPMI) that have been brought to room temperature before collection.*

- **Peripheral Blood Specimens:** Peripheral blood specimens may be submitted in certain clinical conditions (e.g. circulating tumor cells).

**Unacceptable Conditions:**
- Frozen specimens
- Specimens for FISH study only > one week old
- Specimens for concurrent FISH and cytogenetic studies > 48 hours old*
- Formalin, alcohol or paraffin-preserved specimens

**Stability (collection to initiation of testing):**
- **Ambient:** 24 - 48 hours*
- **Frozen:** Unacceptable

*Cell viability of specimens requiring cell culture may be compromised in specimens older than 48 hours upon receipt. Refrigeration at 2° - 8° C may assist when a delay is not preventable. Do not freeze or place specimens directly on ice.

**Reference Values:** By report; interpretive

**CPT Code(s):** 88271, 88275, 88291
FISH Study: Neoplastic Interphase IGH/MAF

Methodology: Interphase nuclei fluorescence in-situ hybridization (FISH) fusion rearrangement analyses; a concurrent or previous conventional cytogenetic workup is required/recommended (where possible)

Frequency Performed: Monday - Saturday
Routinely Reported: 5 - 12 days

Use: This test is used to detect IGH/ FGFR3 fusion gene rearrangements, which are most commonly associated with plasma cell disorders.

Specimen Requirements:
- **Bone Marrow Aspirate**: Obtain 1 - 2 cc of in a green-top sodium heparin tube and immediately rotate it thoroughly to ensure adequate mixing with the anticoagulant.
- **Bone Marrow Core Biopsy**: Deposit samples in a sterile container containing tissue culture medium with antibiotics (RPMI) that have been brought to room temperature before collection.*
- **Peripheral Blood Specimens**: Peripheral blood specimens may be submitted in certain clinical conditions (e.g. circulating tumor cells).

Unacceptable Conditions:
- Frozen specimens
- Specimens for FISH study only > one week old
- Specimens for concurrent FISH and cytogenetic studies > 48 hours old*
- Formalin, alcohol or paraffin-preserved specimens

Stability (collection to initiation of testing):
- **Ambient**: 24 - 48 hours*
- **Frozen**: Unacceptable

* Cell viability of specimens requiring cell culture may be compromised in specimens older than 48 hours upon receipt. Refrigeration at 2° - 8° C may assist when a delay is not preventable. Do not freeze or place specimens directly on ice.

Reference Values: By report; interpretive
CPT Code(s): 88271, 88275, 88291
**FISH Study: Neoplastic Interphase IGH/MYC**

**Methodology:** Interphase nuclei fluorescence in-situ hybridization (FISH) fusion rearrangement analyses; a concurrent or previous conventional cytogenetic workup is required/recommended (where possible)

**Frequency Performed:** Monday - Saturday

**Routinely Reported:** 5 - 12 days

**Use:** This test is used to detect IGH/ MYC fusion gene rearrangements, which are most commonly associated with Burkitt lymphoma but have also been described in both B-cell ALL and in other non-Hodgkin lymphomas

**Specimen Requirements:**

- **Bone Marrow Aspirate:** Obtain 1 - 2 cc of in a green-top sodium heparin tube and immediately rotate it thoroughly to ensure adequate mixing with the anticoagulant.

- **Bone Marrow Core Biopsy:** Deposit samples in a sterile container containing tissue culture medium with antibiotics (RPMI) that have been brought to room temperature before collection.*

- **Peripheral Blood Specimens:** Peripheral blood specimens may be submitted in certain clinical conditions (e.g. circulating blasts).

**Unacceptable Conditions:**

- Frozen specimens
- Specimens for FISH study only > one week old
- Specimens for concurrent FISH and cytogenetic studies > 48 hours old*
- Formalin, alcohol or paraffin-preserved specimens

**Stability (collection to initiation of testing):**

- **Ambient:** 24 - 48 hours*
- **Frozen:** Unacceptable

* Cell viability of specimens requiring cell culture may be compromised in specimens older than 48 hours upon receipt. Refrigeration at 2° - 8° C may assist when a delay is not preventable. Do not freeze or place specimens directly on ice.

**Reference Values:** By report; interpretive

**CPT Code(s):** 88271, 88275, 88291
FISH Study: Neoplastic Interphase MDM2 with D12Z3 (12q15) (For Formalin-Fixed Paraffin-Embedded Tissue) (FFPE)

Methodology: Interphase nuclei fluorescence in-situ hybridization (FISH) break-apart analyses; previous or concurrent conventional cytogenetic workup recommended (where possible)

Frequency Performed: Monday - Saturday

Routinely Reported: 5 - 14 days

Use: This test is used to confirm histological discrimination of well-differentiated liposarcoma/ atypical lipomatous tumor (WDL/ALT) from lipoma.

Specimen Requirements:
- Formalin-fixed, paraffin-embedded tissues
- FFPE-isolated nuclei
- De-paraffinated, four-micron, slide-mounted tissue sections

The identification of tissues/cells to be targeted and DNA probe selection is the responsibility of the requesting or submitting parties.

Tissue sections and tissues utilized to obtain nuclei isolated from paraffin blocks submitted for interphase FISH analysis must include concurrent evaluation by qualified individuals utilizing additional non-FISH morphometric features to ensure that the requested FISH test(s) are applied to the appropriate tissues/cells.

Reference Values: By report; interpretive

CPT Code(s): 88367 x 2 (computer-assisted), 88368 x 2 (manual)
Methodology: Interphase nuclei fluorescence in-situ hybridization (FISH) break-apart rearrangement analyses; a concurrent or previous conventional cytogenetic workup is required/recommended (where possible)

Frequency Performed: Monday - Saturday

Routinely Reported: 5 - 12 days

Use: This test is used to detect rearrangements involving the MLL gene locus at 11q23, which may result in the formation of a large variety of hybrid gene fusion products and are seen in ALL, AML and bi-phenotypic acute leukemias.

Specimen Requirements: Bone Marrow Aspirate: Obtain 1 - 2 cc of in a green-top sodium heparin tube and immediately rotate it thoroughly to ensure adequate mixing with the anticoagulant.

Bone Marrow Core Biopsy: Deposit samples in a sterile container containing tissue culture medium with antibiotics (RPMI) that have been brought to room temperature before collection.*

Peripheral Blood Specimens: Peripheral blood specimens may be submitted in certain clinical conditions (e.g. circulating blasts).

Do not freeze or fix samples in any manner contrary to the maintenance of cell viability. Maintain sample sterility; keep all specimens at room temperature; and deliver samples to the laboratory within 24 - 48 hours. Ship specimens at room temperature for overnight delivery.

Reference Values: By report; interpretive

CPT Code(s): 88271, 88275, 88291
FISH Study: Neoplastic Interphase MYC

Methodology: Interphase nuclei fluorescence in-situ hybridization (FISH) break-apart rearrangement analyses; a concurrent or previous conventional cytogenetic workup is required/recommended (where possible)

Frequency Performed: Monday - Saturday

Routinely Reported: 5 - 12 days

Use: This test is used to detect MYC gene rearrangements, which are most commonly associated with Burkitt lymphoma but have also been described in both B-cell ALL and in other non-Hodgkin lymphomas.

Note: This test does not identify specific fusion partners but will detect the MYC rearrangements, which may be a variant of the common 8/14 translocation, such as the 8/22 and 2/8 translocations.

Specimen Requirements: Bone Marrow Aspirate: Obtain 1 - 2 cc of in a green-top sodium heparin tube and immediately rotate it thoroughly to ensure adequate mixing with the anticoagulant.

Bone Marrow Core Biopsy: Deposit samples in a sterile container containing tissue culture medium with antibiotics (RPMI) that have been brought to room temperature before collection.*

Peripheral Blood Specimens: Peripheral blood specimens may be submitted in certain clinical conditions (e.g. circulating tumor cells).

Unacceptable Conditions:
- Frozen specimens
- Specimens for FISH study only > one week old
- Specimens for concurrent FISH and cytogenetic studies > 48 hours old*

Formalin, alcohol or paraffin-preserved specimens

Stability (collection to initiation of testing):
- Ambient: 24 - 48 hours*
- Frozen: Unacceptable

* Cell viability of specimens requiring cell culture may be compromised in specimens older than 48 hours upon receipt. Refrigeration at 2° - 8° C may assist when a delay is not preventable. Do not freeze or place specimens directly on ice.

Reference Values: By report; interpretive

CPT Code(s): 88271, 88275, 88291
FISH Study: Neoplastic Interphase NMYC

Methodology: Interphase nuclei fluorescence in-situ hybridization (FISH) copy-number change analyses; a concurrent or previous conventional cytogenetic workup is required/recommended (where possible)

Frequency Performed: Monday - Saturday
Routinely Reported: 5 - 12 days

Use: This test is used to detect amplification of the NMYC gene in neuroblastoma.

Specimen Requirements:

Bone Marrow Aspirate: Obtain 1 - 2 cc of in a green-top sodium heparin tube and immediately rotate it thoroughly to ensure adequate mixing with the anticoagulant.

Bone Marrow Core Biopsy: Deposit samples in a sterile container containing tissue culture medium with antibiotics (RPMI) that have been brought to room temperature before collection.*

Peripheral Blood Specimens: Peripheral blood specimens may be submitted in certain rare clinical conditions (e.g. significant circulating tumor cells).

Unacceptable Conditions:

• Frozen specimens
• Specimens for FISH study only > one week old
• Specimens for concurrent FISH and cytogenetic studies > 48 hours old*
• Formalin, alcohol or paraffin-preserved specimens

Stability (collection to initiation of testing):

• Ambient: 24 - 48 hours*
• Frozen: Unacceptable

* Cell viability of specimens requiring cell culture may be compromised in specimens older than 48 hours upon receipt. Refrigeration at 2° - 8° C may assist when a delay is not preventable. Do not freeze or place specimens directly on ice.

Reference Values: By report; interpretive

CPT Code(s): 88271, 88275, 88291
FISH Study: Neoplastic Interphase PML/RARA

Methodology: Interphase nuclei fluorescence in-situ hybridization (FISH) fusion rearrangement analyses; a concurrent or previous conventional cytogenetic workup is required/recommended (where possible)

Frequency Performed: Monday - Saturday
Routinely Reported: 5 - 12 days

Use: This test is used to detect the presence of PML/RARA fusions, which are most commonly the result of a reciprocal 15/17 translocation in APL (AML-M3).

Specimen Requirements:

Bone Marrow Aspirate: Obtain 1 - 2 cc of in a green-top sodium heparin tube and immediately rotate it thoroughly to ensure adequate mixing with the anticoagulant.

Bone Marrow Core Biopsy: Deposit samples in a sterile container containing tissue culture medium with antibiotics (RPMI) that have been brought to room temperature before collection.*

Peripheral Blood Specimens: Peripheral blood specimens may be submitted in certain clinical conditions (e.g. circulating blasts).

Unacceptable Conditions:
- Frozen specimens
- Specimens for FISH study only > one week old
- Specimens for concurrent FISH and cytogenetic studies > 48 hours old*
- Formalin, alcohol or paraffin-preserved specimens

Stability (collection to initiation of testing):
- Ambient: 24 - 48 hours*
- Frozen: Unacceptable

* Cell viability of specimens requiring cell culture may be compromised in specimens older than 48 hours upon receipt. Refrigeration at 2° - 8° C may assist when a delay is not preventable. Do not freeze or place specimens directly on ice.

Reference Values: By report; interpretive

CPT Code(s): 88271, 88275, 88291
**FISH Study: Neoplastic Interphase RB1 with LAMP1 (Deletion 13q)**

**Methodology:** Interphase nuclei fluorescence in-situ hybridization (FISH) copy-number change analyses; a concurrent or previous conventional cytogenetic workup is required/recommended (where possible)

**Frequency Performed:** Monday - Saturday

**Routinely Reported:** 5 - 12 days

**Use:** This test is used to detect the presence of chromosome 13 long-arm deletions and monosomy 13, which are commonly observed in CLL/SLL and plasma cell disorders.

**Specimen Requirements:**
- **Bone Marrow Aspirate:** Obtain 1 - 2 cc of in a green-top sodium heparin tube and immediately rotate it thoroughly to ensure adequate mixing with the anticoagulant.
- **Bone Marrow Core Biopsy:** Deposit samples in a sterile container containing tissue culture medium with antibiotics (RPMI) that have been brought to room temperature before collection.*
- **Peripheral Blood Specimens:** Peripheral blood specimens may be submitted in certain clinical conditions (e.g. circulating lymphoma cells).

**Unacceptable Conditions:**
- Frozen specimens
- Specimens for FISH study only > one week old
- Specimens for concurrent FISH and cytogenetic studies > 48 hours old*
- Formalin, alcohol or paraffin-preserved specimens

**Stability (collection to initiation of testing):**
- **Ambient:** 24 - 48 hours*
- **Frozen:** Unacceptable

*Cell viability of specimens requiring cell culture may be compromised in specimens older than 48 hours upon receipt. Refrigeration at 2° - 8°C may assist when a delay is not preventable. Do not freeze or place specimens directly on ice.

**Reference Values:** By report; interpretive

**CPT Code(s):** 88271, 88275, 88291
FISH Study: Neoplastic Interphase
RUNX1T1/RUNX1

Methodology: Interphase nuclei fluorescence in-situ hybridization (FISH) fusion rearrangement analyses; a concurrent or previous conventional cytogenetic workup is required/recommended (where possible)

Frequency Performed: Monday - Saturday
Routinely Reported: 5 - 12 days
Use: This test is used to detect the presence of RUNX1/RUNX1T1 fusion rearrangements, which is most commonly the result of a reciprocal 8/21 translocation and associated with AML (primarily AML-M2).

Specimen Requirements: Bone Marrow Aspirate: Obtain 1 - 2 cc of in a green-top sodium heparin tube and immediately rotate it thoroughly to ensure adequate mixing with the anticoagulant.

Bone Marrow Core Biopsy: Deposit samples in a sterile container containing tissue culture medium with antibiotics (RPMI) that have been brought to room temperature before collection.*

Peripheral Blood Specimens: Peripheral blood specimens may be submitted in certain clinical conditions (e.g. circulating blasts).

Unacceptable Conditions:
• Frozen specimens
• Specimens for FISH study only > one week old
• Specimens for concurrent FISH and cytogenetic studies > 48 hours old*
• Formalin, alcohol or paraffin-preserved specimens

Stability (collection to initiation of testing):
• Ambient: 24 - 48 hours*
• Frozen: Unacceptable

* Cell viability of specimens requiring cell culture may be compromised in specimens older than 48 hours upon receipt. Refrigeration at 2°-8°C may assist when a delay is not preventable. Do not freeze or place specimens directly on ice.

Reference Values: By report; interpretive
CPT Code(s): 88271, 88275, 88291
FISH Study: Neoplastic Interphase SYT – SS18 – 18q11.2 - (For Formalin-Fixed Paraffin-Embedded Tissue) (FFPE)

Methodology: Interphase nuclei fluorescence in-situ hybridization (FISH) break-apart analyses; previous or concurrent conventional cytogenetic workup recommended (where possible)

Frequency Performed: Monday - Saturday

Routinely Reported: 5 - 14 days

Use: This test is used to diagnose and manage soft tissue tumors, such as synovial sarcoma.

Specimen Requirements:
- Formalin-fixed, paraffin-embedded tissues
- FFPE-isolated nuclei
- De-paraffinated, four-micron, slide-mounted tissue sections

The identification of tissues/cells to be targeted and DNA probe selection is the responsibility of the requesting or submitting parties.

Tissue sections and tissues utilized to obtain nuclei isolated from paraffin blocks submitted for interphase FISH analysis must include concurrent evaluation by qualified individuals utilizing additional non-FISH morphometric features to ensure that the requested FISH test(s) are applied to the appropriate tissues/cells.

Reference Values: By report; interpretive

CPT Code(s): 88367 x 2 (computer assisted), 88368 x 2 (manual)
**FISH Study: Neoplastic Interphase TP53 (Deletion 17p)**

**Methodology:** Interphase nuclei fluorescence in-situ hybridization (FISH) copy-number change analyses; a concurrent or previous conventional cytogenetic workup is required/recommended (where possible)

**Frequency Performed:** Monday - Saturday

**Routinely Reported:** 5 - 12 days

**Use:** This test is used to detect the deletion (loss of heterozygosity) of the tumor-suppressor gene TP53, which can be seen in plasma cell myeloma or CLL.

**Specimen Requirements:**

**Bone Marrow Aspirate:** Obtain 1 - 2 cc of in a green-top sodium heparin tube and immediately rotate it thoroughly to ensure adequate mixing with the anticoagulant.

**Bone Marrow Core Biopsy:** Deposit samples in a sterile container containing tissue culture medium with antibiotics (RPMI) that have been brought to room temperature before collection.*

**Peripheral Blood Specimens:** Peripheral blood specimens may be submitted in certain clinical conditions (e.g. circulating tumor cells).

**Unacceptable Conditions:**

- Frozen specimens
- Specimens for FISH study only > one week old
- Specimens for concurrent FISH and cytogenetic studies > 48 hours old*
- Formalin, alcohol or paraffin-preserved specimens

**Stability (collection to initiation of testing):**

- **Ambient:** 24 - 48 hours*
- **Frozen:** Unacceptable

*Cell viability of specimens requiring cell culture may be compromised in specimens older than 48 hours upon receipt. Refrigeration at 2° - 8° C may assist when a delay is not preventable. Do not freeze or place specimens directly on ice.

**Reference Values:** By report; interpretive

**CPT Code(s):** 88271, 88275, 88291
### FISH Screen: Prenatal Aneuploidy (Amniotic Fluid Only)

**Methodology:** Interphase nuclei fluorescence in-situ hybridization (FISH) analysis for 13, 18, 21, X/Y aneuploidy; requires concurrent classic cytogenetic analysis; **not for standalone use**

**Frequency Performed:** Monday - Saturday

**Routinely Reported:** 10 - 14 days

**Use:** This screening test is only used to detect the presence of common forms of aneuploidy fetal conditions, which include trisomies 21, 18 and 13, as well as various sex chromosome aneuploidies.

**Specimen Requirements:**
- **Amniotic Fluid:** Aseptically collect approximately 1 cc of per week of gestational age in two sterile 15 mL conical centrifuge tubes and sequentially label the tubes. The initial 1 - 2 cc should not be included for chromosome studies (but may be utilized for AFP testing).
- Do not freeze or fix samples in any manner contrary to the maintenance of cell viability. Maintain sample sterility; keep all specimens at room temperature; and deliver samples to the laboratory within 24 - 48 hours. Ship specimens at room temperature for overnight delivery.
- Contact UF PathLabs prior to submission (approved by consultation).

**Reference Values:** By report; interpretive

**CPT Code(s):** 88271 x 5, 88274, 88291
FISH Study: Prenatal Metaphase Microdeletion

Methodology: Metaphase microdeletion fluorescence in-situ hybridization (FISH) analysis for specific conditions; requires concurrent classic cytogenetic analysis; not for standalone use

Frequency Performed: Monday - Saturday
Routinely Reported: 10 - 14 days

Use: This test is used to detect the presence of a specific fetal microdeletion for any of the microdeletion syndromes for which testing is available by our laboratory. Orders should include a relevant family history and or specific ultrasound findings.

Specimen Requirements:

Amniotic Fluid: Aseptically collect approximately 1 cc of per week of gestational age in two sterile 15 mL conical centrifuge tubes and sequentially label the tubes. The initial 1 - 2 cc should not be included for chromosome studies (but may be utilized for AFP testing).

Chorionic Villi: Collect 10 - 30 mg of utilizing aspiration medium containing sodium heparin.* After assessment of the appropriate amount and quality of villi, transfer to a sterile centrifuge tube with transportation medium.

Do not freeze or fix samples in any manner contrary to the maintenance of cell viability. Maintain sample sterility; keep all specimens at room temperature; and deliver samples to the laboratory within 24 - 48 hours. Ship specimens at room temperature for overnight delivery.

Contact UF PathLabs prior to submission (approved by consultation).

Unacceptable Conditions:
- Frozen specimens
- Specimens greater than 48 hours old*

Stability (collection to initiation of testing):
- Ambient: 24 - 48 hours*
- Frozen: Unacceptable

* Cell viability of specimens requiring cell culture may be compromised in specimens older than 48 hours upon receipt. Refrigeration at 2° - 8° C may assist when a delay is not preventable. Do not freeze or place specimens directly on ice.

Contact the UF Path Labs prior to submission (approved by consultation).

Reference Values: By report; interpretive

CPT Code(s): Per routine test 88271, 88275, 88291
**Methodology:** Metaphase and/or chromosome fluorescence in-situ hybridization (FISH) analyses; requires cell culture and a concurrent or previous routine karyotyping

**Frequency Performed:** Monday - Saturday

**Routinely Reported:** 10 - 28 days

**Use:** This test is used to assist in determining sex chromosome constitution in patients suspected to have conditions in which mosaicism is likely (e.g., ambiguous genitalia, Turner syndrome, etc.)

**Specimen Requirements:**
- **Peripheral Blood:** Collected aseptically in sodium heparin tubes (usually green top tubes) and immediately rotated thoroughly to prevent clotting. For infants obtain approximately 2 cc and for children and adults obtain 5 - 7 cc.

- **Skin biopsy or other tissues:** In an aseptic manner, obtain approximately 2 mm x 2 mm, which is deep enough to ensure that the dermal layer is included. Deposit the specimen in a sterile container containing tissue culture medium with antibiotics which has been brought to room temperature prior to collection.* Alternate solid tissue samples include autopsy specimens (e.g., lung, cartilage, etc.).

**Note:** A separate blood sample is required if a concurrent CGH microarray study is desired.

Do not freeze or fix samples in any manner contrary to the maintenance of cell viability. Maintain sample sterility; keep all specimens at room temperature; and deliver samples to the laboratory within 24 - 48 hours. Ship specimens at room temperature for overnight delivery.

**Unacceptable Conditions:**
- Frozen specimens
- Specimens greater than 48 hours old*

**Stability (collection to initiation of testing):**
- Ambient: 24 - 48 hours*
- Frozen: Unacceptable

* Cell viability of specimens requiring cell culture may be compromised in specimens older than 48 hours upon receipt. Refrigeration at 2° - 8° C may assist when a delay is not preventable. Do not freeze or place specimens directly on ice.

**Reference Values:** By report; interpretive

**CPT Code(s):** 88271 x 2, 88273, 88275, 88291
## FISH Study: X/Y Interphase (Bone Marrow)

### Methodology:
Interphase nuclei fluorescence in-situ hybridization (FISH) copy number analyses; a concurrent or previous conventional cytogenetic workup is required/recommended (where possible)

### Frequency Performed:
Monday - Saturday

### Routinely Reported:
5 - 12 days

### Use:
This test is used to monitor sex-mismatched bone marrow and/or stem cell transplantations status.

### Specimen Requirements:

**Bone Marrow Aspirate:** Obtain 1 - 2 cc of in a green-top sodium heparin tube and immediately rotate it thoroughly to ensure adequate mixing with the anticoagulant.

**Bone Marrow Core Biopsy:** Deposit samples in a sterile container containing tissue culture medium with antibiotics (RPMI) that have been brought to room temperature before collection.*

**Peripheral Blood Specimens:** Peripheral blood specimens may be submitted in certain clinical conditions if warranted.

### Unacceptable Conditions:
- Frozen specimens
- Specimens for FISH study only > one week old
- Specimens for concurrent FISH and cytogenetic studies > 48 hours old*
- Formalin, alcohol or paraffin-preserved specimens

### Stability (collection to initiation of testing):
- **Ambient:** 24 - 48 hours*
- **Frozen:** Unacceptable

Do not freeze or fix samples in any manner contrary to the maintenance of cell viability. Maintain sample sterility; keep all specimens at room temperature; and deliver samples to the laboratory within 24 - 48 hours. Ship specimens at room temperature for overnight delivery.

* Cell viability of specimens requiring cell culture may be compromised in specimens older than 48 hours upon receipt. Refrigeration at 2° - 8° C may assist when a delay is not preventable. Do not freeze or place specimens directly on ice.

### Reference Values:
By report; interpretive

### CPT Code(s):
88271, 88275, 88291
Flow Cytometry on Bone Marrow Aspirate with or without Bone Marrow Biopsy

**Methodology:** Flow cytometry with or without microscopic examination

**Frequency Performed:** Monday - Saturday

**Routinely Reported:** Within 2 days (Stat cases may be completed within 24 hours.)

**Use:** This test is used to diagnose hematolymphoid malignancies involving bone marrow.

**Specimen Requirements:**
For bone marrow kits (#0097 without RPMI or #0098 with RPMI), contact the UF PathLabs Client Services Department at (888) 375-LABS (5227).

5 - 10 mL of peripheral blood in a lavender- (EDTA), green- (sodium heparin) or yellow-top (ACD) tube is accepted.

If cytogenetics studies are requested, one additional green-top (sodium heparin) tube with 5 mL of specimen should be submitted.

A 1 mL tube of bone marrow aspirate is acceptable if the collection is minimal. You must clearly indicate that only one tube has been submitted and prioritize the requested tests.

If no significant amount of bone marrow aspirate is obtained, a fresh bone marrow biopsy in saline or RPMI (cell culture medium) may be submitted for flow cytometry and cytogenetic studies.

Formalin-fixed bone marrow biopsies or clots can be accepted for morphological evaluation and immunohistochemical studies, but they cannot be used for flow cytometry immunophenotyping.

**Unacceptable Conditions:**
- Frozen specimens
- Specimens greater than 24 hours old
- Inaccurately labeled specimens
- Specimens fixed in formalin for FLOW

**Stability (collection to initiation of testing):**
- Ambient: 12 hours
- Refrigerated: 24 hours

**Storage/Transport Temperature:** The fresh bone marrow specimen can be transported with a cold pack or wet ice, but do not fix or freeze specimens (no dry ice).
**Other Requirements:** A copy of the CBC and differential with clinical history should be submitted with the specimens. For your convenience, you may also check the boxes on requisition form to provide brief clinical information. Although we accept specimens older than 24 hours after collection, the viability of cells may deteriorate over time. Clotted specimens are less than optimal; hemolyzed and, frozen samples are unacceptable.

For more information, contact the UF PathLabs Client Services Department at **(888) 375-LABS (5227).**

**Reference Values:** Interpretive report

**CPT Code(s):** The CPT coding varies, depending upon actual testing performed, but common CPT codes are listed as the following:

85097 bone marrow aspirate, 88108 cytospin technical, 88313 iron stain on smear, 88184 first marker flow cytometry, technical, 88185 each additional marker, flow cytometry technical, 88187 flow cytometry interpretation, 2 - 8 markers, 88188 Flow cytometry interpretation, 9 - 15 markers, 88189 Flow cytometry interpretation, 16 or more markers, 88305 formalin-fixed bone marrow biopsy or other tissue biopsy, 88311 decal, formalin-fixed bone marrow biopsy (if submitted), 88313 reticulin or iron stains on bone marrow biopsy (if submitted), 88319 Myeloperoxidase or non-specific esterase stain (for acute leukemia)
Flow Cytometry on Fresh Tissue and/or Body Fluid

**Methodology:** Flow cytometry with or without microscopic examination

**Frequency Performed:** Monday - Saturday

**Routinely Reported:** Within 2 days (Stat cases may be completed within 24 hours.)

**Use:** This test is used to diagnose hematolymphoid malignancies in tissue or bodily fluids.

**Specimen Requirements:** Fragments of fresh excised tissue(s) should be kept moist in saline or culture medium (RPMI) at all times. It can be covered with saline or wrapped in medium-soaked gauze for transportation times of less than 24 hours.

Place fresh core needle biopsies or other small biopsies in saline or cell culture medium (RPMI).

Provide a sample of fine-needle aspiration, with freshly prepared smear or cytopathology slides, if available.

For large volumes of body fluid, spin and remove the large fluid volume and send the cell pellet in RPMI or similar culture medium. Small volumes of body fluid that can easily be transported can be submitted directly. No anticoagulant is necessary unless grossly contaminated with blood.

**Storage/Transport Temperature:** The fresh tissue or fluid specimen can be transported with a cold pack or wet ice, but do not fix or freeze specimens (no dry ice).

**Unacceptable Conditions:**
- Frozen specimens
- Specimens older than 24 hours
- Inaccurately labeled specimens

**Stability (collection to initiation of testing):**
- Ambient: 12 hours
- Refrigerated: 24 hours

**Other Requirements:** It is important to submit a brief clinical history with the specimens. For your convenience, you may also check the boxes on requisition form to provide brief clinical information. Although we accept specimens older than 24 hours after collection, the viability of cells may deteriorate over time. Frozen or formalin-fixed samples are unacceptable for flow cytometry studies.
For more information, contact the UF PathLabs Client Services Department at (888) 375-LABS (5227).

Reference Values: Interpretive report

CPT Code(s): The CPT coding varies, depending upon actual testing performed, but common CPT codes are listed as the following:

- 88108 cytospin technical
- 88184 first marker flow cytometry, technical
- 88185 each additional marker, flow cytometry technical
- 88187 flow cytometry interpretation, 2 - 8 markers
- 88188 flow cytometry interpretation, 9 - 15 markers
- 88189 flow cytometry interpretation, 16 or more markers
Flow Cytometry on Peripheral Blood

**Methodology:** Flow cytometry with or without microscopic examination

**Frequency Performed:** Monday - Saturday

**Routinely Reported:** Within 2 days (Stat cases may be completed within 24 hours.)

**Use:** This test is used to diagnose hematolymphoid malignancies in blood.

**Specimen Requirements:** 5 - 10 mL of peripheral blood in a lavender- (EDTA), green- (sodium heparin) or yellow-top (ACD) tube is accepted.

If cytogenetics studies are requested, one additional green-top sodium heparin tube with 5 mL of peripheral blood specimen should be submitted.

A freshly prepared peripheral blood smear is also beneficial.

**Storage/Transport Temperature:** The fresh tissue or fluid specimen can be transported with a cold pack or wet ice, but do not fix or freeze specimens (no dry ice).

**Unacceptable Conditions:**
- Frozen specimens
- Specimens greater than 24 hours old
- Inaccurately labeled specimens

**Stability (collection to initiation of testing):**
- Ambient: 12 hours
- Refrigerated: 24 hours

**Other Requirements:** A copy of the CBC and differential with clinical history should be submitted with the specimens. For your convenience, you may also check the boxes on the requisition form to provide brief clinical information. Although we accept specimens greater than 24 hours old after collection, the viability of cells may deteriorate over time. Clotted, hemolyzed and frozen samples are unacceptable.

For more information, contact the UF PathLabs Client Services Department at (888) 375-LABS (5227).

**Reference Values:** Interpretive report
CPT Code(s): The CPT coding varies, depending upon actual testing performed, but common CPT codes are listed as the following:

85060 peripheral blood review, 88108 cytospin technical, 88184 first marker flow cytometry, technical, 88185 each additional marker, flow cytometry technical, 88187 flow cytometry interpretation, 2 - 8 markers, 88188 flow cytometry interpretation, 9 - 15 markers, 88189 flow cytometry interpretation, 16 or more markers, 88319 myeloperoxidase or non-specific esterase stain (for acute leukemia)
Gastric/Gastroesophageal (GE) Junction HER2/Neu Immunohistochemistry with Reflex to FISH

Methodology: Immunohistochemistry
Frequency Performed: Weekly
Routinely Reported: Immunohistochemistry is reported within 7 days. If Gastric HER2/Neu FISH is requested, the report will be provided within 9 days
Use: This test is used to determine eligibility for anti-HER2/Neu therapies in gastric and gastroesophageal (GE) junction tumors.
Specimen Requirements: A paraffin block containing the representative gastric/GE junction tumor or at least 5 unstained slides
Unacceptable Conditions: Frozen
Stability: Indefinite
Reference Values: See Interpretative Data
Interpretative Data:

Surgical Specimens (Resections): A score of 0 is no reactivity or membranous reactivity (staining) in < 10% of invasive tumor cells. A score of 1+ is faint/barely perceptible membranous reactivity (staining) in ≥ 10% of invasive tumor cells; cells are reactive (stained) only in part of their membrane. Score of 2+ is weak-to-moderate complete, basolateral or lateral membranous reactivity (staining) in ≥ 10% of invasive tumor cells. Score of 3+ is strong complete, basolateral or lateral membranous reactivity (staining) in > or = 10% of invasive tumor cells.

Biopsy Specimens: A score of 0 is no reactivity or no membranous reactivity (staining) in less than 5 clustered tumor cells. A score of 1+ is tumor cell clusters (greater than or equal to 5 cells) with a faint/barely perceptible membranous reactivity (staining) regardless of percentage of invasive tumor cells stained. A score of 2+ is tumor cell clusters (greater than or equal to 5 cells) with a weak-to-moderate complete, basolateral or lateral membranous reactivity (staining) regardless of percentage of invasive tumor cells stained. A score of 3+ is tumor cell clusters (greater than or equal to 5 cells) with a strong complete, basolateral or lateral membranous reactivity (staining) regardless of percentage of invasive tumor cells stained.
<table>
<thead>
<tr>
<th>HER2 Interpretation</th>
<th>Staining Intensity Score</th>
<th>Surgical Resections</th>
<th>Biopsies</th>
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</thead>
<tbody>
<tr>
<td><strong>Negative</strong></td>
<td>0</td>
<td>No reactivity or membranous reactivity in &lt; 10% of tumor cells</td>
<td>No reactivity or membranous reactivity in &lt; 5 clustered tumor cells</td>
</tr>
<tr>
<td><em><em>Negative</em> (reflex FISH)</em>*</td>
<td>1+ (40x)</td>
<td>Faint/barely perceptible membranous reactivity in &gt; 10% of tumor cells; cells are reactive only in part of their membrane</td>
<td>Tumor cell cluster (&gt; 5 cells) with a faint/barely perceptible membranous reactivity irrespective of percentage of tumor cells stained.</td>
</tr>
<tr>
<td><em><em>Equivocal</em> (reflex FISH)</em>*</td>
<td>2+ (10 - 20x)</td>
<td>Weak to moderate complete, basolateral or lateral membranous reactivity in &gt; 10% of tumor cells</td>
<td>Tumor cell clusters (&gt; 5 cells) with a weak to moderate complete, basolateral or lateral membranous reactivity irrespective or percentage of tumor cells stained.</td>
</tr>
<tr>
<td><strong>Positive</strong></td>
<td>3+ (2.5 – 5x)</td>
<td>Strong complete, basolateral or lateral membranous reactivity in &gt; 10% of tumor cells</td>
<td>Tumor cell clusters (&gt; 5 cells) with a strong complete, basolateral or lateral membranous reactivity irrespective of percentage of tumor cells stained.</td>
</tr>
</tbody>
</table>

References:


Ruschoff J. HER2 diagnostics in gastric cancer-guideline validation and development of standardized immunohistochemical testing. Virch Arch 2010; 457:299

CPT Code(s): 88360 FISH reflex; 88368 x 2
Gastric Parietal Cell Autoantibodies

**Methodology:** Indirect immunofluorescence

**Frequency Performed:** Weekly

**Routinely Reported:** 1 - 7 business days

**Use:**
- **Diagnosis of Pernicious Anemia:** Gastric parietal cell autoantibodies detected in the presence of biochemically defined pernicious anemia and vitamin B12 deficiency identify an autoimmune etiology as the cause of the subject’s pernicious anemia.

- **Prediction of Pernicious Anemia:** Parietal cell autoantibodies detected in an asymptomatic individual indicates an increased risk for the subsequent development of chronic lymphocytic gastritis, achlorhydria and pernicious anemia.

**Specimen Requirements:**
Collect blood in a 1-5 mL serum separator tube. Centrifuge, separate and transfer the serum to a plastic vial. Ship specimens with a frozen cold pack for overnight delivery.

**Stability (collection to shipping of the sample):**
- **Ambient:** 24 hours
- **Refrigerated:** 24 hours
- **Frozen:** 1 year (Avoid repeated freeze/thaw cycles.)

**Reference Values:** Negative (interpretive report provided)

**CPT Code(s):** 88347
Gastrointestinal Pathology

Methodology: Microscopic exam
Frequency Performed: Monday - Friday
Routinely Reported: 1 - 3 days
Result: Interpretive report
Specimen Requirements: Tissue must be fixed in 10% formalin.

For fixative and more information, contact the UF PathLabs Client Services Department at (888) 375-LABS (5227).

Storage/Transport Temperature: Submit specimens according to Biological Substance, Category B, shipping guidelines.

Unacceptable Conditions:
• Frozen
• Specimens not in appropriate fixative

Stability (collection to initiation of testing):
• Ambient: Indefinitely
• Refrigerated: Indefinitely
• Frozen: Unacceptable

CPT Code(s): 88302, 88304, 88305, 88307 or 88309, depending on the case complexity, 8312 and 88313 if special stains are used, 88342 if immunoperoxidase stains are utilized
Genitourinary Pathology

Methodology: Microscopic exam

Frequency Performed: Monday - Friday

Routinely Reported: 1 - 3 days

Result: Interpretive report

Specimen Requirements: Tissue must be fixed in 10% formalin.

For prostate kits (#0095), fixative and more information, contact the UF PathLabs Client Services Department at (888) 375-LABS (5227).

Storage/Transport Temperature: Submit specimens according to Biological Substance, Category B, shipping guidelines.

Unacceptable Conditions:
- Frozen specimens
- Specimens not in appropriate fixative

Stability (collection to initiation of testing):
- Ambient: Indefinitely
- Refrigerated: Indefinitely
- Frozen: Unacceptable

CPT Code(s): 88302, 88304, 88305, 88307 or 88309, depending on the case complexity, 88312 and 88313 if special stains are used, 88342 if immunoperoxidase stains are utilized.
Gestational Trophoblast Disease Evaluation (Partial vs. Complete Mole)

[p57 Immunohistochemistry (IHC), DNA Ploidy by Flow Cytometry]

**Methodology:** Flow cytometry and IHC staining with p57

**Frequency Performed:** Weekly

**Routinely Reported:** 7 days

**Use:** This test is used to evaluate gestational trophoblastic diseases, including partial and complete molar pregnancy.

**Specimen Requirements:** Paraffin block

**Storage/Transport:** Ship specimens at 20° - 25° C to protect them from excessive heat. Include a surgical pathology report.

**Unacceptable Specimens:**
- Specimens that do not contain placental villi with trophoblast
- Specimens in fixatives other than 10% formalin
- Specimens in Bouin, B5, Omni or Carnoy’s Solution

**Stability (collection to initiation of testing):**
- **Ambient:** Formalin-fixed paraffin block
- **Antibody:** p57kip2
- **Detection Method:** EnVision + Dual Link System HRP

**CPT Code(s):** 88182, 88342
## Glutamic Acid Decarboxylase Autoantibodies (GADA)

**Methodology:** Radioimmunoassay  
**Frequency Performed:** Weekly  
**Routinely Reported:** 1 - 3 days  

**Use:**  
**Diagnosis of Type 1 Diabetes:** The presence of autoantibodies against GAD65 (GADA) in patients with diabetes mellitus indicates the presence of autoimmune, type 1 diabetes.  

**Prediction of Type 1 Diabetes:** Autoantibodies against GAD65 (GADA) in an asymptomatic individual places the subject at increased risk for the development of type 1 diabetes.  

**Specimen Requirements:** Collect blood in a 1-5 mL serum separator tube. Centrifuge, separate and transfer the serum to a plastic vial. Ship specimens with a frozen cold pack for overnight delivery.  

**Stability (collection to shipping of the sample):**  
- Ambient: 24 hours  
- Refrigerated: 24 hours  
- Frozen: 1 year (Avoid repeated freeze/thaw cycles.)

**Reference Values:** < 1.1 u/mL  
**CPT Code(s):** 86341
**Gynecologic Pathology**

**Methodology:** Microscopic exam

**Frequency Performed:** Monday - Friday

**Routinely Reported:** 1 - 3 days

**Result:** Interpretive report

**Specimen Requirements:** Tissue must be fixed in formalin. For fixative, a GYN kit (#0102) or more information, contact the UF PathLabs Client Services Department at (888) 375-LABS (5227).

**Storage/Transport Temperature:** Submit specimens according to Biological Substance, Category B, shipping guidelines.

**Unacceptable Conditions:**
- Frozen specimens
- Specimens not in appropriate fixative

**Stability (collection to initiation of testing):**
- Ambient: Indefinitely
- Refrigerated: Indefinitely
- Frozen: Unacceptable

**CPT Code(s):** 88302, 88304, 88305, 88307 or 88309, depending on the case complexity; 88312 and 88313 if special stains are used; 88342 if immunoperoxidase stains are utilized
Methodology: Enzyme-Linked Immunosorbent Assay (ELISA)

Frequency Performed: Mondays, Wednesdays and Fridays

Routinely Reported: Within 2 - 3 days

Use: This assay is used in the diagnosis of the heparin-induced thrombocytopenia, which is an adverse drug reaction to heparin due to IgG antibodies to complexes of heparin and platelet factor 4. HIT is associated with platelet activation, venous and arterial thrombosis and a moderate thrombocytopenia. It is not associated with bleeding.

Specimen Requirements: One 4 mL light blue-cap tube (3.2% sodium citrate) or a clotted blood tube (a red- or gold-top serum separator tube)

Reference Values:

- **Negative:** < 3.8 Relative absorbance units*
- **Borderline:** 3.8 - 4.2 Relative absorbance units*
- **Positive:** > 4.2 Relative absorbance units*

*Relative absorbance units represent the ratio between the absorbance of the patient specimen in the ELISA and the absorbance of a negative control.

The assay detects IgG and IgM antibodies to a complex of heparin and the platelet protein termed platelet factor 4 (PF4), a strongly positively charged tetrameric protein derived from the alpha-granules of platelets. PF4 binds heparin very strongly. Heparin-PF4 binding induces a conformational change in PF4 exposing certain cryptic epitope(s), to which the IgG antibody binds.

HIT should be suspected clinically in a patient who is experiencing suspicious clinical features and who received heparin 5 - 10 days previously. This time can be reduced to several hours when heparin is given to a patient who has previously received the drug in the past 120 days.

HIT should be suspected when the platelet count has decreased by 50% or more below baseline values or has decreased to less than 150,000 with a minimal platelet decrease of 30,000.

In HIT, the platelet nadir is typically ≥ 20,000/µL.
The HIT antibody assay should be requested if and only if there is a clinical suspicion of heparin-induced thrombocytopenia. A positive antibody assay is frequently encountered in asymptomatic patients who have recently received high doses of unfractionated heparin.

**Unacceptable Conditions:**
- Ambient
- Frozen specimens
- Specimens greater than 24 hours old

**Stability (collection to initiation of testing):**
- Ambient: Unacceptable
- Refrigerated: 24 hours
- Frozen: Unacceptable

**CPT Code(s):** 86022
HER2/Neu by Fluorescence In-Situ Hybridization (FISH)

Methodology: FISH

Frequency Performed: Monday - Friday

Routinely Reported: 7 days

Result: Interpretive report

Use: This test is used as a qualitative predictor of response to certain breast cancer therapies; it detects the HER2/Neu protein in breast cancer patients, which affects patient survival time and relapse.

Specimen Requirements: Tissue in formalin-fixed, paraffin-embedded tissue or at least 5 unstained slides.

Storage/Transport Temperature: Submit specimens according to Biological Substance, Category B, shipping guidelines.

Unacceptable Conditions: Frozen specimens

Stability (collection to initiation of testing):
Ambient:

Fixed Slides: Indefinitely

CPT Code(s): 88368 x 2
HercepTest ™ (HER2/Neu) Image Quantitation with Reflex to FISH (Breast)

Methodology: Immunohistochemistry and Image Quantitation using ACIS III

Frequency Performed: Weekly

Routinely Reported: Immunohistochemistry is reported within 7 days. If FISH is required and requested, the additional report will be provided within an additional 2 - 7 days.

Use: This test is used to determine if Herceptin therapy is warranted in invasive breast tumors. Interpretation of breast tumors is based on the 2007 ASCO/CAP guidelines. If requested, indeterminate results and triple negative cases can be reflexed for Her2Neu FISH testing. A separate report will be issued.

Specimen Requirements: A paraffin block containing representative breast tumors

Fixation: 10% formalin

Storage/Transport: Ship specimens at 20° - 25° C to protect them from excessive heat. Include a surgical pathology report.

Unacceptable Conditions:
- Frozen

Stability (collection to initiation of testing):
- Ambient: Indefinitely

Reference Values: Breast:
- 0.0 - 1.7 Negative: No staining or weak, incomplete membrane staining in any portion of the invasive tumor or weak complete membrane staining in less than 10% of the cells
- 1.8 - 2.9 Indeterminate: Complete membrane staining that is non-uniform or weak but with obvious circumferential distribution in at least 10% of the tumor cells; or intense complete staining in 305 or less of the tumor cells
- ≥ 3.0 Positive: Uniform intense membrane staining of more than 30% of invasive tumor

Interpretation Data: Breast: The HercepTest™ is interpreted using quantitative analysis using the DAKO ACIS III instrument. The assay is performed on paraffin-embedded tissue using the FDA-approved staining method (polyclonal antibody and LSAB detection system).

CPT Code(s): 88361 FISH Reflex: 88368 x 2
Human Papillomavirus (HPV) Detection, High Risk

**Methodology:** Nucleic acid probe

**Frequency Performed:** Monday - Friday

**Routinely Reported:** 4 days

**Use:** The HPV DNA, high-risk test is used in conjunction with liquid-based cytology for cervical intraepithelial lesions.

**Specimen Requirements:**

- **Cervical Brushes:** Specimens must be collected prior to the application of acetic acid or iodine if colposcopic examination is being performed. The samples should be collected by using a Digene cervical brush and stored in Digene STM solution.

- **Cervical Biopsies:** Specimens must be freshly collected, 2 - 5 mm in cross section. The biopsy specimen must be placed immediately into 1.0 mL of STM and stored frozen.

- **Specimens in ThinPrep® Cytotec PreservCyt® Solution:** There must be at least 4 mL of PreservCyt® solution remaining for the HPV DNA test.

- **Specimen in SurePath™ (AutoCyte) Solution:** There must be 2 mL of SurePath™ solution remaining for the HPV DNA test.

**Remarks:** Vaginal specimens are not preferred.

**Handling:** Cervical-brush specimens may be shipped without refrigeration to a testing laboratory; however, fresh specimens should be shipped in an insulated container using either an overnight or second-day delivery vendor.

Cervical biopsy specimens may be shipped at 2° - 30° C for overnight delivery to the testing laboratory.

**Unacceptable Conditions:**
- Frozen specimens
- Swabs or samples in any other transport media

**Stability (collection to initiation of testing):**
- **Ambient:** SurePath™; 4 weeks at 15° - 30° C.
- **Ambient:** Thin Prep® or PreservCyt®; 3 weeks at 15° - 30° C.

**Reference Values:** Negative (Interpretative report provided)
Interpretation Data: HPV DNA was detected by using the FDA-approved testing kit, Hybrid Capture 2. The test detects HPV high-risk genotypes: 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59 and 68.

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Interpretation Text</th>
</tr>
</thead>
<tbody>
<tr>
<td>Detected</td>
<td>High-risk HPV DNA was detected in this patient sample.</td>
</tr>
<tr>
<td>Not Detected</td>
<td>High-risk HPV DNA was not detected in this patient sample.</td>
</tr>
<tr>
<td>QNS</td>
<td>Due to inadequate specimens, resubmission of samples is suggested.</td>
</tr>
</tbody>
</table>

CPT Code(s): 87621
Insulinoma Associated-2 Autoantibodies (IA-2A)

Methodology: Radioimmunoassay
Frequency Performed: Weekly
Routinely Reported: 1 - 7 business days

Use:
- **Diagnosis of Type 1 Diabetes**: The presence of autoantibodies against IA-2 (IA-2A) in patients with diabetes mellitus indicates the presence of autoimmune, type 1 diabetes.
- **Prediction of Type 1 Diabetes**: Autoantibodies against IA-2 (IA-2A) in an asymptomatic individual places the subject at increased risk for the development of type 1 diabetes.

Specimen Requirements:
- Collect blood in a 1-5 mL serum separator tube. Centrifuge, separate and transfer the serum to a plastic vial. Ship specimens with a frozen cold pack for overnight delivery.

Stability (collection to shipping of the sample):
- Ambient: 24 hours
- Refrigerated: 24 hours
- Frozen: 1 year (Avoid repeated freeze/thaw cycles.)

Reference Values: < 0.76 u/mL
CPT Code(s): 86341
**Immunofluorescence: Direct, Skin**

**Methodology:** Direct immunofluorescence

**Frequency Performed:** Monday - Friday

**Routinely Reported:** 5 - 7 days

**Result:** Interpretive report

**Use:** This test is used to detect antibody deposition in tissue. Used in diagnosis of Bullous Disease.

**Specimen Requirements:** Skin biopsy tissue prepared in Michel's fixative.

To obtain DIF kits and/or Michel's fixative, contact UF PathLabs Client Services Department at (888) 375-LABS (5227).

**Unacceptable Conditions:**
- Formalin-fixed tissue
- Tissue in formalin
- Frozen tissue

**Stability (collection to initiation of testing):**
- **Ambient:** 10 days
- **Refrigerated:** 10 days
- **Frozen:** Unacceptable

**CPT Code(s):** 88346 x 5 IgG, IgM, IgA, C3, & fibrinogen
Immunofluorescence: Indirect, Blood

Methodology: Indirect immunofluorescence

Frequency Performed: Monday - Friday

Routinely Reported: 5 - 7 days

Result: Interpretive report

Use: This test is used to identify specific antigens or antibodies.

Specimen Requirements: Blood: One 5 mL plain red-top tube

Serum: Serum separator tube and 2 mL of serum at 20° - 25° C. (Minimum: 0.5 mL)

To obtain an immunofluorescence kit and detailed collection instructions, contact UF PathLabs Client Services Department at (888) 375-LABS (5227).

Stability (collection to initiation of testing):
• Ambient: 4 days
• Refrigerated: 3 months
• Frozen: Indefinitely

CPT Code(s): 88347
Immunohistochemistry/In-Situ Hybridization
(Technical Only)

Methodology: Immunohistochemistry and in-situ hybridization

Frequency Performed: Monday - Friday

Routinely Reported: 2 days

Result: N/A

Use: Technical-only stains to aid in diagnosis

Specimen Requirements: Send formalin-fixed tissues on unstained, charged (+) slides. See appendix for list of available stains

For fixative and more information, contact the UF PathLabs Client Services Department at (888) 375-LABS (5227).

Storage/Transport Temperature: Ship specimens at 20° - 25° C and according to Biological Substance, Category B, shipping guidelines.

Unacceptable Conditions:
• Frozen specimens

Stability (collection to initiation of testing):
• Ambient: Indefinitely
• Frozen: Unacceptable

CPT Code(s): 88342, 88365
Insulin Autoantibodies

Methodology: Radioimmunoassay

Frequency Performed: Monthly

 Routinely Reported: 10 - 20 business days

Use: Diagnosis of Type 1 Diabetes: The presence of autoantibodies against insulin (IAA) in patients with diabetes mellitus indicates the presence of autoimmune, type 1 diabetes. It is advised that blood for IAA testing be drawn before insulin therapy is initiated. For the IAA result to be valid, the patient must not be insulin treated for more than 1 week.

Prediction of Type 1 Diabetes: Autoantibodies against insulin in an asymptomatic individual places the subject at increased risk for the development of type 1 diabetes.

Specimen Requirements: Collect blood in a 1- 5 mL serum separator tube. Centrifuge, separate and transfer the serum to a plastic vial. Ship specimens with a frozen cold pack for overnight delivery.

Stability (collection to shipping of the sample):
• Ambient: 24 hours
• Refrigerated: 24 hours
• Frozen: 1 year (Avoid repeated freeze/thaw cycles.)

Reference Values: < 120 nU/mL

CPT Code(s): 86337
Islet Cell Autoantibodies

**Methodology:** Indirect immunofluorescence

**Frequency Performed:** Weekly

**Routinely Reported:** 1 - 7 business days

**Use:** Diagnosis of Type 1 Diabetes: The presence of autoantibodies against insulin (IAA) in patients with diabetes mellitus indicates the presence of autoimmune, type 1 diabetes. It is advised that blood for IAA testing be drawn before insulin therapy is initiated. For the IAA result to be valid, the patient must not be insulin treated for more than 1 week.

Prediction of Type 1 Diabetes: Autoantibodies against insulin in an asymptomatic individual places the subject at increased risk for the development of type 1 diabetes.

**Specimen Requirements:** Collect blood in a 1-5 mL serum separator tube. Centrifuge, separate and transfer the serum to a plastic vial. Ship specimens with a frozen cold pack for overnight delivery.

**Stability (collection to initiation of testing):**
- **Ambient:** Specimens < 24 hours old
- **Frozen:** Acceptable
- **Refrigerated:** 24 hours

**Reference Values:** Negative (< 5 JDF) (quantitative results reported in JDF units)

**CPT Code(s):** 88347
**Islet Cell Cytoplasmic Autoantibodies**

**Methodology:** Indirect immunofluorescence

**Frequency Performed:** Weekly

**Routinely Reported:** 1 - 7 business days

**Use:**
- **Diagnosis of Type 1 Diabetes:** The presence of islet cell cytoplasmic autoantibodies (ICA) in patients with diabetes mellitus indicates the presence of autoimmune, type 1 diabetes.

- **Prediction of Type 1 Diabetes:** The presence of islet cell cytoplasmic autoantibodies (ICA) in an asymptomatic individual places the subject at increased risk for the development of type 1 diabetes.

**Specimen Requirements:**
Collect blood in a 1 - 5 mL serum separator tube.
Centrifuge, separate and transfer the serum to a plastic vial. Ship specimens with a frozen cold pack for overnight delivery.

**Stability (collection to shipping of the sample):**
- **Ambient:** 24 hours
- **Refrigerated:** 24 hours
- **Frozen:** 1 year (Avoid repeated freeze/thaw cycles.)

**Reference Values:**
Negative (≤ 5 JDF) (quantitative results reported in JDF units)

**CPT Code(s):** 88347
Islet Cell Cytoplasmic/Insulin Autoantibodies

Methodology: Indirect immunofluorescence, radioimmunoassay

Frequency Performed: Weekly

Routinely Reported: 10 - 20 business days

Use: Diagnosis of Type 1 Diabetes: The presence of autoantibodies against insulin (IAA) in patients with diabetes mellitus indicates the presence of autoimmune, type 1 diabetes. It is advised that blood for IAA testing be drawn before insulin therapy is initiated. For the IAA result to be valid, the patient must not be insulin treated for more than 1 week.

Prediction of Type 1 Diabetes: Autoantibodies against insulin in an asymptomatic individual places the subject at increased risk for the development of type 1 diabetes.

Specimen Requirements: Collect blood in a 1-5 mL serum separator tube. Centrifuge, separate and transfer the serum to a plastic vial. Ship specimens with a frozen cold pack for overnight delivery.

Stability (collection to shipping of the sample):
- Ambient: 24 hours
- Refrigerated: 24 hours
- Frozen: 1 year (Avoid repeated freeze/thaw cycles.)

Reference Values: Negative (quantitative results reported in JDF units)

CPT Code(s): 86337, 88347
Janus Tyrosine Kinase 2 (JAK2 V617F c. 1849 G>T) Gene Qualitative Mutation Analysis

**Methodology:** Real-time PCR  
**Frequency Performed:** Monday - Friday  
**Routinely Reported:** 7 days  
**Use:** This test is typically ordered to diagnose myeloproliferative neoplasms, including polycythemia vera, essential thrombocytosis or primary myelofibrosis.

**Specimen Requirements:** Blood or bone marrow in (lavender top) EDTA or (yellow top) ACD tube; one 3 mL of blood or 1 mL bone marrow shipped at 4°C is accepted. Severely hemolyzed whole blood or clotted/frozen blood/bone marrow specimen is not accepted. Cell pellets with at least 10^6-cells, shipped at 4°C, are acceptable.

**Reference Values:** Negative (Interpretative report provided)

**Interpretation Data:**

<table>
<thead>
<tr>
<th>JAK2</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Positive:</strong> JAK2 V617F mutation is detected.</td>
</tr>
<tr>
<td><strong>Negative:</strong> JAK2 V617F mutation is not detected.</td>
</tr>
</tbody>
</table>

JAK2 positive indicates the JAK2 mutation at codon 617 is present in patient blood/bone marrow sample; however, a negative result does not necessarily exclude the presence of other JAK2 mutations, such as exon 12/13, or the mutation is less than 2% in the sample. Exon 12/13 mutation analysis is suggested when the JAK2 V617F is negative, and there is a high clinical suspicion for myeloproliferative neoplasm (MPN).

**Unacceptable Conditions:**  
- **Ambient:** Specimens greater than 24 hours old  
- **Frozen specimens**

**Stability (collection to initiation of testing):**  
- **Ambient:** 24 hours  
- **Refrigerated:** 72 hours

**CPT Code(s):** 83907, 83891, 83892, 83896 x 2, 83898 x 2, 83905, 83912
Ki-67 Image Analysis

**Methodology:** Immunohistochemistry with image quantitation.

**Frequency Performed:** Weekly

**Routinely Reported:** 7 days

**Use:** Determining proliferative fraction of tumors.

**Specimen Requirements:** A paraffin block

**Storage/Transport:** Ship specimens at 20° - 25° C to protect them from excessive heat. Include a surgical pathology report.

**Unacceptable Conditions:**
- Frozen specimens

**Stability (collection to initiation of testing):**
- **Ambient:** Indefinitely

**Interpretation Data:** Assays are performed on paraffin-embedded, formalin-fixed tissue. The positive percentage of tumor cells is quantitated using the DAKO ACIS III instrument.

**Ki-67 Antibody Clone:** MIB1

**Detection Method:** EnVision + Dual Link System HRP

**CPT Code(s):** 88361
# Kidney/Renal Calculi (Stones)

**Methodology:** Reflectance Fourier Transform Infrared Spectroscopy (FTIR)/polarizing microscopy (send-out)

**Frequency Performed:** Weekly

**Routinely Reported:** 1 - 5 days

**Result:** Tabulated report.

**Use:** This test is used to evaluate the composition of renal calculi.

**Specimen Requirements:**

**Collection:**Calculi specimen

**Storage/Transport Temperature:** Air-dry the calculi and transport it in an empty urine cup

**Stability (collection to initiation of testing):**
- Indefinitely

**CPT Code(s):** 82365
KRAS Mutation Detection

**Methodology:** Polymerase Chain Reaction/DNA Pyrosequencing

**Frequency Performed:** Monday - Friday

**Routinely Reported:** 5 - 10 days

**Use:** The test detects 7 KRAS gene mutations in codons 12 and 13. The mutations at these two codons are linked to resistance to cancer therapies that target the KRAS pathway in colorectal and other cancers.

**Specimen Requirements:** Paraffin-embedded, formalin-fixed tissue block

In case the blocks are not available, 5 unstained slides are acceptable. Ship specimens at 20° - 25° C. Tissues not fixed in formalin are unacceptable.

**Unacceptable Conditions:**
- Frozen specimens
- Specimens in formalin substitute

**Stability (collection to initiation of testing):**
- Ambient: Indefinitely

**Reference Values:** No mutation detected

**Interpretation Data:**

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Interpretation Text</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mutation Detected</td>
<td>A mutation was detected in KRAS codon 12 or 13.</td>
</tr>
<tr>
<td>No Mutation Detected</td>
<td>No KRAS mutation was identified in the provided specimen of this patient.</td>
</tr>
<tr>
<td>QNS</td>
<td>Due to an inadequate specimen or less than 50% tumor cells present in the tissue</td>
</tr>
</tbody>
</table>

**CPT Code(s):** 88381 microdissection/88382 with H & E slides preparation, 83907 lysis, 83891 DNA extraction, 83898 x 3 amplification, 83904 sequencing, 83912 interpretation, 88383 exam and select archive tissue (molecular)
Methylene Tetrahydrofolate Reductase (MTHFR) Polymorphism

Methodology: Polymerase chain reaction followed by restriction enzyme digestion and agarose gel electrophoresis

Routinely Reported: Within 10 days

Use: Methylene tetrahydrofolate reductase (MTHFR) is an NADH-dependent enzyme that converts methylene tetrahydrofolate to methyl tetrahydrofolate. Homocysteine is converted to methionine in a vitamin B12 dependent step. Reduced MTHFR activity is associated with decreased → homocysteine methionine conversion and increased plasma homocysteine concentrations. Elevated homocysteine has an association with vascular thrombosis. Homozygosity for MTHFR gene mutation C677T is associated with elevated plasma homocysteine especially in the setting of folate deficiency.

Specimen Requirements: One 4 mL lavender- (purple) cap tube (EDTA)

Unacceptable Conditions:
- Frozen specimens
- Any-other-color-capped tubes

Stability (collection to initiation of testing):
- Ambient: 3 days
- Refrigerated: 1 week

Reference Values: Negative for the methylene tetrahydrofolate reductase C677T mutation

CPT Code(s): 83891, 83892, 83894, 83912, 83896, 83898
**Micro Array - Comparative Genomic Hybridization (aCGH)**

**Methodology:** Oligonucleotide genomic microarray platform; requires cell culture

**Frequency Performed:** Monday - Saturday

**Routinely Reported:** 14 - 28 days

**Use:** This test provides a higher resolution level compared to chromosome based (CGH) testing for genomic copy number variations.

**Specimen Requirements:**

**Peripheral Blood:** Peripheral blood must be collected aseptically in sodium heparin tubes (usually green-top tubes) and immediately rotated thoroughly to prevent clotting. For infants, obtain approximately 2 cc. Obtain 5 - 7 cc for children and adults.

*Note:* A separate blood sample is required if a concurrent conventional blood chromosome and/or FISH studies are desired.

Do not freeze or fix samples in any manner contrary to the maintenance of cell viability. Maintain sample sterility; keep all specimens at room temperature; and deliver samples to the laboratory within 24 - 48 hours. Ship specimens at room temperature for overnight delivery.

**Unacceptable Conditions:**
- Frozen specimens
- Specimens greater than 48 hours old

**Stability (collection to initiation of testing):**
- Ambient: 24 - 48 hours
- Refrigerated: Unacceptable

**Reference Values:** By report; interpretive

**CPT Code(s):** 88391, 883894-MS9, 83900, 88399, 88230, 88291
Microsatellite Instability - HNPCC/Lynch Syndrome

Methodology: Polymerase chain reaction/DNA fragment analysis

Frequency Performed: Monday - Friday

Routinely Reported: 5 - 10 business days

Use: This test is used to diagnose carcinomas associated with microsatellite instability (MSI), such as those in HNPCC/Lynch syndrome.

Specimen Requirements: Paraffin-embedded tissue; send tissue blocks that contain normal and tumor tissues to the lab. In case the blocks are not available, 5 unstained slides of each tissue types are accepted. Ship the specimen at 20° - 25° C. Tissues fixed in formalin substitute are unacceptable. A tumor region with less than 50% of tumors is not acceptable.

Blood or buccal cells can be accepted as normal control of the MSI study. Ship 3 mL of blood in EDTA (purple-top tube) or ACD (yellow-top tube) at 4° C. Severely hemolyzed whole blood or clotted/ frozen blood/bone marrow specimen is not accepted.

Reference Values: MSI stable

Interpretation Data:

<table>
<thead>
<tr>
<th>MSI</th>
<th>Interpretation</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>MSI-High:</strong></td>
<td>This patient has a tumor with two or more unstable microsatellite markers.</td>
</tr>
<tr>
<td><strong>MSI-Low:</strong></td>
<td>This patient has a tumor with one unstable microsatellite marker.</td>
</tr>
<tr>
<td><strong>MSI-Stable:</strong></td>
<td>This patient has a tumor with no detectable instability.</td>
</tr>
</tbody>
</table>

Microsatellite instability high (MSI-H) indicates a significant level of microsatellite instability in a tumor. MSI-H is present in > 90% of patients with hereditary non-polyposis colorectal cancer (HNPCC) and in 15 - 20% of sporadic colorectal tumors. Genetic counseling and/or germ-line mutation analysis of mismatch-repair genes (MSH2, MLH1, and MSH6) are recommended to the patient/family with microsatellite instability-high tumors and a high suspicion of HNPCC.

MSI-low or MSI stable indicates no significant genomic microsatellite instability in a tumor. Stable genomic microsatellites would be rare in hereditary nonpoly-
posis colorectal cancer; however, it does not completely exclude the possibility of that or other inherited syndromes. Correlate with clinical findings or genetic counseling is recommended. This interpretation may not apply to cancers other than colon cancers.

**CPT Code(s):**

- 88381 microdissection, 83907 x 2 lysis, 83891 x 2 DNA extraction, 83898 x 7 amplification, 83894 x 2 capillary electrophoresis, 83912 interpretation, 88386 exam and selection archive tissue, molecular
Muscle Pathology

Methodology: Microscopic exam
Frequency Performed: Monday - Friday
Routinely Reported: 1 - 3 days
Result: Interpretive report
Use: This test is used to diagnose muscle diseases in patients.

Specimen Requirements: To obtain a muscle biopsy kit (#0105) and detailed collection instructions, contact UF PathLabs Client Services Department at (888) 375-LABS (5227). The majority of the specimen should be sent on saline-dampened gauze. A small portion should be sent in EM fixative (glutaraldehyde).

UF PathLabs’ Client Services Department must be notified when sending a specimen. Only ship muscle biopsy specimens Monday - Thursday.

Unacceptable Conditions:
- Frozen specimens
- Inappropriate fixative
- Frozen fixatives
- Specimens greater than 24 hours old
- Specimens that are shipped late on Fridays or Saturdays

Stability (collection to initiation of testing):
- Ambient: Immediate delivery
- Refrigerated: 24 hours

CPT Code(s): 88305, 88313 x 2, 88314, 88319 x 7
Nail Testing For Fungus (Onychomycosis)

**Methodology:** Microscopic exam

**Frequency Performed:** Monday - Friday

**Routinely Reported:** 3 days

**Use:** This test is used to detect and diagnose infections of the nail using a PAS stain.

**Specimen Requirements:** Place nail fragments in an empty sterile container 10% formalin.

For containers and fixative, contact UF PathLabs Client Services Department at (800) 375-5227.

**Storage/Transport Temperature:** Submit specimens according to Biological Substance, Category B, shipping guidelines.

**Unacceptable Conditions:**
- Frozen specimens
- Refrigerated
- Specimens in formalin substitute (alcohol-based)

**Stability (collection to initiation of testing):**
- **Ambient:** 1 week
- **Frozen:** Unacceptable
- **Refrigerated:** Unacceptable

**Reference Values:** Positive, negative

**CPT Code(s):** 88305, 88312
Nerve Pathology

**Methodology:** Microscopic exam

**Frequency Performed:** Monday - Friday

**Routinely Reported:** 1 - 3 days

**Result:** Interpretive report

**Use:** This test is used to aid in diagnosing nerve disorders. Nerve biopsies will assist in making a diagnosis if there is damage to small nerves; the axon portion of a nerve; and/or if neuropathy is present.

**Specimen Requirements:** To obtain nerve biopsy kits (#0105) and detailed collection instructions, contact UF PathLabs Client Services Department at (888) 375-LABS (5227).

UF PathLabs’ Client Services Department must be notified when sending a specimen. Only ship nerve biopsy specimens Monday - Thursday.

**Unacceptable Conditions:**
- Frozen specimens
- Specimens in inappropriate fixative
- Frozen fixatives
- Specimens greater than 24 hours old
- Specimens shipped on Fridays or Saturdays

**Stability (collection to initiation of testing):**
- **Ambient:** Immediate delivery
- **Frozen:** Acceptable but not recommended
- **Refrigerated:** 24 hours

**CPT Code(s):** 88305, 88348
Neuropathology

Methodology: Microscopic exam

Frequency Performed: Monday - Friday

Routinely Reported: 1 - 3 days

Result: Interpretive report

Specimen Requirements: Tissue must be fixed in 10% formalin.

For fixative and more information, contact the UF PathLabs Client Services Department at (888) 375-LABS (5227). Neuropathology in association with autopsies is also available. Call for delivery procedures.

Storage/Transport Temperature: Submit specimens according to Biological Substance, Category B, shipping guidelines.

Unacceptable Conditions:
- Frozen specimens
- Specimens in inappropriate fixative

Stability (collection to initiation of testing):
- Ambient: Indefinitely
- Refrigerated: Indefinitely
- Frozen: Unacceptable

CPT Code(s): 88302, 88304, 88305, 88307 or 88309, depending on the case complexity, 88312 and 88313 if special stains are used, 88342 if immunoperoxidase stains are required
Oral Pathology

Methodology: Microscopic exam
Frequency Performed: Monday - Friday
Routinely Reported: 1 - 3 days
Result: Interpretive report
Specimen Requirements: Tissue must be fixed in 10% formalin.

If immunobullous disease is suspected, submit half of the tissue in Michel’s fixative for a direct immunofluorescence study. See Immunofluorescence - Direct, Skin in this directory for specimen collection instructions and requirements.

For an oral pathology kit (#0096 without Michel’s fixative or #0096-A with Michel’s fixative) and more information, contact the UF PathLabs Client Services Department at (888) 375-LABS (5227).

Storage/Transport Temperature: If requesting a DIF, only use Michel’s fixative. Submit specimens according to Biological Substance, Category B, shipping guidelines.

Unacceptable Conditions:
- Frozen specimens
- Specimens in inappropriate fixative

Stability (collection to initiation of testing):
- Ambient: Indefinitely
- Refrigerated: Indefinitely
- Frozen: Unacceptable

CPT Code(s): 88302, 88304, 88305, 88307 or 88309, depending on the case complexity, 88312 and 88313 if special stains are used, 88342 if immunoperoxidase stains are utilized
Ovarian Autoantibodies

Methodology: Indirect immunofluorescence
Frequency Performed: Weekly
Routinely Reported: 1 - 7 business days

Use: Diagnosis of Autoimmune Gonadal Failure: The presence of ovarian, Leydig cell testicular and/or placental autoantibodies in women of reproductive age with gonadal failure or in men with gonadal failure indicates that the gonadal failure is of autoimmune origin.

Prediction of Autoimmune Gonadal Failure: The detection of ovarian, Leydig cell testicular and/or placental autoantibodies in women of reproductive age or men places the subject at increased risk for the development of autoimmune gonadal failure.

Specimen Requirements: Collect blood in a 1-5 mL serum separator tube. Centrifuge, separate and transfer the serum to a plastic vial. Ship specimens with a frozen cold pack for overnight delivery.

Stability (collection to shipping of the sample):
• Ambient: 24 hours
• Refrigerated: 24 hours
• Frozen: 1 year (Avoid repeated freeze/thaw cycles.)

Reference Values: Negative
CPT Code(s): 88347
Pap Smear Test: Conventional

Methodology: Routine cytopathologic evaluation

Frequency Performed: Monday - Friday

 Routinely Reported: Within 5 days

Use: A Pap smear examines the cells of the cervix and detects cell abnormalities. Both, cancerous and precancerous cells can be detected. Pap tests are recommended in women ages 21 - 64, every two years with normal Pap results. Vaginal Pap smears can also be performed but must be noted on the requisition.

Specimen Requirements: Collection and Transportation: In general, the ideal time to perform a Pap test is more than 12 days after the last menstrual period and 24 hours or more after douching or sexual intercourse. Perform the test before a bimanual exam. The proper technique for a conventional Pap smear, using the scrape and cytobrush and/or swab, is as follows:

Place the patient in the lithotomy position.

Using an unlubricated vaginal speculum (saline may be used as a lubricant) visualize the cervix as fully as possible. Be sure the slide being used is already labeled in pencil with the proper patient information and site of sample. Label the slide(s) with the patient’s first and last name, date of birth, and specimen source directly on the frosted end of the glass, in pencil, before beginning the procedure. The laboratory will not accept unlabeled slides. A rare patient may have 2 cervices and then designate as right or left.

- If on visual inspection, the cervix is coated with excessive mucus, inflammatory debris, blood or other contaminants, lightly dab the surface with a saline-moistened 4x4 or swab to remove obscuring substances that will make the smear unsatisfactory for interpretation without disturbing the surface epithelium.

- After visualization of the cervix is accomplished, insert the cytobrush into the endocervical canal and rotate it half a turn. Withdraw the cytobrush and spread the collected material quickly and evenly onto the half of the slide opposite the frosted end. The endocervical mucus will prevent air-drying during
collection of the subsequent cervical component. Using the extended-tip spatula, scrape material with the spatula from the whole circumference of the cervix (in a 360° turning motion). Withdraw the spatula and spread the collected material quickly and evenly onto the half of the slide adjacent to the frosted end. Fix the specimen immediately by dropping the slide into fixative or spraying it with fixative, holding the spray bottle approximately 8 to 12 inches from the slide. Complete the cytology test request form, including relevant clinical information.

The importance of immediate and generous fixation with Pap fixative cannot be overstated. The smear should be left on a level surface (not at an angle) and allowed to dry if spray-fixed.

If an accurate hormonal assessment is necessary (MI), a lateral vaginal wall scraping should be submitted separately. Do not submit for hormonal assessment if there is clinical evidence of active inflammation.

- Avoid using KY Jelly lubricant on the speculum (Use warmed water instead.). Be mindful that powder from gloves doesn’t contaminate the specimen or glass slides. If using powdered gloves rinse them after placing on your hands under running water.

Send the smear to the laboratory in a protective slide holder, along with the matched requisition properly inserted in biohazard bag. The laboratory will proceed with the staining, screening and review of the specimen by a cytotechnologist and/or pathologist, according to established guidelines. Do not place thick mucus plugs on the Pap slide, as this interferes with staining and obscures important cellular detail.

**Reference:** 4th Edition of Koss pg. 6

**Storage/Transport Temperature:** Submit specimens according to Biological Substance, Category B, shipping guidelines.

**Unacceptable Conditions:**
- Incomplete requisition (especially the federally required indication for the procedure)
- Broken slides fragmented beyond repair
- Incomplete and/or improper labeling of slides
- Insufficient pertinent clinical history
- Specimens that are not immediately fixed on a slide
- Obscuring inflammation, debris or excessive air drying
- Broken slides, which will be rejected and discarded as a biohazard
Always record if a cytobrush was used to obtain the Pap test. Failing to record the use of a cytobrush may result in erroneous atypical results for the patient.

**Stability (collection to initiation of testing):**
- **Ambient:** Indefinitely
- **Frozen:** Unacceptable
- **Refrigerated:** N/A

**Reference Values:** Interpretative report

**CPT Code(s):** 88164, 88142 (if applicable)
Pap Test: SurePath™ Liquid-Based

Methodology: SurePath™ slide processor

Frequency Performed: Monday - Friday

Routinely Reported: Within 5 days

Use: A Pap smear examines the cells of the cervix and detects cell abnormalities. Both, cancerous and precancerous cells can be detected. Pap tests are recommended in women ages 21 - 64, every two years with normal Pap results. Vaginal Pap smears can also be performed but must be noted on the requisition.

The BD SurePath™ liquid-based Pap test is an FDA-approved, thin-layer, cell-preparation process that is intended for use in the screening and detection of cervical cancer, precancerous lesions, atypical cells and all other cytologic categories, as defined by the Bethesda System for Reporting Cervical/Vaginal Cytologic Diagnoses.¹


Specimen Requirements: Collection Protocol:

Step 1: Collect the cytology sample using either a broom-like device or a combination brush/spatula with detachable heads.

Step 2: Drop the detachable head into a SurePath™ vial.

Step 3: Place the cap on the vial securely.

Storage/Transport Temperature: Submit specimens according to Biological Substance, Category B, shipping guidelines.

Remarks: This test requires a SurePath™ special collection kit (#0102-S) that must be ordered separately through UF PathLabs Client Services Department at (888) 375-LABS (5227).

Unacceptable Conditions:
- Lack of a properly completed requisition (especially federally required information)
- Incomplete and/or improper labeling of slides
- Insufficient pertinent clinical history
- Specimens that are not immediately fixed on slides
- Obscuring inflammation, debris or excessive air-drying
• A broken slide will be rejected and discarded as a biohazard.
• Always record if a cytobrush was used to perform the Pap test. Failing to record the use of a cytobrush may result in erroneous atypical results for the patient.

**Stability (collection to initiation of testing):**
• Ambient
  • **SurePath™:** 4 weeks at 4° - 37° C

**Reference Values:** Interpretive report provided

**CPT Code(s):** 88141, 88142

*Note:* Store SurePath™ preservative fluid without cytologic samples at 15° - 30° C in the vials provided. Do not use SurePath™ solution beyond the expiration date marked on the vial.

*Warning:* SurePath™ preservative contains denatured ethanol, which may be fatal or cause blindness (if swallowed); its vapor is harmful if inhaled. SurePath™ is flammable; keep it away from fire, heat, sparks and flames. Other solutions must not be substituted for SurePath™ preservative.
Pap Test: SurePath™ Liquid-Based with Reflex to Human Papillomavirus (HR-HPV) DNA Probe, High Risk

Methodology: PrepStain™ slide processor/routine cytopathologic evaluation/nucleic acid probe

Frequency Performed: Monday - Friday

Routinely Reported: 5 - 7 days

Use: The BD SurePath™ liquid-based Pap test is an FDA-approved, thin-layer cell-preparation process intended for use in the screening and detection of cervical cancer, precancerous lesions, atypical cells and all other cytologic categories as defined by the Bethesda System for Reporting Cervical/Vaginal Cytologic Diagnoses.

Interpretation Data: Women with atypical squamous cells of undetermined significance (ASC-US) should be managed using a program of either repeat cervical cytopathology testing, immediate colposcopy or DNA testing for high-risk types of human Papillomavirus (HPV). Testing for HR-HPV DNA is the preferred approach when liquid-based cytopathology is used for screening. All women who test positive for high-risk HPV DNA should be referred for colposcopic evaluation. Women with ASC-US who test negative for high-risk HPV DNA can be followed up with repeat cytologic testing at 12 months (2001 ASCCP Guidelines -JAMA 2002; 287:2120-2129)

A positive high-risk HPV test result indicates that the patient may be infected with one or more of the following HPV genotypes: 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59 and 68, which are associated with cervical cancer and its precursor lesions; however, cross-reactions with other genotypes may occur. Results should be correlated with the cytologic/histologic findings.

The performance characteristics of this test were determined by UF PathLabs, utilizing the FDA-approved Digene HPV-HR Hybrid Capture 2 DNA test.

Specimen Requirements: Storage/Transport Temperature: Submit specimens according to Biological Substance, Category B, shipping guidelines.
Remarks: This test includes a cytopathology, SurePath™ liquid-based Pap test and an HPV HR-DNA probe. HPV is reflexed only if the SurePath™ test is interpreted as atypical squamous cells of undetermined significance in patients ages 21 and over.

Unacceptable Conditions:
- Lack of a properly completed requisition (especially federally required information)
- Incomplete and/or improper labeling of slides
- Insufficient pertinent clinical history
- Specimens that are not immediately fixed on slides
- Obscuring inflammation, debris or excessive air-drying
- A broken slide will be rejected and discarded as a biohazard.
- Always record if a cytobrush was used to perform the Pap test. Failing to record the use of a cytobrush may result in erroneous atypical results for the patient.

Stability (collection to initiation of testing):
- Ambient:
  - SurePath™: 4 weeks at 4° - 37° C

Reference Values: Interpretive report; high-risk HPV DNA negative or positive

Note: A negative result does not rule out the presence of an HPV genotype absent from the test panel, a low-level infection or specimen sampling error.

CPT Code(s): CPT codes vary based on the testing performed; 88141, 88142. If reflexed to HPV, add 87621 high-risk HPV.
Pap Test: ThinPrep®

Methodology: ThinPrep® 2000 system preparation with routine cytopathologic evaluation

Frequency Performed: Monday - Friday

Routinely Reported: Within 5 days

Result: Interpretive report

Use: A Pap smear examines the cells of the cervix and detects cell abnormalities. Both, cancerous and precancerous cells can be detected. Pap tests are recommended in women ages 21 - 64, every two years with normal Pap results. Vaginal Pap smears can also be performed but must be noted on the requisition.

The ThinPrep® Pap test addresses these limitations with liquid-based preparation, improving specimen adequacy and significantly increasing test sensitivity. The ThinPrep® Pap test is the first test of this kind. Since its introduction, it has contributed to a further 28% reduction in invasive cervical cancers in the United States.¹


Specimen Requirements: Collection and Transport: This assay requires a ThinPrep® Pap test special collection kit (#0102-T), which can be ordered separately through UF PathLabs Client Services Department by calling (888) 375-LABS (5227).

Brush Spatula Protocol: Obtain an adequate sampling from the ectocervix by using a plastic spatula. If desired, use lukewarm water to warm and lubricate the speculum. Water-soluble gel lubricant, sparingly applied to the posterior blade of the speculum, can be used if necessary.¹ Rotate the contoured end of plastic spatula 360° around the entire exocervix while maintaining tight contact with the exocervical surface.

Rinse the spatula in the PreservCyt™ solution as quickly as possible by swirling the spatula vigorously in the vial 10 times; then, discard the spatula.
Obtain an adequate sampling from the endocervix by using an endocervical brush device. Insert the brush into the cervix until only the bottommost fibers are exposed. Slowly rotate 1/4 or 1/2 turn in one direction. Do not over-rotate.

Rinse the brush as quickly as possible in the PreservCyt™ solution by rotating the device in the solution 10 times while pushing against the PreservCyt™ vial wall. Swirl the brush vigorously to further release specimen material; then, discard the brush.

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

Record the patient’s name and date of birth on the vial, in addition to recording the patient information and medical history on the cytology requisition form.

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


**Broom-Like Device Protocol**

Obtain an adequate sampling from the cervix by using a broom-like device. If desired, use lukewarm water to warm and lubricate the speculum. Water-soluble gel lubricant, sparingly applied to the posterior blade of the speculum, can be used if necessary. Insert the central bristles of the broom into the endocervical canal deep enough to allow the shorter bristles to fully contact the ectocervix. Push gently and rotate the broom in a clockwise direction five times.

Rinse the broom as quickly as possible into the PreservCyt™ solution vial by pushing the broom into the bottom of the vial 10 times, forcing the bristles apart. As a final step, swirl the broom vigorously to further release specimen material; then, discard the collection device.

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

Record the patient’s name and Date of Birth on the vial, and the patient information and medical history on the cytology requisition form.

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

**Storage/Transport Temperature:** Submit specimens according to Biological Substance, Category B, shipping guidelines.

**Remarks:** This test requires a ThinPrep® Pap Test™ special collection kit that must be ordered separately through UF PathLabs Client Services Department at (888) 375-LABS (5227).

Human Papillomavirus (HR-HPV) DNA Probe testing can be performed with the PreservCyt® Solution vial. For more information, refer to Human Papillomavirus (HPV-HR) DNA Probe, High Risk, or Cytopathology, ThinPrep® Pap with Reflex to Human Papillomavirus (HPV) DNA Probe, High Risk in this directory.

**Unacceptable Conditions:**
- Lack of a properly completed requisition (especially federally required information)
- Incomplete and/or improper labeling of slides
- Insufficient pertinent clinical history
- Specimens that are not immediately fixed on slides Obscuring inflammation, debris or excessive air-drying
- A broken slide will be rejected and discarded as a biohazard.

Always record if a cytobrush was used to perform the Pap test. Failing to record the use of a cytobrush may result in erroneous atypical results for the patient.

**Stability (collection to initiation of testing):**
- Ambient:
- ThinPrep®: 3 weeks at 4° - 37° C

**CPT Code(s):** 88141, 88142
Pap Test: ThinPrep® with Reflex to Human Papillomavirus (HPV-HR) DNA Probe, High Risk

**Methodology:** ThinPrep® 2000 system/routine cytopathologic evaluation/nucleic acid probe

**Frequency Performed:** Monday - Friday

**Routinely Reported:** 5 - 10 days

**Result:** Interpretive report; high-risk HPV DNA negative or positive.

**Use:** A Pap smear examines the cells of the cervix and detects cell abnormalities. Both, cancerous and precancerous cells can be detected. Pap tests are recommended in women ages 21 - 64, every two years with normal Pap results. Vaginal Pap smears can also be performed but must be noted on the requisition.

The ThinPrep® Pap test addresses these limitations with liquid-based preparation, improving specimen adequacy and significantly increasing test sensitivity. The ThinPrep® Pap test is the first test of this kind. Since its introduction, it has contributed to a further 28% reduction in invasive cervical cancers in the United States.¹


Women with atypical squamous cells of undetermined significance should be managed using a program of either repeat cervical cytopathology testing, immediate colposcopy or DNA testing for high-risk types of HPV. Testing for HPV DNA is the preferred approach when liquid-based cytopathology is used for screening. All women who test positive for high-risk HPV DNA should be referred for colposcopic evaluation. Women with ASC-US who test negative for high-risk HPV DNA can be followed up with repeat cytologic testing at 12 months (2001 ASCCP Guidelines -JAMA 2002; 287:2120-2129).

A positive high-risk HPV test result indicates that the patient may be infected with one or more of the following HPV genotypes: 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59 and 68, which are associated with cervical cancer and its precursor lesions; however, cross-reactions with other genotypes may occur.
Results should be correlated with cytologic/histologic findings.

**Specimen Requirements:**

**Cervical Brushes:** Specimens must be collected prior to the application of acetic acid or iodine if a colposcopic examination is being performed. The samples should be collected by using a Digene cervical brush and stored in Digene STM solution.

**Cervical Biopsies:** Specimens must be freshly collected, 2 - 5 mm in cross section. The biopsy specimen must be placed immediately into 1 mL of STM and stored frozen.

**Specimens in ThinPrep® Cytoc PreservCyt™ Solution:** There must be at least 4 mL of PreservCyt™ solution remaining for the HPV DNA test.

**Storage/Transport Temperature:** Submit specimens according to Biological Substance, Category B, shipping guidelines.

**Unacceptable Conditions:**
- Lack of a properly completed requisition (especially federally required information)
- Incomplete and/or improper labeling of slides
- Insufficient pertinent clinical history
- Specimens that are not immediately fixed on slides
- Obscuring inflammation, debris or excessive air-drying
- A broken slide will be rejected and discarded as a biohazard.
- Always record if a cytobrush was used to perform the Pap test. Failing to record the use of a cytobrush may result in erroneous atypical results for the patient.

**Stability (collection to initiation of testing):**
- Ambient:
- ThinPrep®: 3 weeks at 4° - 37° C

**CPT Code(s):** 88141, 88142; if reflexed to HPV, add 87621 high-risk HPV

*Note: A negative result does not rule out the presence of an HPV genotype absent for the test panel, a low level infection or specimen sampling error.*
Parentage Test

**Methodology:** Polymerase chain reaction of short tandem repeats

**Frequency Performed:** Per request

**Routinely Reported:** Two weeks; the person requesting the test specifies who should receive the report. Usually, one copy is for the participants and one for the attorney(s). Depositions can be arranged if and when required.

**Use:** Parentage testing is most commonly performed to aid in cases of disputed paternity and child support; however, there are situations in which a person wants to know who the biological father of a child is for reasons unrelated to litigation or child support. Similarly, questions sometimes arise regarding the family relationships between individuals as in immigration proceedings, for example. In all these circumstances, DNA testing constitutes a powerful tool that aids significantly in the resolution of these issues.

**Parentage Testing for Legal Purposes:** For the test to be admissible in court, every part of the procedure must conform to the requirements of the judicial system. This mainly involves steps to document the identification of the participants and the chain of custody of the specimens.

**Identification of Participants:** Although the participants can obtain the mouth samples themselves, samples have to be collected by following accepted legal procedures. These procedures include the presence of a witness having no interest in the results of the test; documentation of the identity of the participants; documentation of the identity and integrity of the samples; fingerprints; and instant pictures of the participants (one of the mother with the child and another of the alleged father). All this is done at our facility when the participants come for sample collection. If samples are collected elsewhere, the participants will have to arrange, with the agreement of all parties involved, to collect the samples in a suitable place and in the presence of an appropriate witness. The attorneys of the case may help with these arrangements.

**Chain of Custody:** Every step, from specimen collection to specimen storage, to specimen testing and result reporting, is documented by recording the name of the person handling the specimens and the purpose of such handling.
**Testing Not Involving Legal Proceedings:** If the testing is not intended to be part of a legal action, the identification procedures are not necessary. This may facilitate the process of specimen collection and reduce the cost. The results will be as accurate as for those that are part of legal proceedings but will not be valid in a court of law. This means that if at a later time legal issues develop, the test will have to be repeated at full cost to the participants.

**Special Cases:** Sometimes the mother is not tested or the father is unavailable but his relatives are, or there are other special circumstances. In most cases, it is possible to do the tests and arrive at appropriate conclusions; however, in general, the power of the analysis decreases, and the chances of less-definitive or inconclusive results are higher.

**Specimen Requirements:** Buccal swab

The samples are collected from the mouth of each participant using a soft brush. No foods or drinks should be taken for one hour prior to collection. If a child to be tested is nursing, the child should not nurse for one hour prior to collection. The inside of one cheek is brushed either up and down or back and forth 8 to 10 times through the entire cheek surface. With the same brush, the procedure is repeated on the other cheek. Then the brush is placed in the plastic pouch provided and sealed. The plastic pouch has a label where the name of the participant, race and relationship to the child are recorded, along with the date and time of collection and name of witness. The participant and the witness have to write their initials on the label. The brush provided is soft (softer than a regular tooth brush) and the procedure produces no pain or discomfort.

**Reference Values:** The results are summarized in a detailed report that provides an interpretation regarding exclusion of paternity or likelihood of paternity. The report can be used as a legal document if the test is part of legal proceedings.

**CPT Code(s):** N/A

The most direct way to arrange for specimen collection is to make an appointment to come to our facility. Progress in DNA analysis has made an impact in multiple areas of medicine and biology. One of those areas is individual identification, that is, the ability to detect specific markers that, in combination, are unique to a given person. Parentage testing is most commonly performed to aid in cases of disputed
paternity and child support; however, there are situations in which a person wants to know who the biological father of a child is for reasons unrelated to litigation or child support. Similarly, questions sometimes arise regarding the family relationships between individuals as in immigration proceedings, for example. In all these circumstances, DNA testing constitutes a powerful tool that aids significantly in the resolution of these issues.

Unacceptable Conditions:
- Frozen specimens

Stability (collection to initiation of testing):
- Ambient: 48 hours
- Refrigerated: Unacceptable
- Frozen: Unacceptable
| **Paroxysmal Nocturnal Hemoglobinuria (PNH) - CD55/59 Erythrocytes, FLAER Granulocytes/Monocytes** |
|---|---|
| **Methodology:** | Flow cytometry |
| **Frequency Performed:** | Monday - Saturday |
| **Routinely Reported:** | 1 - 3 days |
| **Result:** | See report |
| **Use:** | This test is used to diagnose PNH and quantify PNH clones in blood. PNH may be associated with hemolytic anemia, leukopenia, thrombocytopenia and aplastic anemia. This method uses expression of CD55/59 on erythrocytes and the more sensitive fluorescent aerolysin (FLAER) on granulocytes/monocytes. |
| **Specimen Requirements:** | Within 5 days (Stat cases may be completed within 24 hours).  
- 2 x 5 - 10 mL peripheral blood in a lavender-top tube (EDTA)  
- Peripheral blood only; it must be received in the lab within 24 of collection hours, but no later than 72 hours. |
| **Storage/Transport Temperature:** | Fresh peripheral blood specimens can be transported with a cold pack or wet ice, but do not fix or freeze specimens (no dry ice).  |
| **Unacceptable Conditions:** | Specimens greater than 24 hours old  |
| **Stability (collection to initiation of testing):** |  
- **Ambient:** 24 hours  
- **Refrigerated:** 24 hours  
- **Frozen:** Unacceptable  |
| **Reference Values:** | Negative; presence of PNH clone is reported and quantified using CD55/59(for RBCS), FLAER for granulocytes and monocytes |
| **CPT Code(s):** | 88184, 88185, 88186, 88187, 88188, 88189 |
Pediatric Islet Autoantibody Panel

(Islet Cell Cytoplasmic Autoantibodies (ICA), Glutamic Acid Decarboxylase Autoantibodies (GADA), Insulinoma-2 Associated Autoantibodies (IA-2A) and Insulin Autoantibodies (IAA))

**Methodology:** Indirect immunofluorescence (ICA); radioimmunoassay (GADA, IA-2A and IAA)

**Performed:** Weekly

**Reported:** 10 - 20 business days

**Use:**

- **Diagnosis of Type 1 Diabetes:** The presence of autoantibodies against the cytoplasm of ICA, GADA, IA-2A and/or IAA in patients with diabetes mellitus indicates the presence of autoimmune, type 1 diabetes (aka type 1A diabetes). It is advised that blood for IAA testing be drawn before insulin therapy is initiated. For the IAA result to be valid, the patient must not be insulin treated for more than one week.

- **Prediction of Type 1 Diabetes:** Autoantibodies against the cytoplasm of ICA, GADA, IA-2A and/or IAA in an asymptomatic individual places the subject at increased risk for the development of type 1 diabetes.

**Specimen Requirements:**

Collect blood in a 5 mL serum separator tube. Centrifuge, separate and transfer the serum to a plastic vial. Ship specimens with a frozen cold pack for overnight delivery.

**Stability (collection to shipping of the sample):**

- **Ambient:** 24 hours
- **Refrigerated:** 24 hours
- **Frozen:** 1 year (Avoid repeated freeze/thaw cycles.)

**Reference Values:**

**ICA:**

- **Negative (quantitative results reported in JDF units):** < 10 JDF units
- **Positive:** ≥ 10 JDF units

**GADA:**

- **Negative:** < 1.1
- **Positive:** ≥ 1.1 U/mL

**IA-2A:**

- **Negative:** < 0.76
- **Positive:** ≥ 0.76
IAA:
- **Negative**: < 95 nU/mL
- **Indeterminate**: 95 - 125 nU/mL
- **Positive**: > 125 nU/mL

**CPT Codes:**
- **ICA**: 86337, 88347
- **GADA**: 86341
- **IA-2A**: 86341
- **IAA**: 86337
## Pediatric Pathology

**Methodology:** Microscopic exam  
**Frequency Performed:** Monday - Friday  
**Routinely Reported:** 1 - 3 days  
**Result:** Interpretive report  
**Specimen Requirements:** Tissue fixed in 10% neutral-buffered formalin or zinc formalin  

For fixative and more information, contact the UF PathLabs Client Services Department at (888) 375-LABS (5227).

**Storage/Transport Temperature:** Submit specimens according to Biological Substance, Category B, shipping guidelines.

**Unacceptable Conditions:**
- Frozen specimens
- Specimens not in appropriate fixative

**Stability (collection to initiation of testing):**
- **Ambient:** Indefinitely
- **Refrigerated:** Indefinitely
- **Frozen:** Unacceptable

**CPT Code(s):** 88302, 88304, 88305, 88307 or 88309, depending on the case complexity, 88312 and 88313 if special stains are used, 88342 if immunoperoxidase stains are required.
Placental (Syncytiotrophoblast) Autoantibodies

Methodology: Indirect immunofluorescence
Frequency Performed: Weekly
Routinely Reported: 1 - 7 business days

Use: Diagnosis of Autoimmune Gonadal Failure: The presence of ovarian, Leydig cell testicular and/or placental autoantibodies in women of reproductive age with gonadal failure or in men with gonadal failure indicates that the gonadal failure is of autoimmune origin.

Prediction of Autoimmune Gonadal Failure: The detection of ovarian, Leydig cell testicular and/or placental autoantibodies in women of reproductive age or men places the subject at increased risk for the development of autoimmune gonadal failure.

Specimen Requirements: Collect blood in a 1-5 mL serum separator tube. Centrifuge, separate and transfer the serum to a plastic vial. Ship specimens with a frozen cold pack for overnight delivery.

Stability (collection to shipping of the sample):
- Ambient: 24 hours
- Refrigerated: 24 hours
- Frozen: 1 year (Avoid repeated freeze/thaw cycles.)

Reference Values: Negative
CPT Code(s): 88347
## Podiatry Pathology

**Methodology:** Microscopic exam  
**Frequency Performed:** Monday - Friday  
**Routinely Reported:** 1 - 3 days  
**Result:** Interpretive report  
**Specimen Requirements:** Skin tissue must be fixed in 10% formalin. If immunobullous disease is suspected, submit half of the tissue in Michel’s fixative for a direct immunofluorescence study.

For podiatry kits (#101), fixative and more information, contact the UF PathLabs Client Services Department at (888) 375-LABS (5227). Culture collection medium is provided in the podiatry kits.

**Storage/Transport Temperature:** Submit specimens according to Biological Substance, Category B, shipping guidelines.  
**Unacceptable Conditions:**  
- Frozen specimens  
- Specimens not in appropriate fixative  

**Stability (collection to initiation of testing):**  
- **Ambient:** Indefinitely  
- **Refrigerated:** Indefinitely  
- **Frozen:** Unacceptable

**CPT Code(s):** Please contact the UF PathLabs Client Services Department at (888) 375-LABS (5227) for CPT codes.
Prenatal Tissue Culture Only

**Methodology:** Cell culture for cell-line buildup only; for reference lab send-out

**Frequency Performed:** Monday - Saturday

**Routinely Reported:** 14 - 28 days (subject to a broad range of variables)

**Use:** This test is used for esoteric send-out testing, which may require a given quantity of cells or living tissue cultures (e.g., specific enzyme test for metabolic disorders, etc.).

**Specimen Requirements:**

**Amniotic Fluid:** Aseptically collect approximately 1 cc of per week of gestational age in two sterile 15 mL conical centrifuge tubes and sequentially label the tubes. The initial 1 - 2 cc should not be included for chromosome studies (but may be utilized for AFP testing).

**Chorionic Villi:** Collect 10 - 30 mg of villi utilizing aspiration medium that contains sodium heparin.* After assessing the appropriate amount and quality of villi, transfer it to a sterile centrifuge tube with transportation medium.

**Fetal Tissue Samples:** As aseptically as possible, obtain approximately 2 mm x 2 mm x 2 mm in size (recommended tissues for abortus materials include recognizable fetal components, such as skin, lung and cartilage and extra-embryonic tissues, such as chorionic villi). Transfer each sample to a separate sterile 15 mL conical centrifuge tube containing tissue culture medium that has been brought to room temperature prior to collection.* Do not place the sample in hot or cold medium. To enhance the possibility of a successful cytogenetic study, we recommend that at least two tissue types be sent in separate containers.

Do not freeze or fix samples in any manner contrary to the maintenance of cell viability. Maintain sample sterility; keep all specimens at room temperature; and deliver samples to the laboratory within 24 - 48 hours. Ship specimens at room temperature for overnight delivery.

**Unacceptable Conditions:**
- Frozen specimens
- Specimens greater than 48 hours old*
Stability (collection to initiation of testing):

- **Ambient**: 24 - 48 hours*
- **Frozen**: Unacceptable

* Cell viability of specimens requiring cell culture may be compromised in specimens older than 48 hours upon receipt. Refrigeration at 2° - 8° C may assist when a delay is not preventable. Do not freeze or place specimens directly on ice.

Reference Values: Reference lab report

CPT Code(s): 88233
Prothrombin G20210A Mutation (Factor 2 Mutation)

Methodology: Polymerase chain reaction with sequence specific primers (PCR-SSP) combined with agarose gel electrophoresis

Frequency Performed: Monday - Friday

Routinely Reported: Within 10 days

Use: Prothrombin is the precursor of the serine protease thrombin, a key enzyme in the process of hemostasis and thrombosis. A G to A transition at the nucleotide position 20210 of the prothrombin gene is a common polymorphism in Caucasian populations. Nucleotide 20210 corresponds to a location in the in the 3’-untranslated region of the mRNA. The prothrombin G20210A polymorphism is associated with elevated plasma prothrombin concentrations (in the range of 115 - 130%) and an increased risk of venous thrombosis. Individuals heterozygous for the mutation have approximately a three-fold increased risk of thrombosis.

Specimen Requirements: One 4 mL lavender (purple) cap tube (EDTA)

Unacceptable Conditions:
• Frozen specimens

Stability (collection to initiation of testing):
• Ambient: 72 hours
• Refrigerated: 1 week
• Frozen: Unacceptable

Reference Values: Negative for the prothrombin G20210A mutation

CPT Code(s): 83891, 83894 x 2, 83898 x 2, 83912
Pulmonary Pathology

Methodology: Microscopic exam
Frequency Performed: Monday - Friday
Routinely Reported: 1 - 3 days
Result: Interpretive report
Specimen Requirements: Tissue must be fixed in 10% formalin

For fixative and more information, contact the UF PathLabs Client Services Department at (888) 375-LABS (5227).

Storage/Transport Temperature: Submit specimens according to Biological Substance, Category B, shipping guidelines.

Unacceptable Conditions:
- Frozen specimens
- Specimens not in appropriate fixative

Stability (collection to initiation of testing):
- Ambient: Indefinitely
- Refrigerated: Indefinitely
- Frozen: Unacceptable

CPT Code(s): 88302, 88304, 88305, 88307 or 88309, depending on the case complexity, 88312 and 88313 if special stains are used, 88342 if immunoperoxidase stains are utilized
Renal Pathology

Methodology: Microscopic exam
Frequency Performed: Monday - Friday
Routinely Reported: 1 - 3 days
Result: Interpretive report
Use: The renal biopsy technique has greatly enhanced our understanding of the pathology, pathogenic mechanisms and classification of renal diseases. It represents a valuable procedure to diagnose renal disease, assess the prognosis, aid in the selection of a specific therapeutic approach and monitor disease progression. The technique is useful in the evaluation of diseases that affect both native and allograft kidneys. To obtain the maximum amount of information from a renal biopsy specimen, a combination of light, immunofluorescence and electron microscopy are utilized. Since these different forms of microscopy require different methods of fixation and processing, the renal biopsy core fragment is usually divided into three parts; however, depending on the length of the biopsy core or the suspected disease process, the method of dividing the biopsy core may be modified.

Specimen Requirements:
- Tissue in buffered formalin fixative for light microscopy, glutaraldehyde for electron microscopy and Michel’s media for immunofluorescence
- Pre-prepared slides
- Paraffin blocks
- Refer to Appendix I (Renal Pathology Specimen Preparation and Shipping Instructions) in this directory for detailed instructions on how to divide specimens for light, immunofluorescence and electron microscopy.

To obtain a renal biopsy kit (#0104) and detailed collection instructions, contact UF PathLabs Client Services Department at (888) 375-LABS (5227).

Storage/Transport Temperature: Ship collected specimens in kits at 20° - 25° C. Submit a clinical history and preliminary report if applicable.
Unacceptable Conditions:
- Frozen specimens
- Specimens not in appropriate fixative
- Specimens greater than 72 hours old

Stability (collection to initiation of testing):
- Ambient: 72 hours
- Refrigerated: 72 hours
- Frozen: Unacceptable

CPT Code(s): 88305 Level IV surgical pathology (and/or), 88346 immunofluorescence, each antibody (and/or), 88348 electron microscopy
Steroidal Autoantibody Panel (Adrenocortical/Ovarian/Testicular/Placental Autoantibodies)

**Methodology:** Indirect immunofluorescence

**Frequency Performed:** Monday - Friday

**Routinely Reported:** 1 - 7 business days

**Use:**
- **Diagnosis of Autoimmune Gonadal Failure:** The presence of ovarian, Leydig cell testicular and/or placental autoantibodies in women of reproductive age with gonadal failure or in men with gonadal failure indicates that the gonadal failure is of autoimmune origin.

- **Prediction of Autoimmune Gonadal Failure:** The detection of ovarian, Leydig cell testicular and/or placental autoantibodies in women of reproductive age or men places the subject at increased risk for the development of autoimmune gonadal failure.

**Specimen Requirements:**
- Collect blood in a 1-5 mL serum separator tube. Centrifuge, separate and transfer the serum to a plastic vial. Ship specimens with a frozen cold pack for overnight delivery.

**Stability (collection to shipping of the sample):**
- **Ambient:** 24 hours
- **Refrigerated:** 24 hours
- **Frozen:** 1 year (Avoid repeated freeze/thaw cycles.)

**Reference Value:** Negative

**CPT Code(s):** 88347 x 4
Surgical Pathology

Methodology: Microscopic exam
Frequency Performed: Monday - Friday
Routinely Reported: 1 - 3 days
Result: Interpretive report
Specimen Requirements: Tissue must be fixed in 10% formalin

For fixative and more information, contact the UF PathLabs Client Services Department at (888) 375-LABS (5227).

Storage/Transport Temperature: Submit specimens according to Biological Substance, Category B, shipping guidelines.

Unacceptable Conditions:
• Frozen specimens
• Specimens not in appropriate fixative

Stability (collection to initiation of testing):
• Ambient: Indefinitely
• Refrigerated: Indefinitely
• Frozen: Unacceptable

CPT Code(s): 88302, 88304, 88305, 88307 or 88309, depending on the case complexity, 88312 and 88313 if special stains are used, 88342 if immunoperoxidase stains are utilized
**T-Cell Clonality (Gamma-Variable Gene)**

**Methodology:** Polymerase chain reaction/DNA fragment analysis

**Frequency Performed:** Monday - Friday

**Routinely Reported:** 5 - 10 business days

**Use:** This test is used to demonstrate clonality in T-cell lymphomas/leukemias.

**Specimen Requirements:**
- Paraffin-embedded tissue; send one tissue block or 4 unstained slides. Ship specimens at 20° - 25° C. Tissue fixed in formalin substitute and/or that does not contain lymphocytes is unacceptable.
- Blood or bone marrow in EDTA or ACD tube; one 3 mL blood or 1 mL bone marrow shipped at 4° C is accepted. Severely hemolyzed whole blood or clotted/frozen blood/bone marrow specimens are not accepted.
- Tissue with a minimum size of 5 mm cube, shipped frozen or on ice in RPMI 1640, is accepted.
- Cell pellets with at least 1 million cells, shipped at 4° C, are acceptable.

**Reference Values:** Negative

**Interpretation Data:**

<table>
<thead>
<tr>
<th>T-Cell Clonality</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Positive:</strong> A monoclonal T-cell population is detected.</td>
</tr>
<tr>
<td><strong>Negative:</strong> A monoclonal T-cell population is not detected.</td>
</tr>
<tr>
<td><strong>Indeterminate:</strong> Refer to interpretation notes.</td>
</tr>
<tr>
<td><strong>QNS:</strong> There is not sufficient material to perform the test.</td>
</tr>
</tbody>
</table>

TCR gene rearrangements are detected by using a multiplex PCR master mix, which contains 4 primers from the conserved V region that are clustered into 4 families (I-IV) and 4 primers from the J region. The primers cross the hyper variable antigen binding CDR region (Clonality is determined by analyzing bands on gel electrophoresis.).
A false negative may be due to:
1. The clonal population being under the test limitation.
2. Poor sample quantity (an inadequate amount of tissue).
3. Poor sample quality (such as degraded DNA specimen).

CPT Code(s): 83907 Lysis, 83891 DNA extraction, 83898 x 8 Amplification, 83894 x 2 gel electrophoresis, 83912 Report with interpretation
**Testicular (Leydig Cell) Autoantibodies**

**Methodology:** Indirect immunofluorescence

**Frequency Performed:** Weekly

**Routinely Reported:** 1 - 7 business days

**Use:**
- **Diagnosis of Autoimmune Gonadal Failure:** The presence of ovarian, Leydig cell testicular and/or placental autoantibodies in women of reproductive age with gonadal failure or in men with gonadal failure indicates that the gonadal failure is of autoimmune origin.

- **Prediction of Autoimmune Gonadal Failure:** The detection of ovarian, Leydig cell testicular and/or placental autoantibodies in women of reproductive age or men places the subject at increased risk for the development of autoimmune gonadal failure.

**Specimen Requirements:**
Collect blood in a 1-5 mL serum separator tube. Centrifuge, separate and transfer the serum to a plastic vial. Ship specimens with a frozen cold pack for overnight delivery.

**Stability (collection to shipping of the sample):**
- **Ambient:** 24 hours
- **Refrigerated:** 24 hours
- **Frozen:** 1 year (Avoid repeated freeze/thaw cycles.)

**Reference Values:** Negative

**CPT Code(s):** 88347
Methodology: Radioimmunoassay
Frequency Performed: Weekly
Routinely Reported: 1 - 7 business days

Use:
- **Diagnosis of Autoimmune Thyroid Disease:** The detection of either thyroperoxidase autoantibodies (TPOA) or thyroglobulin autoantibodies (TGA) in the presence of biochemically defined hypothyroidism or euthyroid goiter identifies an autoimmune etiology as the cause of the subject’s thyroid disease.

- **Prediction of Autoimmune Thyroid Disease:** The detection of TPOA and/or TGA in an asymptomatic individual indicates an increased risk for the subsequent development of autoimmune thyroid disease that can produce goiter and/or either hypothyroidism (Hashimoto thyroid or atrophic thyroiditis) or hyperthyroidism (Graves’ disease).

Specimen Requirements:
- Collect blood in a 1-5 mL serum separator tube. Centrifuge, separate and transfer the serum to a plastic vial. Ship specimens with a frozen cold pack for overnight delivery.

Stability (collection to shipping of the sample):
- **Ambient:** 24 hours
- **Refrigerated:** 24 hours
- **Frozen:** 1 year (Avoid repeated freeze/thaw cycles.)

Reference Values: Negative
CPT Code(s): 86800
Thyroid Peroxidase Autoantibodies (TPOA)

**Methodology:** Radioimmunoassay

**Frequency Performed:** Weekly

**Routinely Reported:** 1 - 5 business days

**Use:**
- **Diagnosis of Autoimmune Thyroid Disease:** The detection of either thyroid peroxidase autoantibodies (TPOA) or thyroglobulin autoantibodies (TGA) in the presence of biochemically defined hypothyroidism or euthyroid goiter identifies an autoimmune etiology as the cause of the subject’s thyroid disease.

- **Prediction of Autoimmune Thyroid Disease:** The detection of TPOA and/or TGA in an asymptomatic individual indicates an increased risk for the subsequent development autoimmune thyroid disease that can produce goiter and/or either hypothyroidism (Hashimoto thyroid or atrophic thyroiditis) or hyperthyroidism (Graves’ disease).

**Specimen Requirements:**
Collect blood in a 1- 5 mL serum separator tube. Centrifuge, separate and transfer the serum to a plastic vial. Ship specimens with a frozen cold pack for overnight delivery.

**Stability (collection to shipping of the sample):**
- **Ambient:** 24 hours
- **Refrigerated:** 24 hours
- **Frozen:** 1 year (Avoid repeated freeze/thaw cycles.)

**Reference Values:** Negative

**CPT Code(s):** 86376
Methodology: Fluorescence in-situ hybridization (FISH)

Frequency Performed: Weekly

Routinely Reported: Within 7 days

Use: The UroVysion® Bladder Cancer Kit is an FDA-approved test that is designed to detect aneuploidy for chromosomes 3, 7 and 17, as well as the loss of the 9p21 locus via fluorescence in situ hybridization (FISH), in urine specimens.

Results from the UroVysion® Kit are intended:

As an aid for the initial diagnosis of bladder carcinoma in patients with hematuria (in conjunction with current standard diagnostic procedures such as urinary cytology).

As subsequent monitoring for tumor recurrence in patients who have been previously diagnosed with bladder cancer.

Specimen Requirements: At least 35 mL of voided urine specimens or bladder wash

Specimen containers with preservative are available upon request. Alternatively, specimen can be preserved by mixing 2:1 with PreservCyt®. If urine is not shipped immediately after collection, refrigerate immediately and ship via overnight courier within 24 hours. Ship on ice packs. Specimens need to be stored and shipped at 2° - 8° C. In order to obtain the greatest yield of diagnostic material, a second-morning, clean catch voided urine specimen should be collected.

Unacceptable Conditions:

- Urine volume less than 35 mL
- Specimens not fixed with a UF PathLabs-provided Stabilur® tablet or in Saccomanno or PreservCyt® fixative
- Specimens stored or shipped at temperatures at or above 25° C (room temperature)
- Specimens more than 72 hours old

Stability (collection to initiation of testing):

- Ambient: 12 hours
- Refrigerated: Specimens greater than 24 hours old; specimens greater than 72 hours old (with a Stabilur® tablet)
- Frozen: Unacceptable

Reference Values: Negative (interpretative report provided)
Normal signal pattern (2 signals per probe)

CPT Code(s): 88120 (manual); 88121 (computer-assisted)
Zap-70/CD38 in CLL

**Methodology:** Flow cytometry

**Frequency Performed:** Monday - Saturday

**Routinely Reported:** 5 days

**Result:** Interpretive report

**Use:** Zap-70 and CD38 expression are prognostic markers in CLL.

**Specimen Requirements:** Peripheral blood only

The Zap-70 assay for chronic lymphocytic leukemia/small lymphocytic lymphoma requires fresh peripheral blood specimens (less than 24 hours old after collection) for optimal results.

Collect 5 mL in an EDTA (purple-top) tube received within 24 hours of collection; performed on peripheral blood only.

For more information, contact the UF PathLabs Client Services Department at (888) 375-LABS (5227).

**Storage/Transport Temperature:** Ship at 20° - 25° C. Submit specimens according to Biological Substance, Category B, shipping guidelines.

**Unacceptable Conditions:**
- Bone marrow
- Frozen specimens
Specimens greater than 24 hours old

**Stability (collection to initiation of testing):**
- Ambient: Unacceptable
- Refrigerated: 24 hours
- Frozen: Unacceptable

**Remarks:** This test utilizes the markers CD19/intra-cytoplasmic ZAP-70/CD5 and CD38

**CPT Code(s):** 88184, 88185, 88186, 88187, 88188, 88189
Appendix
A. FISH Panels

For each required FISH analysis, select the entire panel or customize your own panel. If the probe is unspecified, call UF PathLabs at (800) 375-LABS (5227) for availability.

<table>
<thead>
<tr>
<th>ALL Panel (all listed)</th>
<th>MDS /MPD Panel (after negative cytogenetics; all listed)</th>
</tr>
</thead>
<tbody>
<tr>
<td>• t(12;21) ETV6/RUNX1</td>
<td>• t(9;22) BCR/ABL1</td>
</tr>
<tr>
<td>• 4/10/17 aneuploidy</td>
<td>• 11q23 (MLL)</td>
</tr>
<tr>
<td>• 5q</td>
<td>• 7q31</td>
</tr>
<tr>
<td>• 8 cen</td>
<td>• 20q12</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>AML Panel (all listed)</th>
<th>Lymphomas (select from list below)</th>
</tr>
</thead>
<tbody>
<tr>
<td>• t(15;17)</td>
<td>• C-MYC</td>
</tr>
<tr>
<td>• Inv 16 CBFB</td>
<td>• IGH/BCL2</td>
</tr>
<tr>
<td>• t(8;21) ETO/AML1</td>
<td>• t(11;14)Cyclin D1</td>
</tr>
<tr>
<td>• 8 cen</td>
<td>• BCL6</td>
</tr>
<tr>
<td>• MLL</td>
<td>• ALK</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>CLL Panel (all listed)</th>
<th>Plasma Cell Myeloma Panel (all listed)</th>
</tr>
</thead>
<tbody>
<tr>
<td>• del 13q</td>
<td>• del(13q)</td>
</tr>
<tr>
<td>• trisomy 12</td>
<td>• p53</td>
</tr>
<tr>
<td>• del 11q22 ATM</td>
<td>• IGH/CCND1 [t(11;14)]</td>
</tr>
<tr>
<td>• del 17 (p53)</td>
<td>• IGH/FGFR3 [t(4;14)]</td>
</tr>
<tr>
<td>• IGH break-apart (14q32)</td>
<td>• IGH/MAF [t(14;16)]</td>
</tr>
</tbody>
</table>
### B. Formalin-Fixed Paraffin-Embedded Tissue FISH Tests

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<th>Soft-Tissue Sarcomas</th>
<th>Interphase FISH Test:</th>
<th>Useful for Detecting:</th>
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<tr>
<td></td>
<td>DDIT3 (12q13.3)</td>
<td>Myxoid/Round-cell liposarcoma</td>
</tr>
<tr>
<td></td>
<td>SS18 (SYT) (18q11.2)</td>
<td>Synovial sarcoma</td>
</tr>
<tr>
<td></td>
<td>FUS (16p11.2)</td>
<td>Myxoid Liposarcoma, Low-grade fibromyxoid sarcoma</td>
</tr>
<tr>
<td></td>
<td>MDM2 (12q15)</td>
<td>Amplification in well-differentiated liposarcomas</td>
</tr>
<tr>
<td></td>
<td>FOXO1 (13q14.11)</td>
<td>Alveolar rhabdomyosarcoma</td>
</tr>
<tr>
<td></td>
<td>EWSR1 (22q12)</td>
<td>Ewing’s sarcoma</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Lung Carcinomas (coming soon; contact UF PathLabs for availability.)</th>
<th>Interphase FISH Test:</th>
<th>Useful for Detecting:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>ALK</td>
<td>ALK gene rearrangement in lung carcinomas</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Lymphomas (coming soon; contact UF PathLabs for availability.)</th>
<th>Interphase FISH Test:</th>
<th>Useful for Detecting:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>C-myc</td>
<td>Burkitt or aggressive lymphomas</td>
</tr>
<tr>
<td></td>
<td>BCL2</td>
<td>Follicular lymphomas</td>
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<tr>
<td></td>
<td>CCND1</td>
<td>Mantle-cell lymphomas</td>
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<tbody>
<tr>
<td>UF PathLabs offers the following microsatellite instability tests by immunohistochemistry:</td>
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<td>• MLH-1</td>
</tr>
<tr>
<td>• MSH-2</td>
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<tr>
<td>Molecular microsatellite instability (MSI) testing</td>
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<tr>
<td>• KRAS mutation analysis</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Lung Carcinoma</th>
</tr>
</thead>
<tbody>
<tr>
<td>• ALK FISH</td>
</tr>
<tr>
<td>• BRAF mutation analysis</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Melanoma</th>
</tr>
</thead>
<tbody>
<tr>
<td>• BRAF mutation analysis</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Leukemias/Lymphoma</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Cytogenetics</td>
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<tr>
<td>• FISH, including panels for CLL/SLL, lymphoma, B-ALL, AML, MDS and plasma-cell myeloma</td>
</tr>
</tbody>
</table>
### D. Immunohistochemistry Test Menu (Listed Alphabetically)

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<th>Test Name</th>
<th>Alternate Name</th>
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</thead>
<tbody>
<tr>
<td>Alpha-1-anti chymotrypsin (A-1-AT)</td>
<td>Alpha-1-anti trypsin (A-1-AT)</td>
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<tr>
<td>ACTH</td>
<td>Adenovirus</td>
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<tr>
<td>Alpha-fetoprotein (AFP)</td>
<td>ALK-1</td>
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<tr>
<td>Amyloid A</td>
<td>Amyloid precursor protein (APP)</td>
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<tr>
<td>BA047 (IN11)</td>
<td>B72.3</td>
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<tr>
<td>Beta-catenin</td>
<td>BCL2</td>
</tr>
<tr>
<td>BCL6</td>
<td>Ber-EP4 (EpCam)</td>
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<tr>
<td>BK Virus (CA22)</td>
<td>BCL1</td>
</tr>
<tr>
<td>Cadherin</td>
<td>BCL6</td>
</tr>
<tr>
<td>Calponin</td>
<td>CD1a</td>
</tr>
<tr>
<td>Calretinin</td>
<td>CD3</td>
</tr>
<tr>
<td>Catepsin</td>
<td>CD4</td>
</tr>
<tr>
<td>CD5</td>
<td>CD5</td>
</tr>
<tr>
<td>CD7</td>
<td>CD8</td>
</tr>
<tr>
<td>CD80</td>
<td>CD10</td>
</tr>
<tr>
<td>CD15 (Leu-M1)</td>
<td>CD15</td>
</tr>
<tr>
<td>CD20</td>
<td>CD21</td>
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<tr>
<td>CD23</td>
<td>CD30</td>
</tr>
<tr>
<td>CD34 - Stem cell</td>
<td>CD34</td>
</tr>
<tr>
<td>CD34 - Endothelial</td>
<td>CD43</td>
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<tr>
<td>CD44</td>
<td>CD44 (LCA, CLA)</td>
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<tr>
<td>CD45RO (UCHL1)</td>
<td>CD45RO</td>
</tr>
<tr>
<td>CD56 (NCAM)</td>
<td>CD56</td>
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<tr>
<td>CD57 (Leu7)</td>
<td>CD57</td>
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<tr>
<td>CD61</td>
<td>CD68 (KPI)</td>
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<td>CD71 (Erythroid)</td>
<td>CD71</td>
</tr>
<tr>
<td>CD79a</td>
<td>CD99 (Ewings)</td>
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<tr>
<td>CD123</td>
<td>CD138 (Syndecan-1)</td>
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<tr>
<td>Cyclin Dep Kinase-4 (CDK4)</td>
<td>CEA-polyclonal</td>
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<tr>
<td>CEA-monoclonal</td>
<td>CDX2</td>
</tr>
<tr>
<td>CDX2</td>
<td>Chromogranin</td>
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<tr>
<td>Cytokeratin 34BE12</td>
<td>Cytokeratin AE1/3</td>
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<tr>
<td>Cytokeratin CAM 5.2</td>
<td>Cytokeratin 5/6 (CK 5/6)</td>
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<tr>
<td>Cytokeratin 17</td>
<td>Cytokeratin 19</td>
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<td>Cytokeratin 20</td>
<td>Cytokeratin MAK-6</td>
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<tr>
<td>Cytokeratin 5/3 (CK903)</td>
<td>D2-40</td>
</tr>
<tr>
<td>D2-40</td>
<td>DOG-1 (GIST)</td>
</tr>
<tr>
<td>Desmin</td>
<td>E-cadherin</td>
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<tr>
<td>Epitope (EBV-LMP)</td>
<td>Epstein Barr virus in-situ (EBV-LMP)</td>
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<tr>
<td>Estrogen receptor (ER)</td>
<td>Epithelial membrane antigen (EMA)</td>
</tr>
<tr>
<td>Factor 13a (F XIIIa)</td>
<td>Estrogen receptor (ER)</td>
</tr>
<tr>
<td>FSH</td>
<td>Factor 13a (F XIIIa)</td>
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<tr>
<td>Gaelectin-3</td>
<td>Galectin-3</td>
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<tr>
<td>Gastrin</td>
<td>Glycogen A</td>
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<tr>
<td>Gross cystic disease fluid protein (GCDFP)</td>
<td>Glycogen A</td>
</tr>
<tr>
<td>GFAP</td>
<td>Glypican-3</td>
</tr>
<tr>
<td>Glucagon</td>
<td>Growth hormone (GH)</td>
</tr>
<tr>
<td>GLUT-1</td>
<td>H. pylori</td>
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<tr>
<td>Glutamine synthetase (Glu)</td>
<td>Herp B core antigen (HB core)</td>
</tr>
<tr>
<td>Glycotherin</td>
<td>Hep B surface antigen (HB surf)</td>
</tr>
<tr>
<td>HMBE-1</td>
<td>HMB35 Muscle actin</td>
</tr>
<tr>
<td>HCG</td>
<td>Human herpes virus 8 (HHV8)</td>
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<tr>
<td>Hemoglobin A</td>
<td>Human Pap Virus, high risk, in-situ (HPV-HR)</td>
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<tr>
<td>HepPar 1</td>
<td>HMB45</td>
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<tr>
<td>HER2/Neu (IHC)</td>
<td>Human placental lactogen (HPL)</td>
</tr>
<tr>
<td>Herpes virus I &amp; II (HSV)</td>
<td>IDH-1</td>
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<tr>
<td>IgA</td>
<td>IgG</td>
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<tr>
<td>IgM</td>
<td>Inhibin</td>
</tr>
<tr>
<td>Insulin</td>
<td>JC Virus</td>
</tr>
<tr>
<td>Kappa (IHC)</td>
<td>Kappa (IHC)</td>
</tr>
<tr>
<td>Lambda (IHC)</td>
<td>Lambda (IHC)</td>
</tr>
<tr>
<td>Ki-67 (MIB1)</td>
<td>Ki-67 (MIB1)</td>
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<tr>
<td>LH</td>
<td>Lysozyme</td>
</tr>
<tr>
<td>Mammaglobin</td>
<td>MDM2</td>
</tr>
<tr>
<td>Melan A</td>
<td>Melan A</td>
</tr>
<tr>
<td>MOC-31</td>
<td>MOC-31</td>
</tr>
<tr>
<td>MSH-2</td>
<td>MSH-2</td>
</tr>
<tr>
<td>MSH-6</td>
<td>MSH-6</td>
</tr>
<tr>
<td>MUM-1</td>
<td>MUM-1</td>
</tr>
<tr>
<td>Myeloperoxidase</td>
<td>Myeloperoxidase (MPO)</td>
</tr>
<tr>
<td>Napsin</td>
<td>MITF</td>
</tr>
<tr>
<td>Tau</td>
<td>Myogenin</td>
</tr>
<tr>
<td>TFE-3</td>
<td>Neu-N</td>
</tr>
<tr>
<td>Succinate Dehydrogenase B (SDHB)</td>
<td>Neurofilament</td>
</tr>
<tr>
<td>S-100</td>
<td>Neuron-specific enolase (NSE)</td>
</tr>
<tr>
<td>S-100</td>
<td>OCT-2</td>
</tr>
<tr>
<td>S-100</td>
<td>OCT-3/4</td>
</tr>
<tr>
<td>SDHB</td>
<td>p16ink</td>
</tr>
<tr>
<td>SDHB</td>
<td>p504s (AMACR)</td>
</tr>
<tr>
<td>SDHB</td>
<td>p53</td>
</tr>
<tr>
<td>SDHB</td>
<td>p63</td>
</tr>
<tr>
<td>SDHB</td>
<td>pH3 (mitotic figures)</td>
</tr>
<tr>
<td>SDHB</td>
<td>Parainfluenza virus</td>
</tr>
<tr>
<td>SDHB</td>
<td>Parvovirus B19</td>
</tr>
<tr>
<td>SDHB</td>
<td>PAX-5</td>
</tr>
<tr>
<td>SDHB</td>
<td>PAX-8</td>
</tr>
<tr>
<td>SDHB</td>
<td>PDGF-beta</td>
</tr>
<tr>
<td>SDHB</td>
<td>PE 10 (Surfactant A, APO A)</td>
</tr>
<tr>
<td>SDHB</td>
<td>Perforin</td>
</tr>
<tr>
<td>SDHB</td>
<td>Placental Alk Phos (PLAP)</td>
</tr>
<tr>
<td>SDHB</td>
<td>PMS-2</td>
</tr>
<tr>
<td>SDHB</td>
<td>Progesterone receptor (PR)</td>
</tr>
<tr>
<td>SDHB</td>
<td>Prolactin</td>
</tr>
<tr>
<td>SDHB</td>
<td>PSA</td>
</tr>
<tr>
<td>SDHB</td>
<td>PSAP</td>
</tr>
<tr>
<td>SDHB</td>
<td>Parathyroid hormone (PTH)</td>
</tr>
<tr>
<td>SDHB</td>
<td>Prostate triple stain (p63 + 34BE12 + p504s)</td>
</tr>
<tr>
<td>SDHB</td>
<td>Renal cell carcinoma antigen</td>
</tr>
<tr>
<td>SDHB</td>
<td>Respiratory syncytial virus (RSV)</td>
</tr>
<tr>
<td>SDHB</td>
<td>S-100</td>
</tr>
<tr>
<td>SDHB</td>
<td>SALL4</td>
</tr>
<tr>
<td>SDHB</td>
<td>Smoothelin</td>
</tr>
<tr>
<td>SDHB</td>
<td>SMootherlin</td>
</tr>
<tr>
<td>SDHB</td>
<td>Smooth muscle myosin heavy chain (SMMHC)</td>
</tr>
<tr>
<td>SDHB</td>
<td>Surfactant A</td>
</tr>
<tr>
<td>SDHB</td>
<td>Surfactant B</td>
</tr>
<tr>
<td>SDHB</td>
<td>Synaptophysin</td>
</tr>
<tr>
<td>SDHB</td>
<td>Transthyretin</td>
</tr>
<tr>
<td>SDHB</td>
<td>Mast cell tryptase</td>
</tr>
<tr>
<td>SDHB</td>
<td>Trypsin</td>
</tr>
<tr>
<td>SDHB</td>
<td>TSH</td>
</tr>
<tr>
<td>SDHB</td>
<td>TTF-1</td>
</tr>
<tr>
<td>SDHB</td>
<td>Tubulin</td>
</tr>
<tr>
<td>SDHB</td>
<td>Ubiquitin</td>
</tr>
<tr>
<td>SDHB</td>
<td>Uroplakin</td>
</tr>
<tr>
<td>SDHB</td>
<td>Villin</td>
</tr>
<tr>
<td>SDHB</td>
<td>Varicella Zoster virus (VZV)</td>
</tr>
<tr>
<td>SDHB</td>
<td>WT-1 (Wilms' tumor 1)</td>
</tr>
</tbody>
</table>

Available Soon
(Contact UF PathLabs for availability.)

- Napsin
- TFE-3
- Succinate Dehydrogenase B (SDHB)
- Langerin (CD207)

Toll-Free: (888) 375-LABS (5227) | Fax: (352) 265-9901 | pathlabs.ufl.edu
## E. Immunohistochemistry Test Menu (Listed by Specialty)

<table>
<thead>
<tr>
<th>Specialty</th>
<th>Test Menu</th>
</tr>
</thead>
</table>
| **Breast** | ER (Quantitative with image analysis)  
PR (Quantitative with image analysis)  
HER2/Neu (IHC with reflex to FISH)  
Calponin  
E-cadherin  
Gross cystic disease fluid protein (GCDFP)  
Mammaglobin  
p63  
Smooth muscle myosin heavy chain (SMMHC) |
| **Hematopathology** | BCL2  
BCL6  
CD1a  
CD3  
CD4  
CD5  
CD7  
CD8  
CD10  
CD15 (Leu-M1)  
CD20  
CD21  
CD23  
CD30  
CD34  
CD45 (LCA, CLA)  
CD45RO (UCHL1)  
CD56 (NCAM)  
CD71 (Erythroid)  
CD99 (Ewing’s sarcoma)  
CD123  
CD138 ( Syndecan-1)  
C-kit (CD117)  
IgA  
IgG  
IgM  
Epstein Barr virus LMP (EBV-LMP)  
Epstein Barr virus in-situ (EBER)  
Factor 13a (XIIIa)  
Glycophorin A  
Hemoglobin A  
Kappa (IHC)  
Lambda (IHC)  
Kappa, in-situ (K-ISH)  
Lambda, in-situ (L-ISH)  
Lysozyme  
Mast cell tryptase  
MUM-1  
OCT-2  
PAX-5  
S-100 |
| **Infectious** | Adenovirus  
BK Virus  
Cytomegalovirus (CMV)  
Epstein Barr virus LMP (EBV-LMP)  
Epstein Barr virus in-situ (EBER)  
H. pylori  
Herpes virus I & II (HSV)  
Human herpes virus 8 (HHV8)  
Human Pap Virus, high risk, in-situ (HPV-HR)  
JC Virus  
p16ink (Marker of HPV)  
Parainfluenza virus  
Parvovirus B19  
Toxoplasma  
Respiratory syncytial virus (RSV)  
Varicella Zoster virus (VZV) |
| **Gastrointestinal/Liver** | Beta-catenin  
CEA-monoconal  
CEA-polyclonal  
CDX2  
C-kit (CD117)  
DOG-1 (GIST)  
Glutamin synthetase (Liver marker)  
Glypican-3 (Liver marker)  
HepPar 1  
Hep B core antigen (HB core)  
Hep B surface antigen (HB surf)  
Microsatellite instability:  
• MLH-1  
• MSH-2  
• MSH-6  
• PMS-2  
Villin |
| **Neuropathology** | Pituitary:  
• ACTH  
• FSH  
• GH  
• LH  
• Prolactin  
• TSH  
BAF-47 (INI-1)  
Chromogranin  
GFAP  
IDH-1  
Neurofilament  
Neu-N  
Tau  
Ubiquitin  
Synaptophysin  
Ki-67  
pHH3 (mitotic figures meningioma, gliomas) |
| **Genitourinary** | CD44 (bladder reactive vs. CIS)  
Cytokeratin 20 (bladder reactive vs. CIS)  
p53 (bladder reactive vs. CIS)  
p63  
Prostate triple stain (p63 + 34BE12 + p504s)  
PAX-8  
Renal cell carcinoma antigen  
Smoothelin (muscularis propria)  
Uroplakin |
| **Neuropathology** | CD30  
C-kit (CD117)  
D2-40  
Glypican-3  
Human placental lactogen (HPL)  
OCT 3/4  
Placental Alk Phos (PLAP)  
SALL4 |
| **Germ cell tumor** | Alpha-fetoprotein (AFP)  
Epstein Barr virus LMP (EBV-LMP)  
Epstein Barr virus in-situ (EBER)  
Factor 13a (XIIIa)  
Glycophorin A  
Hemoglobin A  
Kappa (IHC)  
Lambda (IHC)  
Kappa, in-situ (K-ISH)  
Lambda, in-situ (L-ISH)  
Lysozyme  
Mast cell tryptase  
MUM-1  
OCT-2  
PAX-5  
S-100 |
| **Neuropathology** | CD30  
C-kit (CD117)  
D2-40  
Glypican-3  
Human placental lactogen (HPL)  
OCT 3/4  
Placental Alk Phos (PLAP)  
SALL4 |
| **Hematopathology** | BCL2  
BCL6  
CD1a  
CD3  
CD4  
CD5  
CD7  
CD8  
CD10  
CD15 (Leu-M1)  
CD20  
CD21  
CD23  
CD30  
CD34  
CD45 (LCA, CLA)  
CD45RO (UCHL1)  
CD56 (NCAM)  
CD71 (Erythroid)  
CD99 (Ewing’s sarcoma)  
CD123  
CD138 ( Syndecan-1)  
C-kit (CD117)  
IgA  
IgG  
IgM  
Epstein Barr virus LMP (EBV-LMP)  
Epstein Barr virus in-situ (EBER)  
Factor 13a (XIIIa)  
Glycophorin A  
Hemoglobin A  
Kappa (IHC)  
Lambda (IHC)  
Kappa, in-situ (K-ISH)  
Lambda, in-situ (L-ISH)  
Lysozyme  
Mast cell tryptase  
MUM-1  
OCT-2  
PAX-5  
S-100 |
| **Infectious** | Adenovirus  
BK Virus  
Cytomegalovirus (CMV)  
Epstein Barr virus LMP (EBV-LMP)  
Epstein Barr virus in-situ (EBER)  
H. pylori  
Herpes virus I & II (HSV)  
Human herpes virus 8 (HHV8)  
Human Pap Virus, high risk, in-situ (HPV-HR)  
JC Virus  
p16ink (Marker of HPV)  
Parainfluenza virus  
Parvovirus B19  
Toxoplasma  
Respiratory syncytial virus (RSV)  
Varicella Zoster virus (VZV) |
| **Neuropathology** | Pituitary:  
• ACTH  
• FSH  
• GH  
• LH  
• Prolactin  
• TSH  
BAF-47 (INI-1)  
Chromogranin  
GFAP  
IDH-1  
Neurofilament  
Neu-N  
Tau  
Ubiquitin  
Synaptophysin  
Ki-67  
pHH3 (mitotic figures meningioma, gliomas) |
| **Gastrointestinal/Liver** | Beta-catenin  
CEA-monoconal  
CEA-polyclonal  
CDX2  
C-kit (CD117)  
DOG-1 (GIST)  
Glutamin synthetase (Liver marker)  
Glypican-3 (Liver marker)  
HepPar 1  
Hep B core antigen (HB core)  
Hep B surface antigen (HB surf)  
Microsatellite instability:  
• MLH-1  
• MSH-2  
• MSH-6  
• PMS-2  
Villin |
| **Neuropathology** | CD30  
C-kit (CD117)  
D2-40  
Glypican-3  
Human placental lactogen (HPL)  
OCT 3/4  
Placental Alk Phos (PLAP)  
SALL4 |
| **Germ cell tumor** | Alpha-fetoprotein (AFP)  
Epstein Barr virus LMP (EBV-LMP)  
Epstein Barr virus in-situ (EBER)  
Factor 13a (XIIIa)  
Glycophorin A  
Hemoglobin A  
Kappa (IHC)  
Lambda (IHC)  
Kappa, in-situ (K-ISH)  
Lambda, in-situ (L-ISH)  
Lysozyme  
Mast cell tryptase  
MUM-1  
OCT-2  
PAX-5  
S-100 |
| **Neuropathology** | Pituitary:  
• ACTH  
• FSH  
• GH  
• LH  
• Prolactin  
• TSH  
BAF-47 (INI-1)  
Chromogranin  
GFAP  
IDH-1  
Neurofilament  
Neu-N  
Tau  
Ubiquitin  
Synaptophysin  
Ki-67  
pHH3 (mitotic figures meningioma, gliomas) |
| **Infectious** | Adenovirus  
BK Virus  
Cytomegalovirus (CMV)  
Epstein Barr virus LMP (EBV-LMP)  
Epstein Barr virus in-situ (EBER)  
H. pylori  
Herpes virus I & II (HSV)  
Human herpes virus 8 (HHV8)  
Human Pap Virus, high risk, in-situ (HPV-HR)  
JC Virus  
p16ink (Marker of HPV)  
Parainfluenza virus  
Parvovirus B19  
Toxoplasma  
Respiratory syncytial virus (RSV)  
Varicella Zoster virus (VZV) |
| **Neuropathology** | Pituitary:  
• ACTH  
• FSH  
• GH  
• LH  
• Prolactin  
• TSH  
BAF-47 (INI-1)  
Chromogranin  
GFAP  
IDH-1  
Neurofilament  
Neu-N  
Tau  
Ubiquitin  
Synaptophysin  
Ki-67  
pHH3 (mitotic figures meningioma, gliomas) |
### F. Hematopathology Specimen Requirement Chart

<table>
<thead>
<tr>
<th></th>
<th>Flow Cytometry</th>
<th>Polymerase Chain Reaction</th>
<th>Cytogenetics/FISH</th>
<th>Storage</th>
</tr>
</thead>
</table>
| **Peripheral Blood** | Required Specimen  
• 4 mL and 1 smear from specimen  
• Complete blood count results  
Preferred  
• Purple-top tube (EDTA) | Required Specimen  
• 3 - 5 mL  
Preferred  
• Purple-top tube (EDTA)  
— OR —  
• Yellow-top tube (acid citrate dextrose) | • Green-top tube (sodium heparin)  
• Adults:  
5 - 7 mL  
• Infants:  
1 - 2 mL  
— AND —  
• White blood cell count and manual differential  
• Immature cells must be present. | • Room temperature  
• Transport specimens with a frozen cold pack.  
(DO NOT FREEZE SPECIMENS.) |
| **Bone Marrow Aspirate** | Required Specimen  
• 4 mL and 1 smear from specimen  
• Complete blood count results  
Preferred  
• Purple-top tube (EDTA) | Required Specimen  
• 1 - 2 mL  
Preferred  
• Purple-top tube (EDTA)  
— OR —  
• Yellow-top tube (acid citrate dextrose) | • Green-top tube (sodium heparin)  
• 2 - 3 mL | • Room temperature  
• Transport specimens with a frozen cold pack.  
(DO NOT FREEZE SPECIMENS.) |
| **Fresh Bone Marrow Aspirate** | • Tissue transport medium | • Tissue transport medium | • Tissue transport medium | • Refrigerated  
• Transport specimens with a frozen cold pack.  
(DO NOT FREEZE SPECIMENS.)  
• Cytogenetics Only: Room temperature |
<table>
<thead>
<tr>
<th><strong>Materials Used</strong></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>• Cold pack (Thoroughly refrigerate the cold pack before use.)</td>
<td>• Two containers with fixative for bone marrow core biopsy and aspirate clot</td>
</tr>
<tr>
<td>• <strong>Purple-top tube (EDTA)</strong>: To collect peripheral blood or bone marrow aspirate for flow cytometry</td>
<td>• <strong>Green-top tube (sodium heparin)</strong>: To collect peripheral blood or bone marrow for cytogenetics</td>
</tr>
<tr>
<td>• Two plastic slide holders with five slides each for marrow/peripheral blood smears or touch preps; allow the slides to dry completely before placing them in the plastic holder.</td>
<td>• <strong>Tissue Transport Medium</strong>: For fresh (not fixed) marrow biopsies in cases of “dry taps.” (Store tissue transport medium in a refrigerator, and check the expiration date on the label before use.)</td>
</tr>
</tbody>
</table>

**Specimen Collection***

To add specimen, place tubes upright in holes located below tube slots. Ensure that each specimen container/slide is labeled with:

• The patient’s name;
• Type of specimen; and
• Collection date and time.

*Remember to complete a test requisition and add it to the test kit (Keep the back copy of the requisition for your records).*

**Packing Specimens for Shipping**

1. Secure the lids on all specimen containers, and insert them into the appropriate slots.
2. Place the foam liner on top of the specimens.
3. Position the plastic specimen bag with the outer pocket facing up.
4. Insert the foam kit with the specimens into the bag, and seal it.
5. Place the kit and requisition form(s) inside the box.
6. Place the cold pack inside the outer pocket of the box; the cold pack must not be in direct contact with the specimens.
7. Close the box securely.

**Transporting Specimens**

• If courier service is available, call for specimen pick-up.
• For overnight shipping:
  • Place a specimen transport kit inside a FedEx diagnostic specimen bag. Complete a Federal Express (FedEx) air bill and label it with “PRIORITY OVERNIGHT DELIVERY.”
  • If specimens are being shipped on Friday, label the shipping box with “SATURDAY DELIVERY.”
  • Secure the air bill to the outside of the FedEx bag, and contact FedEx for specimen pick-up by calling (800) 463-3339.
G. Microbiology Laboratory Guidelines

UF PathLabs’ Microbiology Laboratory
(Located at Shands Hospital at the University of Florida)

Hours: 24 hours a day / 7 days a week
Phone: (352) 265-0165
Fax: (352) 265-0204

Medical Director: Kenneth H. Rand, M.D.
Manager: Patricia Giglio
Office: (352) 265-0680, ext. 44875
Office: (352) 265-0165

University of Florida Pathology Laboratories’ Microbiology Laboratory offers microbiology, bacteriology and mycology testing available for outpatient medical facilities. The Microbiology Laboratory is located at Shands Hospital at UF and is directed by a Board-certified infectious disease physician, managed by a master’s-level supervisor and technical specialist, and staffed by medical technologists and laboratory technicians who are licensed by the state of Florida Board of Professional Regulations. Technical personnel staff the Microbiology Laboratory 24 hours a day, 7 days a week, and samples can be received at any time.

The Microbiology Laboratory always strives to improve and expand the quality and scope of its services offered.

Collection
- Each specimen should be considered potentially infectious and handled using Standard Precautions.
- Each specimen should be collected properly in tightly capped containers to avoid leakage and possible rejection of the specimen.
- The most appropriate specimens for isolation of anaerobes are tissue or fluids submitted in anaerobic transport tubes.

Delivery Address
During routine hours of operation, specimens can be delivered to the following address through the United States Postal Service or by a courier service:

University of Florida Pathology Laboratories
4800 SW 35th Drive
Gainesville, FL 32608
## H. 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>
| Anaerobe  | • Optimum recovery of anaerobes occurs with tissue or curetting, which can be placed into the anaerobic collection container. Aspirates collected in a 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 | 1. Avoid all O2 exposure.  
2. Use anaerobe transport tubes or expel air from the syringe  
3. Do not submit needle-syringe; syringe with cap only  
4. Label properly  
5. Send two tubes if STAT gram stain is requested.  
6. Deliver promptly to Lab |
| Genital   | • Swab                                                                                | • Transport medium (if more than a two-hour delay)                       | 1. Collect the culture with a swab inserted through a speculum.  
2. Avoid touching the swab to uninfected surfaces.  
3. Clean the external urethra before taking a urethra specimen.  
4. For GC, inoculate TM at bedside, if possible.  
5. Label properly  
6. Deliver promptly to Lab |
| Nasopharynx| • Calcium alginate swab  
• Transport medium                                                                 | • Do not refrigerate                                                    | 1. Nasal speculum helpful  
2. Pass through the nose into nasopharynx  
3. Allow to remain for a few seconds.  
4. Carefully withdraw  
5. Label properly  
6. Deliver promptly to Lab |
| Nose      | • Swab                                                                                | • Transport medium                                                      | 1. Swab anterior nares only.  
2. Culture quickly  
3. Label properly  
4. Deliver promptly to Lab |
| Sinus     | • Swab (small)                                                                        | • Transport medium                                                      | 1. Insert and remove quickly  
2. Label properly  
3. Deliver promptly to Lab |
| Throat    | • Swab                                                                                | • Transport medium (if more than a two-hour delay)                      | 1. Use tongue blade  
2. Sample only back of throat between and around tonsil area thoroughly  
3. Avoid cheeks, teeth, etc.  
4. Label properly |
| Superficial Wound | • Sterile container, swab/syringe | • Transport to the Lab quickly | 1. Disinfect surface with Hibistat  
2. Aspirate deepest portion of lesion  
3. Swab affected area; crush ampule of culturette  
4. Send to Lab immediately |
|---|---|---|---|
| Burn Wound | • Sterile container; swab | • Transport to the Lab quickly | 1. Disinfect surface with Hibistat  
2. Swab area; crush ampule of culturette; send to Lab  
3. Use dermal punch; obtain 3 - 4 mm punch bx; no formalin; deliver promptly to Lab |
I. Instructions for Preparing and Shipping Muscle Biopsies to UF PathLabs

Important

1. Before shipping any muscle biopsies to UF PathLabs, our Client Services Department must be notified by calling (352) 265-9900 or (888) 375-LABS (5227).

2. Instructions on how to correctly process muscle biopsy specimens are provided below. If you do not use the provided muscle biopsy box, label the outside of the package containing the muscle biopsy with “MUSCLE BIOPSY.”

3. Confirmed arrangements must be made prior to shipping any muscle biopsies to UF PathLabs. Muscle specimens must arrive within 24 hours of their initial biopsy. UF PathLabs accepts muscle specimens Monday through Friday, 8 a.m. - 3:30 p.m. Biopsies sent late on Friday should be avoided. Specimens should be delivered to:

   UF PathLabs
   Attn.: Accessioning
   4800 SW 35th Drive
   Gainesville, FL 32608

4. ACCURATE CLINICAL INFORMATION IS CRITICALLY IMPORTANT FOR THE INTERPRETATION OF MUSCLE BIOPSIES.

Help UF PathLabs administer excellent and timely patient care by providing all relevant clinical information on the attached Clinical Information Form for Muscle Biopsies. Return the completed form to UF PathLabs with the submitted biopsy sample.

1. Using a new scalpel/blade, excise 2 - 6 pieces of muscle (each 1mm x 1mm x 1mm) from an intact area of the overall muscle specimen.

2. Situate the excised muscle specimens in a labeled EM fixative container and seal the container.

3. Wrap the remaining muscle specimen in sterile saline-moistened gauze.

4. Place the gauze-wrapped muscle specimen into the provided plastic bag, and seal the bag tightly.

5. Fill the provided Styrofoam container with regular ice. Secure both muscle specimens in the ice and seal the lid.

6. Ship the container to UF PathLabs. Include the completed Clinical Information Sheet for Muscle Biopsies.
J. Instructions for Preparing and Shipping Nerve Biopsies to UF PathLabs

**Important**

5. Before shipping any nerve biopsies to UF PathLabs, our Client Services Department must be notified by calling *(352) 265-9900* or *(888) 375-LABS (5227).*

6. Instructions on how to correctly process nerve biopsy specimens are provided below. After packing your nerve specimens according to these guidelines, label the outside of all packages containing a nerve biopsy with **NERVE BIOPSY.**

7. Confirmed arrangements must be made prior to shipping any nerve biopsies to UF PathLabs. Nerve specimens must arrive within 24 hours of their initial biopsy. UF PathLabs accepts nerve specimens Monday through Friday, 8 a.m. - 3:30 p.m. Specimens should be delivered to:

   UF PathLabs  
   Attn.: Accessioning  
   4800 SW 35th Drive  
   Gainesville, FL 32608

8. **ACCURATE CLINICAL INFORMATION IS CRITICALLY IMPORTANT FOR THE INTERPRETATION OF NERVE BIOPSIES.**

Help UF PathLabs administer excellent and timely patient care by providing all relevant clinical information on the attached Clinical Information Form for Nerve Biopsies. Return the completed form to UF PathLabs with the submitted biopsy sample.

1. Immediately upon receipt of the specimen, gently lay it flat on the provided cardboard strip.

2. Let the nerve sit for about one minute, so it adheres to the cardboard.

3. Using a new blade cut the cardboard and nerve in half. **Leave the nerve specimen attached to the cardboard.**

4. Place one of the pieces of nerve and cardboard into a formalin container.

5. Place the remaining nerve and cardboard in the EM fixative container.

6. Ensure that both specimens are labeled with at least two unique patient identifiers—typically the patient’s name and date of birth or medical record number.

7. Package the specimen in the provided large protective container. Label the outside of the container with **NERVE BIOPSY.**

8. Complete a Clinical Information Form for Nerve Biopsies.
J. Instructions for Preparing and Shipping Renal Biopsies to UF PathLabs

A. Specimen greater than or equal to 10 mm (1 cm)

*Important:* Identify renal parenchyma and exclude fibrovascular connective tissue. Renal parenchyma is typically tan to pinkish-white and has a uniform consistency. Fibrovascular connective tissue is yellow to whitish-pink and will stretch and become stringy with traction. Include only renal parenchyma when measuring and dividing the specimens.

1. Divide the specimen according to Figure 1-1.
2. Place small sections from each end in electron microscopy fixative (glutaraldehyde).
3. Place sections #1 and #3 in 10% neutral-buffered formalin/buffered zinc formalin. (LIGHT)
4. Place sections #2 and #4 in Michel’s medium. (IMMUNO)
5. Complete the enclosed requisition in the kit, and submit the referring nephrologist’s name and phone number, as well as the submitting pathologist’s name.
6. Place the specimen in the kit, seal the biohazard bag and place it in the FedEx packaging.
7. Call UF PathLabs at (888) 375-LABS (5227) or your local FedEx courier for specimen pick-up.

B. Specimen between 5mm and 10mm (> 0.5 cm and < 1 cm)

1. Divide the specimen according to Figure 1-2. Divide the remainder of the specimen into only three parts. Cut slightly larger pieces from each end. Use the center piece for light microscopy.
2. Place small sections from each end in electron microscopy fixative (glutaraldehyde).
3. Place sections #1 and #3 in Michel’s medium. (IMMUNO)
4. Place section #2 in 10% neutral-buffered formalin/buffered zinc formalin. (LIGHT)
5. Complete the enclosed requisition in the kit, and submit the referring nephrologist’s name and phone number, as well as the submitting pathologist’s name.
6. Place the specimen in the kit, seal the biohazard bag and place it in the FedEx packaging.
7. Call UF PathLabs at (888) 375-LABS (5227) or your local FedEx courier for specimen pick-up.

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Specimen Labeling
The following information must be on the specimen label when submitting a sample for processing:
1. The patient’s full name
2. The patient’s date of birth
3. The collection date of the specimen
4. The type of specimen and/or site

Specimen Delivery Address
During routine hours of operation, specimens can be delivered via courier service to:

- University of Florida Pathology Laboratories
  4800 SW 35th Drive
  Gainesville, FL 32608

Specimen Shipping Guidelines
Specimen shipping guidelines can be viewed online at:

- http://pathlabs.ufl.edu/client-services/specimen-shipping

Courier Services
UF PathLabs’ Client Services Department can arrange for our couriers to retrieve specimens conveniently from your office. In some areas, specimen pick-up and report delivery may be available through independent contractors. Our Client Services Representatives can also set-up Federal Express (FedEx) transportation for overnight deliveries.

Hours of Operation
- Monday – Friday: 8 a.m. - 5 p.m.
- Saturday: Open for prearranged cytogenetics / hematopathology specimens only
- Sunday: Closed

Supplies
Supplies for submitting specimens to UF PathLabs are available to our clients for no additional charge. UF PathLabs-provided supplies can be ordered by calling (888) 375-LABS (5227) or online by visiting:

- http://pathlabs.ufl.edu/client-services/supply-ordering

UF PathLabs Test Directory
The complete UF PathLabs Test Directory can be viewed or downloaded (in .pdf format) online by visiting:
