INFORM®
DIAGNOSTICS
Every Patient Deserves the Right Answer

Client Resource Guide

For Breast, Dermatology, Gastroenterology, Urology, and General Surgery
**Table of Contents**

**General Information** ......................................................................................................................... 1
- Our Vision .................................................................................................................................................. 1
- Our Mission ................................................................................................................................................ 1
- Contact Information ................................................................................................................................. 1
- About Our Quality Assurance .................................................................................................................. 1

**Notice to Clinicians** ............................................................................................................................. 2
- Medical Necessity ................................................................................................................................. 2
- Medicare Reimbursement ...................................................................................................................... 2
- Patient Privacy/HIPAA ............................................................................................................................ 2
- Patient Requests for their Pathology Report ......................................................................................... 2
- Licensure, Certifications and Credentialing ......................................................................................... 2
- Technical Component/Professional Component Testing ........................................................................ 3
- Proficiency Testing/Peer Review ........................................................................................................... 3
- Billing Information ............................................................................................................................... 3
- Reflex Testing ........................................................................................................................................... 4
- Send-Out Testing ................................................................................................................................. 4
- Turnaround Time .................................................................................................................................... 4
- Pathology Orders and Report Delivery ............................................................................................... 5
- Medical Records/Slide Release ............................................................................................................ 5
- Specimens Requiring Cultures ............................................................................................................. 5
- Accidental Receipt of Specimens .......................................................................................................... 5
- Radioactive Materials ............................................................................................................................. 6
- Sharps ..................................................................................................................................................... 6
- Consultations .......................................................................................................................................... 6
- Delivery of Services ............................................................................................................................... 6

**Specimen Collection, Labeling, and Submission** .................................................................................. 7
- Items Supplied to Clients ....................................................................................................................... 7
- Requisitions for All Specimens ............................................................................................................ 7
- Tissue Collection Instructions ............................................................................................................... 8
- Acceptable Transport Media .................................................................................................................. 8
- Unacceptable Transport Media ............................................................................................................. 9
- Labeling Specimen Containers ........................................................................................................... 9
- Labeling and Preparing Slides .............................................................................................................. 9
- Specimen Packaging and Submission ................................................................................................. 9
- Specimen Storage .................................................................................................................................. 11
- Specimen Pick-Up .................................................................................................................................. 11
General Information
Inform Diagnostics is a leading provider of expert pathology services in the fields of breast pathology, dermatopathology, gastrointestinal pathology, hematopathology, neuropathology, general surgical pathology, and urologic pathology.

Our Vision
Our vision is to provide the most reliable, high-quality anatomic pathology services.

Our Mission
Our mission is Every Patient Deserves the Right Answer.

Contact Information

Client Services
Our team is available from 7:00 a.m. to 7:00 p.m. Central time, Monday to Friday.

Phone  866.588.3280
Fax     866.688.3280
TDM testing  844.305.2166

Billing
Phone  888.344.1160
Fax     866.724.0463

About Our Quality Assurance
Inform Diagnostics is committed to end-to-end quality assurance. Our main goals include operational excellence and continuous improvement, therefore we regularly evaluate our quality processes. Our robust quality program is led by our Senior Vice President of Compliance and Ethics.

Critical initiatives to clinicians that are important to Inform Diagnostics:

- Electronic point-to-point tracking for each specimen throughout entire lab process
- Visual “Matchmaker” reconciliation of each block and slide
- “Shadowing” by private couriers of UPS service during the first week of client onboarding
- Barcodes for all specimens
- Video recording of package opening and specimen grossing
- Secured work area with lab table bumpers
- Exclusive security roller bars to ensure specimen integrity
- Click-seal specimen jars to help reduce specimen leakage
- Daily consensus conferences of our subspecialty pathologists to review difficult and interesting cases to ensure proper diagnosis
- Disease-focused reviews of diagnostic criteria to minimize variability and maximize actionable, definitive reports
- Random retrospective reviews of pathologists’ cases to check accuracy
- Collaboration to set consistent criteria, terminology, and evaluation protocols
- UPS® Virtual Drop Box service to improve tracking and visibility and Proactive Response® service for extra monitoring, package research, and delivery services
Notice to Clinicians

Compliance with legal and regulatory requirements is a top priority. This notice provides information about our processes, policies, and some of the critical regulations we follow. Thank you for entrusting your patients’ specimens to Inform Diagnostics.

Medical Necessity

The Centers for Medicare and Medicaid Services (CMS) is responsible for administering Medicare and other federally mandated healthcare programs throughout the United States. Medicare laws prohibit payment for services and items deemed by local Medicare Carriers as not medically reasonable and necessary for the diagnosis or treatment of an illness or injury. In such cases, documentation of “medical necessity” is required before a claim may be paid. Medicare, with a few exceptions, will not pay for routine checkups or screening tests, defined as “diagnostic procedures performed in the absence of signs or symptoms.” In keeping with the requirements of Medicaid and Medicare, it is the policy of Inform Diagnostics only to perform testing that are medically necessary for the diagnosis and treatment of the patient.

Some insurance carriers increasingly request additional medical information in order to approve medically necessary tests. In most cases, the information required and/or requested on the pathology requisition—including relevant clinical history, symptoms, and previous diagnoses—are sufficient to demonstrate medically necessity to most insurance carriers. Inform Diagnostics requires a completed pathology requisition for each specimen submitted to us. See the Requisition Requirements section for the information you must provide for each patient. It is the responsibility of the client to choose testing that meets medical necessity, however, our pathologist may choose to add medically necessary stains and other tests in order to render a diagnosis. For adjunct services beyond immunohistochemistry, our policy is to contact the client before proceeding.

In some circumstances, Inform Diagnostics may contact your office to request additional patient information in order to submit or re-submit a claim to the Center for Medicare & Medicaid Services (CMS) or other insurance payors.

As the ordering clinician, you are responsible for being familiar with the applicable National Coverage Determinations (NCDs) and Local Coverage Determinations (LCDs) that establish requirements for certain laboratory testing and providing the laboratory with the documentation to support medical necessity. Please note that LCDs will be applied based on the testing facility location. Additionally, certain tests will require prior authorization. Some states require additional requirements, and we will contact you accordingly.

Medicare Reimbursement

Inform Diagnostics submits applicable claims to CMS. To review information about the Medicare Fee for Service program, visit its website at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/FeeScheduleGenInfo/.

Patient Privacy/HIPAA

Inform Diagnostics understands that medical information about our patients is Protected Health Information (PHI). We are committed to protecting medical information and complying fully with HIPAA (the Health Insurance Portability and Accountability Act).

View our most up-to-date privacy policy at http://www.informdx.com/Privacy-Practices.

Patient Requests for their Pathology Report

Patients have the right to request their pathology report directly from Inform Diagnostics. They also may direct us to transmit copies of their pathology report to persons or entities they choose. This patient right was provided under a rule published in February of 2014 by CMS, amending both HIPAA and CLIA regulations.

Licensure, Certifications and Credentialing

Inform Diagnostics maintains appropriate and required licensure for all locations. You may find PDF copies of our licenses on our website at http://www.informdx.com/About-Us/Laboratory-Certifications.

If you require information about credentialing for our pathologists, please contact us.
Technical Component/Professional Component Testing

Where allowed by state regulation and payors, we maintain arrangements with some clients to provide either lab processing (technical component) or pathologist interpretation (professional component). In order to provide services to such clients, we must confirm that your facility is CLIA-certified and maintains any and all required state licensure and credentials.

Inform Diagnostics is unable to provide services to any clients that do not meet regulatory requirements. It is your responsibility to be aware of and meet all federal and state regulations that apply to your facility.

Proficiency Testing/Peer Review

Inform Diagnostics does not perform CAP proficiency testing for clients. However, we do provide peer-review contracted service for CLIA-accredited clients who read slides in their office. The fee for this peer-review service will be billed to your office.

Billing Information

Inform Diagnostics is currently contracted with the majority of all U.S. payors.

Each pathology requisition must include patient insurance information or other billing instructions, and an attached copy of the front and back of the patient’s insurance card.

By law, we are authorized to bill CMS only for testing ordered by a physician or other healthcare provider who is authorized to order laboratory testing. We require your NPI number in order to properly identify the authorized provider who ordered testing.

Please note that Inform Diagnostics also bills patients under other entity names that are associated with our in-network agreements with your patients’ insurance providers. Nevertheless, “out of network” billing may occur.

Patients should remember that the Explanation of Benefits (EOB) they may receive from their insurer is not an invoice. They should only pay Inform Diagnostics or one of our affiliated entities if they receive an invoice.

Reasons that a patient may receive an invoice

- Patient responsibility due to deductible or coinsurance
- Our office received incomplete or incorrect information necessary to process insurance claim
- Invalid or incomplete insurance information
- Claim was denied by insurance provider
- Additional information needed from patient to file claim with insurance

Inform Diagnostics does offer payment plans and other arrangements to patients who demonstrate financial hardship.

Inform Diagnostics Billing Services

Toll-free 1.888.344.1160
Fax 1.866.724.0463

Hours of operation Monday–Friday, 7:00 a.m.–8:00 p.m. Central time
Website: www.informdx.com/For-Patients/Pay-a-Bill.aspx
Email: billinginquiries@informdx.com
Reflex Testing

Inform Diagnostics recognizes the ability of any clinician to order testing that you believe to be medically necessary for the diagnosis and/or treatment of your patients.

Reflex testing is that which is subsequently ordered when the results of the initial testing meet certain established criteria. For urology and gastroenterology clients, Inform Diagnostics offers an Approved Protocols Form, enabling you to authorize certain reflex testing in advance when established criteria are met. Use of an Approved Protocols Form helps to avoid delays and calls to your practice.

If an Approved Protocols Form is not in place or does not apply, our pathologists order reflex testing based on best practices and standards of care, as well as their judgment of the medical necessity in each patient’s case.

Send-Out Testing

In certain instances, specimens may require additional specialized testing performed by an outside laboratory. Additionally, Inform Diagnostics facilitates some send-out tests as part of reflex testing (see previous section). For questions, please contact Client Services. Outside laboratories may bill directly for testing they perform, and they maintain their own billing practices and policies.

Turnaround Time

Inform Diagnostics provides the most rapid turnaround time possible without compromising quality. In general, anatomic pathology and cytopathology reports will be generated within 48 hours of specimen accession in our lab. Any subsequent testing or cases requiring immunohistochemistry stains to be performed may delay release of the final report. Reports delivered electronically (to our online portal, a fax, secure printer or an interface) will transmit to client offices after they’re signed out.

The chart demonstrates the typical turnaround cycle. It assumes the specimen is packaged on the day of the procedure and successfully delivered to our lab the morning of the following business day via an overnight carrier, such as UPS.

<table>
<thead>
<tr>
<th>Priority</th>
<th>Definition</th>
<th>TAT</th>
<th>Accession Day/Time</th>
<th>Sign-Out Day/Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stat</td>
<td>Medical necessity for expedited results (patient specimen received Monday–Friday)</td>
<td>8 hours</td>
<td>Monday in by 10:00 a.m.*</td>
<td>Monday out by 6:00 p.m.*</td>
</tr>
<tr>
<td>Routine</td>
<td>Routine processing (patient specimen received Monday–Friday)</td>
<td>48 hours</td>
<td>Monday in by 10:00 a.m.*</td>
<td>Wednesday out by 10:00 a.m.*</td>
</tr>
</tbody>
</table>

*Local time of the processing lab, e.g. Dallas, Boston, or Phoenix

Breast and urology cases can be accepted on Saturdays at our Irving (Texas) lab with prior notice by contacting Client Services by Friday at 7:00 p.m. Central Time at 866.588.3280.

NOTE: Turnaround time is specific to the local time of the processing lab. Transportation or additional testing may impact turnaround time. Refer to specialty sections in this guide for turnaround times for certain tests.

For urgent cases, please contact Client Services and identify the case as Stat. This call will prompt Client Services to send you an Early AM shipping label to ensure the specimen is received early. You also should write Stat at the top of the requisition. Inform Diagnostics uses the term Stat to identify any case where it is medically necessary to receive expedited pathology results. Note that all Mohs cases are given a Stat priority. Ensure that you provide a phone number where you can be reached by our pathologist.
Pathology Orders and Report Delivery

Pathology orders may be sent in a variety of ways:

- Interface to your EHR/ERW
- Fax
- Our web-based PathConnect® system
- Paper requisition

Pathology results are delivered in a variety of ways:

- Fax
- Email
- Interface to your EHR/ERW
- Our web-based PathConnect system
- Express carrier, such as UPS

Inform Diagnostics may provide software, equipment, and services to clients for the installation of the PathConnect system or for the installation of an interface with your EHR. Please note that equipment and supplies provided by Inform Diagnostics must be used exclusively for submitting pathology requests to Inform Diagnostics and receiving results from us. Inform Diagnostics owns the hardware and supplies, which we remove if they are no longer required for pathology services we perform. In addition, we resupply printer toner based on your actual use: we estimate typical toner usage based on the efficiency of the provided equipment and the exclusive use of our equipment for your case volume with Inform Diagnostics. We reserve the right to discontinue the provision of equipment at any time.

Medical Records/Slide Release

For the release of medical records, please contact Client Services and forward the patient’s signed Release of Medical Records. Inform Diagnostics will release the patient’s records only to the person(s) named on the release form (clinician/pathologist, legal counsel, insurance company).

For the release of slides or other pathology materials, Inform Diagnostics requires a signed Record of Loan Form, which may be obtained from Client Services. Slides and other materials are released only to a patient’s clinician or medical institution. Release of slides/materials requires the approval of an Inform Diagnostics pathologist.

Allow 72 hours for laboratory processing before materials are shipped. Standard delivery is ground. For expedited delivery, requesters may provide a FedEx or UPS label or their carrier’s account number. All materials must be returned intact within 14 days unless expressly allowed by Inform Diagnostics in advance.

The slides/blocks are the property of Inform Diagnostics and cannot be released to a third party without prior permission. The recipient must agree to take full responsibility and assume chain of custody of the specimen material until the materials are returned to Inform Diagnostics.

Specimens Requiring Cultures

Inform Diagnostics is an anatomic pathology laboratory. Specimens for cultures should be referred to a clinical reference laboratory specializing in microbiology. Inform Diagnostics does not accept specimens requiring cultures, including stool samples, sputum, and insulin/proinsulin testing.

Accidental Receipt of Specimens

Inform Diagnostics occasionally receives time-sensitive specimens for testing that we do not perform, such as cultures and CLO testing. We will try to contact you for direction, but if we cannot reach you, we will send the specimen to an appropriate lab to preserve viability for your patient.
Radioactive Materials
Inform Diagnostics does not accept tissue containing radioactive materials.

Sharps
Specimens including blades and needles will not be accepted.

Consultations
The pathologists at Inform Diagnostics often render diagnoses on cases for which an expert opinion is desired. A copy of the outside pathology report, patient billing information, and pertinent clinical history should accompany the glass slides. A Pathology Consultation Requisition is required to ensure appropriate delivery and processing. Contact Inform Diagnostics’ Client Services department to obtain a Pathology Consultation Requisition or for assistance.

Delivery of Services
Inform Diagnostics endeavors to provide reliable and valued services to our clients. However, we reserve the right to add or discontinue services in the future to address changing business requirements. Please note that inclusion in this Client Resource Guide is not a guarantee that all listed services and tests will continue to be offered in the future.
Specimen Collection, Labeling, and Submission

Inform Diagnostics is committed to providing clients and patients with the highest quality service through all phases of the laboratory experience. To help us provide the highest possible service, we ask clients to use certain supplies and follow general guidelines. This section describes client supplies, required patient requisition information, required specimen container labeling, and important packaging and shipping instructions.

Items Supplied to Clients

Inform Diagnostics provides specimen collection and shipping supplies to clients. The following supplies are provided directly to clinicians:

**Cytology Supplies**

Slides, slide mailers, fixative, and containers

**Professional Component Supplies**

Slide folders/trays

**Surgical Biopsy Collection Vials**

- 20, 40, and 60 ml biopsy containers. Larger containers (90, 120 and 240) are available upon request. For breast cases, a 500 ml container is available.
- Michel’s medium
- Serum separator tubes
- Phlebotomy collection kits
- Prostate kits
- RPMI containers for lymphomas
- Urine cytology/FISH kits

Contact Client Services to request supplies and to obtain a Client Supply Order Form.

**Shipping Supplies**

For your convenience, Inform Diagnostics supplies pre-labeled carrier boxes for UPS and FedEx, Lab Pak bags, UN3373 (Biological Substance) labels, and zip-lock biohazard bags (with an absorbent liner for the 6” x 9” and 8” x 9” bags).

Please allow 4–5 business days from the time of request for supplies to arrive.

Requisitions for All Specimens

Certain elements are required by regulatory agencies (such as CAP) when submitting specimens to a laboratory. All specimens must be accompanied by an adequately completed requisition. Please complete each requisition with the following information:

1. Inform Diagnostics client ID #
2. Patient’s first and last name (no nicknames, no initials)
3. Date of birth
4. Patient gender
5. Address, including apartment # if applicable
6. Patient insurance information or other billing instructions, and attach a copy of the front and back of the patient’s insurance card
7. Date of collection
8. Specimen source
9. Time of collection, when appropriate
10. Pertinent clinical history, such as chief complaint, history of current symptoms, family and social history, medications, and allergies (if using “Rule Out” or “vs.” only, please include additional signs and symptoms to avoid delays in processing)

11. Test requested
12. ICD-10 code(s)
13. Name and address of ordering clinician
14. Authorized clinician or legally authorized person requesting the test
15. The identity of the person collecting the specimen, if different from the clinician or legally authorized person requesting the test
16. Location where specimen was obtained (such as POS 11, 19, 21, 22, or 24)

Admit and discharge dates, where applicable, for specimens obtained during an inpatient or outpatient stay. Incomplete information will delay processing of your patients’ specimens. Client Services will call to resolve any discrepancies; however, a Discrepancy Resolution Form may be needed in order to complete specimen processing.

Note that Inform Diagnostics will be adding a required field soon to all requisitions for Place of Service.

Tissue Collection Instructions

- Tissues should be placed in 10% buffered formalin without delay, unless a different or additional fixative is specified for a particular evaluation. The volume of formalin must completely cover the specimen and, should exceed the volume of the specimen at a ratio of 15:1. Containers with improper levels of formalin may cause delays due to inadequate fixation.
- Do not wrap tissue in gauze or other type of toweling, as they absorb the fixative and parts of the tissue may not be covered by the fixative, causing the tissue to decompose.
- Best practice is to place tissue directly into formalin container WITHOUT any secondary wrapping (including but not limited to gauze, toweling, sponge, netting, etc.)
- Do not send dry specimens unless explicitly requested in this Guide. See Acceptable Transport Media section below.
- If re-biopsy of tissue is performed, provide the date and specimen accession number of the previous biopsy.
- Tissue specimens from different sites or lesions should be submitted in separate containers.
- Tighten container lid to avoid loss of formalin.

NOTE: Please review the relevant specialty section of this Client Resource Guide for more specific collection and fixative instructions that may be applicable.

Acceptable Transport Media

The ideal transport medium is 10% neutral buffered formalin. Other media are acceptable depending on the specimen.

10% Neutral Buffered Formalin
This is the standard transport medium for all specimens requiring histopathological examination.

RPMI for Flow Cytometry
RPMI is the standard transport medium for specimens requiring work-up for lymphoma, leukemia, and other hematolymphoid malignancies.

Red-top Michel’s Media
Specimens requiring DIF (direct immunofluorescence) should be placed in a red-topped Michel’s media bottle.

Serum Separator Tube
For therapeutic drug monitoring, use a serum separator tube. See Gastroenterology section for complete instructions on submitting specimens for therapeutic drug monitoring.

Cytofixatives
- Green-top cytology slide containers: Use these slide containers for cytology smears
- Spray: Use for fresh specimen smear preparation
- ThinPrep® CytoLyt Solution
**Bouin’s Fixative**

Testis biopsy specimens performed for infertility evaluation should be collected preferably in Bouin’s fixative for superior preservation of architectural details. If Bouin’s fixative is not available, formalin fixation will be accepted.

**100% Alcohol**

Alcohol is recommended only when gout is suspected.

**Unacceptable Transport Media**

**Saline/10% Formalin with Zinc**

Neither are recommended. These are sub-optimal transport media. Please contact Inform Diagnostics Client Services to order supplies.

**Labeling Specimen Containers**

Use a chemical-resistant marker for all labeling. **DO NOT** label the container lid. Instead, label the body of the container with the following:

1. TWO unique identifiers, of which one must be:
   - Patient First and Last Name (no nicknames, first initial and last name are acceptable)

   The other unique identifier can be one of the following:
   - Date of Birth
   - Medical Record Number
   - Unique specimen requisition number (labels provided on requisition)

2. Specific specimen site (this is NOT considered a unique identifier)

The absence of these elements on the specimen container(s) may delay specimen processing. A Discrepancy Resolution Form may be necessary to complete specimen processing.

**Additional Container Labeling**

When affixing additional labeling to the specimen container, such as requisition labels, please ensure the fixative type is not obscured. This will allow our staff to handle the specimen appropriately and process the tissue accurately.

**Labeling and Preparing Slides**

1. Each slide must be marked with two patient identifiers, per recent CAP requirements. Use chemical-resistant marker or pencil for all slide labeling. **Label on the frosted end** of the slide. If slides do not allow for two patient identifiers, the slide holder must be labeled with two patient identifiers.

2. Place specimen on the same side as the label side.

3. If multiple specimen sources are sent on the same patient, identify specimen source on each slide. (For example, for right thyroid, mark “R” on slide, and for left thyroid, mark “L” on slide).

4. Place slides into a slide holder.

5. Wrap slides securely with bubble wrap or rubber bands to ensure that slides do not shift or break during transit.

6. Ensure that cases are properly dried before packaging to prevent slides from shattering or sticking to slide boards upon removal.

Improperly labeled slides will result in delay of specimen processing. A Discrepancy Resolution Form may be necessary to complete specimen processing.

**Specimen Packaging and Submission**

Prior to packaging and sending to our lab, please ensure that the tissue processing requirements can be met if shipping on a Thursday, Friday, or holiday. If you are unsure which location to send specimen, please contact Client Services.
All specimens must be packed in triple layer packing consisting of a primary receptacle, a secondary packaging, and a rigid outer box. The primary receptacle can be a vial, tube, or other container made of rigid plastic or glass including a stopper, cap, or other closure element. The secondary package must fully encapsulate the primary receptacle and include cushioning and/or absorbent materials.

The rigid outer box is the carrier package designed for transit and shipping. This rigid outer box must be a new box provided by Inform Diagnostics. Do not re-use any box including boxes that contained supplies you received from us. Couriers picking up for UPS or FedEx service are instructed not to pick up any box that has the appearance of being a re-used box. If you receive pre-labeled boxes from Inform Diagnostics, use those as your outer packaging; if you receive pre-labeled Lab Paks from us—including pre-labeled Lab Paks enclosed in kit boxes—use those as your outer packaging.

With your specimens, include a Specimen Log that lists all enclosed specimens, and fax the Specimen Log to Inform Diagnostics. Faxing the Specimen Log notifies us of expected incoming specimens. If expected specimens are not received, we will notify you. Contact Client Services for a Specimen Log template.

- Place specimen in the larger pouch of the biohazard bag with absorbent pad and secure closure. Take special care to secure the lid tightly.
- Place folded requisition in the smaller pouch of the biohazard bag.
- Collect and secure all individual biohazard bags into an Inform Diagnostics-branded Lab Pak bag. The Lab Pak bag ensures that your specimens will reach Inform Diagnostics, even if a Pak should come out of a courier box or UPS or FedEx box.

If Sending Via UPS or FedEx

Inform Diagnostics now provides pre-labeled boxes and lab paks for shipping to our labs.

When you request shipping materials (specifically FedEx Clinical Boxes and UPS Laboratory Boxes), the return service label (RSL) will be affixed to the package. If you ship kits in Inform Diagnostics Lab Paks, these also are pre-labeled.

For pre-labeled boxes, RSL receipt tickets are stapled to the adhesive strip of the corresponding labeled box. To remove, pull the receipt ticket until it detaches from the box. (You do not have to remove the staple.) After the receipt ticket is detached, remove the adhesive strip, and seal the box with the staple on the flap. If your office does not use the receipt ticket, it can be discarded.

UPS Boxes

The UPS Laboratory Box has a unique blue-striped marking associated with the healthcare industry. This design heightens awareness and provides higher visibility to UPS employees. Pre-labeled UPS boxes help to ensure that shipments meet IATA and DOT compliance for shipping clinical specimens and/or specimens designated as a Biological Substance, Category B (UN3373). The UN3373 logo and shipping label are placed according to industry standards.

FedEx Boxes

If you ship via FedEx, please use a FedEx Clinical Box, which provides higher visibility to FedEx employees. You must apply a UN3373 label, as required by governing regulatory agencies. These labels can be ordered from Inform Diagnostics.

Other Boxes

If you have a specimen that doesn’t fit into a UPS or FedEx pre-labeled box or Lab Pak, use a new unmarked box. Contact Client Services for an RSL and UN3373 label. To protect the RSL from any damage, tape the RSL to the carton using clear plastic tape and cover the entire RSL. Or, use a clear plastic shipping address pouch. If you use a shipping address pouch, place the RSL so that the entire label is visible in the window. Remove the adhesive strip, and properly seal the pouch to prevent the RSL from damage or falling out. For correct application of the UN3373 label, please follow the instructions included with the RSLs and UN3373 labels that we provide.
Specimen Storage

All specimens in fixatives (other than RPMI) can be stored at room temperature. Specimens in Michel’s medium can be stored at room temperature for up to five days (including transit time to lab).

During hot summer months, May 1 to September 30, store and ship all specimens, blocks and slides on ice, particularly paraffin blocks. Additionally, blocks should not be shipped on Fridays during these summer months, May through September. These requirements are critical for shipments to our labs in Texas and Arizona.

Watch for freezing temperatures during cold months, November 1 to April 30, because specimens can freeze—affecting viability—if placed in lockboxes in non-climate-controlled areas. If your lockbox is outdoors or otherwise subject to freezing temperatures, wait until right before your pickup window to place specimens in it.

Specimens that are not in fixative must be refrigerated. This includes peripheral blood, serum, body fluids, urine, and specimens in RPMI for lymphoma studies.

On rare occasions, weather or other conditions prohibit routine transportation of specimens. The same storage requirements apply until routine transportation resumes.

Specimen Pick-Up

Specimens from clinicians will be arranged to be picked up by UPS, FedEx, or a local courier. Contact Client Services for more information.

If you wish to change your pick-up details—day(s) of the week, time of day, or pick-up location—contact Client Services immediately. **DO NOT give instructions directly to the courier or carrier driver.**

“Will-call” pick-ups are available as an exception to your regular service schedule—contact our Client Services team at least two hours before your desired pick-up time.
Breast

Tissue Types Accepted

- Fine needle aspirations (FNAs)—see Cytopathology section
- Cyst aspirations
- Core needle biopsies (stereotactic, ultrasound, or percutaneous)
- Core needle biopsies for microcalcifications
- Unoriented breast biopsies
- Oriented breast biopsies
- Wire localization biopsies for microcalcifications
- Wire localization excisions
- Lumpectomies
- Lymph node biopsies
- Lymph nodes
- Sentinel lymph nodes
- Male breast biopsies
- Reduction mastectomies
- Capsulectomies

Breast Specimens Not Accepted

- Any specimen that does not fit easily in the provided containers
- Mastectomies other than reductions
- Radical mastectomies

Collection Instructions for Breast Specimens

Breast specimens should be submitted in 10% neutral buffered formalin in a provided container large enough to surround tissue with fixative at a ratio of at least 15:1. Do not stuff tissue into container—the high amount of fixative volume ensures the fixation of the tissue. Containers with improper levels of formalin may cause delays due to inadequate fixation.

To send cases obtained on Fridays, please contact Client Services to notify the lab, and be sure to use the Saturday label. With notice, a lab team is available on Saturdays for accessioning and processing of breast specimens. Breast specimens should not remain in formalin longer than 72 hours.

Additional Required Information for Breast Specimens

All shaded areas on the requisition form are required information.

a. Specimen collection date and time
b. Time placed in fixative
c. Type of specimen: tissue in fixative, peripheral blood, paraffin block, or unstained slides
d. Desired tests
e. Indicate left or right side
f. Site: breast, axilla, chest wall, lymph node, sentinel lymph node
g. Nature of lesion: nodule, cyst, density, calcification, stellate mass, other
h. Type of biopsy: FNA, core, stereotactic, wire-guided needle localization, lumpectomy
i. Distance from nipple
j. Testing options: Biopsy only, Flow & Biopsy, Flow only
k. Orientation information with all sutures documented: double long, double short, single

Additional Test Options (Prognostic and Predictive Markers)
- ER/PR/HER2/Ki67/p53 (IHC)
- HER2 CISH
- HER2 FISH
- Flow cytometry for suspected lymphoma and hematolymphoid malignancies (see page 21 for specimen requirements)

Molecular/Genomic Testing
Genetic testing is provided by Baylor Genetics. In addition to the required Genomic Test Requisition, see the section below for additional required documents.

- **BRCA1 and BRCA2 Screening** (two genes: BRCA1, BRCA2)
  
  **Specimen Information**
  - Requirements:
    - 3–5 ml peripheral blood in an EDTA (purple-top) tube
    - or
    - Saliva collected with Oragene DNA Self-Collection kit
  - Turnaround time: 14 days

- **High-Risk Hereditary Breast Cancer Panel** (seven genes: BRCA1, BRCA2, CDH1, PALB2, PTEN, STK11, TP53)
  
  **Specimen Information**
  - Requirements:
    - 3–5 ml peripheral blood in an EDTA (purple-top) tube
    - or
    - Saliva collected with Oragene DNA Self-Collection kit
  - Turnaround time: 14 days

- **OncAware Complete** (27 genes: APC, ATM, BARD1, BMPR1A, BRCA1, BRCA2, BRIP1, CDH1, CDK4, CDKN2A, CHEK2, EPCAM, MLH1, MRE11A, MSH2, MSH6, MUTYH, NBN, PALB2, PMS2, PTEN, RAD50, RAD51C, RAD51D, SMAD4, STK11, TP53)
  
  **Specimen Information**
  - Requirements:
    - 3–5 ml peripheral blood in an EDTA (purple-top) tube
  - Turnaround time: 30 days or four weeks

For All Genomic Testing
- Additional required documents:
  - Complete patient history and clinical notes along with family history of any cancers, if any. Front and back of patient insurance card
  - Aetna Prior Authorization Request Form (for Aetna patients only)
- Insurance Requirements for Genetic Counseling: If patient’s insurance provider is Cigna, United Healthcare, or Aetna, genetic counseling is required prior to approving coverage for BRCA mutation testing and hereditary panels that include the BRCA gene. If genetic counseling was already performed, please forward those documents along with the patient’s pedigree provided to be included in the prior authorization process.
- Shipping Conditions: Ship at room temperature in an insulated container by overnight courier. Do not heat or freeze. Specimen must arrive within 48 hours.
Dermatology

Particularly for dermatology cases, our pathologists prefer to receive a detailed patient history. If possible, please send the visit note and clinical photo via your EHR, along with the electronic order. Because microscopic histologic patterns can correspond to multiple diagnoses, the clinical history and photo provide helpful input toward rendering a definitive diagnosis.

Tissue Types Accepted and Not Accepted

Specimen types accepted:

- Skin
- Oral, vulvar, and penile mucosa
- Conjunctiva
- Nail clippings
- Hair shafts; specimens for alopecia diagnosis must be a punch or excision. Alopecia testing cannot be performed on shaves.
- Insects for identification/classification
- Sentinel lymph nodes

Not accepted:

- All other tissue types

Fixative

All specimens must be placed in 10% neutral buffered formalin. Exceptions are as follows:

- When the diagnosis of gout is suspected, the specimen must be placed in 100% alcohol or sent fresh. Specimens sent with a needle attached to the syringe will be sent back to the client.
- Nail clippings, skin scrapings, hair shafts, and insects should be placed in a dry container.
- Specimens for direct immunofluorescence (DIF) should be placed in a red-topped Michel’s media container. The specimen cannot be processed for DIF if submitted in formalin.

Additional Diagnostic Offerings

- Melanoma FISH
- Direct immunofluorescence
- Entomologic species identification
- Small fiber neuropathy evaluation by Therapath; contact Client Services for more information

Mohs-Related Specimens

A Mohs procedure (CPTs 17311–17315) includes the removal of all gross tumor and excision of specimens, mapping, and the histopathologic microscopic examination of the specimens. Essentially, the dermatology and pathology services are performed by the same provider. Inform Diagnostics will accept a Mohs-related specimen only in the following scenarios:

- Specimen(s) is submitted for a medically necessary second opinion/consultation
- Specimen(s) submitted consists of new margins that were not previously processed during the Mohs procedure. Please indicate one of the following on the requisition, where applicable:
  - The specimen is from a different site than the Mohs procedure, or
  - A staging specimen is submitted for final staging and examination
- Note: the treating clinician may be required to appeal their services with the insurance provider
Gastroenterology

Tissue Types Accepted and Not Accepted

Specimen types accepted:

- Endoscopic biopsies and polypectomies of the gastrointestinal tract
- Endoscopic mucosal resections
- Core and wedge biopsies of the liver, including non-transplant, transplant, and neoplastic disease
- Bile for cholesterol crystal examination
- Cytologic specimens of the GI tract, including brushings, washings, and fine needle aspirates
- Previously prepared slides for second opinion (consultation)

Specimen types NOT accepted:

- Any specimen that does not appropriately fit into the provided 240 ml specimen jar
- Specimens requiring cultures; please see note on page five
- Specimens for CLO testing

Fixative

- Biopsies and excisions for routine histologic examination: 10% neutral buffered formalin
- Colonic, esophageal, gastric washings, and brushings: 95% ethanol
- Flow cytometry specimens: submit fresh in RPMI; in addition, separate tissue should be submitted in formalin for light microscopic evaluation. Review the complete instructions in the Flow Cytometry section of this Guide.
- Bile for cholesterol crystals: submit fresh

Additional Diagnostic Offerings

Testing is available to screen for Lynch syndrome (HNPCC).

Our comprehensive therapeutic drug monitoring provides easy-to-interpret and actionable results. Testing is available for drug and anti-drug antibody levels for adalimumab (Humira®), certolizumab pegol (Cimzia®), golimumab (Simponi®), infliximab (Remicade®), infliximab-abiq (Renflexis™), infliximab-dyyb (Inflectra®), ustekinumab (Stelara®), and vedolizumab (Entyvio®). Contact our Client Services team to request collection kits.

Specimen and Shipping Information for Therapeutic Drug Monitoring

Requirements:

- Label red-top or serum separator tube with at least two patient identifiers and date of collection. (Acceptable identifiers: full name, DOB, MRN, requisition number).
- 5–7 ml serum in red-top or tiger-top serum separator tube.
- Allow red-top tubes to clot in an upright position at room temperature for 60 minutes, SST for 30 minutes. For SSTs: **if available, CENTRIFUGE: Spin on full speed (2000–2500 rpm for 15 minutes). For red-tops: **if available, CENTRIFUGE and ALIQUOT: Spin on full speed (2000–2500 rpm for 15 minutes) and then aliquot into separate tube labeled with two patient identifiers. ** If not available, send blood same day to be aliquoted upon arrival.

Shipping instructions:

- Package the labeled tubes in biohazard bag. Place with completed requisition and frozen cold pack inside kit in the provided therapeutic drug monitoring collection kit. (See complete shipping instructions inside kit.)
● Ship immediately or refrigerate overnight to ship out the next morning.
● More than one patient specimen may be shipped per kit—keep in separate biohazard bags and include separate requisition.
● Place pickup by calling Inform Diagnostics at 844.305.2166 by 1:00 p.m. in your local time zone.

■ Stability

● Whole blood is serum stable for 72 hours at room temperature, and serum stable for seven days if stored at 1–6°C.
● Unspun tubes must be received within 72 hours from time of collection.
● Spun samples and serum aliquots must be received within seven days from date of collection.
● Spinning down a red-top tube DOES NOT increase sample stability. The serum must be aliquoted into its own tube (labeled with two patient identifiers) for seven-day stability at 1–6°C.

■ TDM turnaround time: 5 days

Insurance Information

■ General rules for screening colonoscopies to be covered under preventive benefits:
   ● The patient must be 50 years of age or older and be asymptomatic for signs or symptoms of colon cancer
   ● If a polyp is biopsied on an asymptomatic patient, most commercial payors will cover pathology services under preventive benefits. However, Medicare will still require patient coinsurance for pathology services.
Urology

Tissue Types Accepted and Not Accepted

Tissue/specimen types accepted:
- All types of biopsy and resection specimens
- Urine for cytologic evaluation
- Kidney biopsy performed for tumor (mass) evaluation

Tissue types NOT accepted:
- Kidney biopsy performed for renal disease

Collection Instructions for Kidney Stones

- Refer to the Specimen Collection, Labeling, and Submission section for labeling details.
- Kidney/renal stones—submit fresh in dry container.
- Refer to the Specimen Packaging and Submission section for further instructions.

Collection Instructions for Prostate Biopsy Specimens

- Refer to the Specimen Collection, Labeling, and Submission section for labeling details.
- Inform Diagnostics will provide either 8-part, 12-part, or 16-part kits. It is best practice to provide each biopsy core(s) from its individual site in its specific jar or biopsy site-labeled cassette to facilitate in providing optimal diagnostic and prognostic information. Do not place multiple cassettes in a single jar. Use of two-jar kits creates processing delays due to the need for clarification on the specimen site.
- Perform biopsy procedure. Place biopsy specimen directly into labeled specimen vial. Secure cap tightly, and place vial into appropriate section of the specimen tray. Multiple core specimens from the same area should be placed in the same collection vial. Discard any unused formalin collection vials.
- Refer to the Specimen Packaging and Submission section for further instructions.
- To send cases obtained on Fridays, please contact Client Services to notify the lab, and be sure to use the Saturday label. With notice, a lab team is available on Saturdays for accessioning and processing of prostate specimens. It is imperative to notify Client Services to ensure that prostate cases sent on Fridays do not over-fixate in formalin over the weekend.

Collection Instructions for Urine Cytology and UroVysion FISH Requests

- Collect urine specimens for cytology evaluation and UroVysion FISH examination in provided kit maintaining 2:1 ratio (2 parts urine and 1 part fixative). The Inform Diagnostics-provided kit is preferred.
- If the UroVysion FISH test is requested, preferred volume is at least 33 ml. If the urine volume is less than 33 ml, the assay will be attempted, however the cell yield may be insufficient for analysis, and a new specimen may be requested.
- In general, catheterized and neobladder specimens are not optimal for UroVysion test, because they may have an insufficient quantity of urothelial cells.
- The best practice and preferred range for urine specimens requiring a UroVysion test is 72 hours. However, the specimen is still viable for this test for two weeks after receipt at Inform Diagnostics if the recommended collection method was followed.
- Urine collected from individuals with bladder or urinary infection may exhibit extensive quantities of bacteria and/or neutrophils that may interfere with the assay.
- For appropriate insurance coverage of UroVysion testing, enter ICD-10 codes as required on the requisition.
- Cytology and UroVysion FISH turnaround time: 5 business days
Additional Requirements for UroVysion Payor Coverage

- Initial diagnosis: UroVysion may be performed based on atypical cytology results. Hematuria is not considered a medically necessary condition for UroVysion testing.
- Surveillance (patient is being monitored for a previously diagnosed bladder cancer): Order must indicate personal history of bladder cancer, and/or ICD-10 code Z85.51. UroVysion may be performed based on:
  - Equivocal cytology results (for low-grade bladder cancer), or
  - Negative or equivocal cytology results (for high-grade bladder cancer)

Voided Urine Fluid Specimen Collection and Handling

- Refer to the Specimen Collection, Labeling, and Submission section for labeling details.
- Use the provided specimen kit.
- Clean catch urine collection is required.
- Use the white cap bottle from the Urine Collection Kit to collect urine specimen.
- Collect 40 cc of urine into white cap specimen jar. Discard any extra urine.
- Add the full container (20 cc) of preservative solution PreservCyt to the urine in the specimen jar for a total of approximately 60 cc.
- If volume of urine is less than 40 cc, try to keep 2:1 ratio of urine and PreservCyt fixative provided.
- Tighten the white cap on the specimen jar until you hear a click, then tighten another quarter turn to complete the seal.
- Refer to the Specimen Packaging and Submission section for further instructions.

Catheterized Urine, Urine Collected after Irrigation or Instrumented Urine

- Refer to the Specimen Collection, Labeling, and Submission section for labeling details.
- Collect freshly obtained urine specimen in white cap jar and add provided PreservCyt fixative keeping 2:1 ratio.
- Tighten the white cap on the specimen jar until you hear a click. Then tighten another quarter turn to complete the seal.
- Refer to the Specimen Packaging and Submission section for further instructions.

Instructions for 3-Day Cytology Kit

- Use Inform Diagnostics-provided kit; remove labels 1, 2, and 3 before giving kit to patient. Apply labels 1, 2, and 3 to three different Inform Diagnostics Urologic Pathology Requisition forms, then hold until patient returns kit.
- Remind patient to use second urination of the morning each day and to use the jars in order.
- Remind patient to close each jar tightly after use, to record the date the specimen is collected on each jar, and to place each jar into one of the provided biohazard bags.
- Remind patient to keep specimens in refrigerator after each collection.
- When patient returns jar to office, place each requisition—with labels 1, 2, and 3—into the respective outside pockets of the biohazard bags containing the jars labeled 1, 2, and 3.

Collection Instructions for Urinalysis Hematuria Profile with Urine Cytology

- Use for the following test panels:
  - Cytology with hematuria analysis (urine cytology and hematuria analysis)
  - Cytology PLUS with hematuria analysis (urine cytology, Feulgen stain cytology, hematuria analysis)
  - Hematuria PLUS Profile (urine cytology, Feulgen stain cytology, UroVysion, hematuria analysis)
Refer to **Specimen Collection, Labeling and Submission** section for labeling details.

Use the provided hematuria specimen kit.

Collect specimen of first-voided urine, mid-stream, into plastic beaker with spout.

Volume requirements:
- Optimum volume: 10.0 ml
- Minimum volume: 1.0 ml

Pour the specimen into the blue-capped jar.
- Do not touch or remove the boric acid preservative tablet from the blue-capped jar.

Process urine specimen with Vacutainer collection tube.
- Submerge tip of transfer straw into specimen container.
- Push UA tube into transfer straw.
- Hold in position until flow stops, then remove transfer straw.
- Invert the tube 8–10 times to mix; do not shake.
- Label tube with patient’s full name, date of birth, date and time of collection.
- Discard transfer straw in sharps collector.

Place the Vacutainer tube and absorbent pads inside the biohazard bag, place cold pack on top and seal.

Store specimen in refrigerator pending shipment.
- Specimen must be processed with 48 hours.

Transport the specimen according to laboratory procedure.

### Additional Diagnostic Offerings

Additional diagnostic offerings are available on the Urologic Pathology Requisition. Contact Client Services to request either an Additional Test Requisition form for individual cases, or an Advanced Protocols Form to set up reflex testing.

- **Urine UroVysion™ FISH** assay is available as a standalone test or reflex test with urine cytology examination. This test enhances the detection of urothelial carcinoma. **UroVysion** FISH can be performed as standalone only when patient has prior history of bladder cancer. All other **UroVysion** FISH testing will require positive cytology result, excluding hematuria only.

- **PINgenius®** is available as a reflex test on prostate biopsies with HGPIN. Developed by Inform Diagnostics, this test predicts the risk of prostate cancer at re-biopsy.

- **PTEN & ERG IHC** is available as a reflex test on prostate biopsies with any Gleason scores, or specific Gleason scores of 3+3 or 3+4. This test improves prostate cancer risk stratification.

- **Prolaris®** is available as a send-out reflex test upon diagnosis of localized prostate cancer, to personalize risk stratification. Be sure to ask your Sales Director or our Client Services team about our bi-directional interface with Myriad Genetics that speeds turnaround time. You’ll receive actionable information faster, in time for post-biopsy patient consultations.

- **Confirm MDx™ epigenetic assay** is available as a send-out reflex test on negative prostate biopsies and prostate biopsies with HGPIN. This test addresses false-negative biopsy concerns.

- **Oncotype DX®** is available as a send-out reflex test on prostate biopsies.

- **Decipher®** is available as a send-out reflex test on prostate biopsies.

### Additional Offering

- **KnowError®** is available as a send-out test for prostate biopsies—either for TWO specimen/cores (the highest Gleason score from each side of the prostate) or ONE specimen/core (with the highest Gleason score). This test verifies patient identification and prevents misidentification error.
General Surgery

Tissue Types Accepted

**GYNECOLOGY**
- Cervical biopsy
- Endometrial biopsy
- Endocervical curettage/curetting
- LEEP biopsy
- CONE biopsy
- Fallopian tubes

**OPHTHALMOLOGY**
- Skin/lid
- Lacrimal/meibomian gland
- Lens/cornea/sclera
- Evisceration (removal of ocular contents)
- Enucleation (removal of eyeball)
- Exenteration (removal of entire orbital contents)

**ORTHOPEDICS**
- Bone fragments
- Cartilage
- Ligaments/tendons
- Bone tumors with X-ray and/or radiology report
- Soft-tissue tumors
  - Lipomas, leiomyomas, angiomas, neuromas/schwannomas

**OTORHINOLARYNGOLOGY**
- Tonsils and adenoids
- Oral and laryngeal tumors
- Sinonasal polyps and mucosa

**NEUROPATHOLOGY**
*Available through Therapath:*
- Skin biopsy for small nerve fiber evaluation
- Skeletal muscle
- Peripheral nerve
- Brain autopsy

*Contact our Client Services team or your Sales representative.*

**FINE NEEDLE ASPIRATIONS**—See *Cytopathology section*
- Adrenal
- Bone
- Kidney
- Liver
- Lung
- Lymph node
- Mediastinum
- Pancreas
- Parotid
- Soft tissue
- Thyroid

**CYTOLOGIC BRUSHINGS**—See *Cytopathology section*
- Esophageal
- Bronchial

**FLUIDS**—See *Cytopathology section*
- Bladder washings
- Bronchial washing and lavage fluid
- Joint fluid
- Pleural and ascitic fluid
- Pelvic and abdominal fluid

**NOT Accepted**
Any specimen that does not fit easily in the 240 ml or 500 ml container (provided)
- Cervical pap smears
- Products of conception (with identifiable fetus)
- Kidney biopsy for non-neoplastic disease
- Tissue for culture
Flow Cytometry on Fresh Tissue and Body Fluid

Flow cytometry is a critical tool at Inform Diagnostics for diagnosis of hematolymphoid disease.

- Aid in identification and classification of suspected lymphoma through FNA, lymph node, or tissue biopsy.
- Diagnose hematolymphoid malignancies in tissue or bodily fluids, including any tissue where there is a suspicion of lymphoma/leukemia, such as lymph nodes, soft tissue, spleen, or other organs.
- Determine the type of leukemia or lymphoma.
- Differentiate malignant lymphomas from nonmalignant lesions of lymph nodes.

Flow cytometry is not confirmatory for metastatic carcinomas, for which a tissue biopsy is usually needed.

Specimen Requirements

Acceptable Specimens and Requirements

Flow cytometry is critical for evaluation of possible hematolymphoid neoplasia. All tissue types submitted for lymphoma evaluation require both formalin-fixed tissue and fresh tissue in RPMI solution. If RPMI solution is not available, a portion of the specimen may be placed in saline, refrigerated, and transported with a cold pack within 24 hours. These sample types will enable all of the necessary testing for the most accurate diagnosis and classification of lymphoma, including morphologic examination, immunohistochemical staining, flow cytometric analysis, FISH analysis, and cytogenetic analysis if needed.

- Sample types accepted:
  - FNA with freshly prepared smear, if available.
  - Core needle biopsy—submit some cores in RPMI and some in formalin.
  - Lymph nodes for lymphoma workup—submit some nodes in RPMI and some in formalin.
  - Other biopsies including large specimens—submit some of the tissue in RPMI and the rest in formalin.

Stability, Storage, and Transport

If available, use the Inform Diagnostics RPMI kit for the flow cytometry sample which includes a return service label for shipment to our Phoenix lab. Contact Client Services to request either an RPMI kit or a return service label in order to send the RPMI specimens to our Phoenix lab for flow cytometry. We can send you an overnight label for our Phoenix lab via email or fax.

- For large volumes of body fluid such as ascitic fluid, spin and remove the large fluid volume, and send the cell pellet in RPMI or similar culture medium. No anticoagulant is necessary unless grossly contaminated with blood.
- From collection to initiation of testing, specimen must be refrigerated or kept cold with an ice pack.
- If RPMI is not available and specimen was already taken, specimen can be covered with saline, refrigerated, and transported with a cold pack to our Phoenix lab within 24 hours.
- Temperature: The fresh tissue or fluid specimen can be transported with an ice pack, but do not fix or freeze specimens (no dry ice).

Requisition and Labeling

Use an Inform Diagnostics Surgical Pathology (GSP) requisition for general surgical cases or a Breast Pathology requisition for breast cases; under Testing Options, check Flow only for specimen(s) in RPMI.

- If sending both formalin-fixed and RPMI specimens for the same patient, make a copy of the requisition and send it with the RPMI specimen(s) to our Phoenix lab.
- Please include all applicable medical records, including documented orders for laboratory services.
Cytopathology

It is known that formalin fumes may be extremely detrimental to cytology specimens. This exposure often occurs during transportation, when smears are shipped in the same container with biopsies. Inform Diagnostics recommends that clients ship cytology and surgical specimens in separate specimen bags to minimize this potential problem.

Labeling and Preparing Slides

1. Each slide must be marked with two patient identifiers, per recent CAP requirements. Use chemical-resistant marker or pencil for all slide labeling. Label on the frosted end of the slide. If slides do not allow for two patient identifiers, the slide holder must be labeled with two patient identifiers.

2. Place specimen on the same side as the label side.

3. If multiple specimen sources are sent on the same patient, identify specimen source on each slide. (For example, for right thyroid, mark “R” on slide, and for left thyroid, mark “L” on slide).

4. Place slides into a slide holder.

Improperly labeled slides will result in delay of specimen processing. A Discrepancy Resolution Form may be necessary to complete specimen processing.

Tissue/Specimen Types Accepted and Not Accepted

- See specific procedure sections below (FNA, Cytologic Brushings, Bile Aspirates, Cytology Fluids) for further information.
- Cervical and endocervical smears (Pap smears) are not accepted for processing.

Fine Needle Aspirations

**Specimen Types Accepted for FNA**

- Thyroid
- Pancreas
- Breast
- Bone
- Parotid
- Lung
- Lymph node
- Liver
- Kidney
- Mediastinum
- Prostate
- Adrenal
- Soft tissue

**Collection Instructions**

- Refer to Labeling and Preparing Slides above for slide and labeling instructions.
- After aspiration, touch the end of the needle to the end of the glass slide and express one to two drops of material. (If too much material is expressed, the slides will be too thick for optimal interpretation. A thin monolayer of cells is desired.)
- Place a second slide on top of the first, allowing the drop to spread, and then gently pull slide apart toward opposite end.
- Immediately, fix one slide with spray or alcohol fixative and mark with “F.”
- Allow the second slide to air-dry and mark it with “A.”
- More slides may be prepared if material is available.
- Rinse the remaining material and the needle in a labeled tube/container containing alcohol fixative (not formalin).
- Rinse FNA in fixative:
  - Rinse the specimen needle directly into a tube/container containing alcohol fixative.
  - If a needle core biopsy is also obtained, touch the core gently to at least two slides (one should be air-dried and the other spray- or alcohol-fixed), then place the needle core in a separate formalin-filled container.
  - In addition to smears, if large amounts of blood clots are in the syringe, the material can be rinsed in a formalin-filled container for cell block processing, labeled with the FNA site and “Cell Block.”
- Refer to the Specimen Packaging and Submission section for further instructions.
Cytologic Brushings

Specimen TypesAccepted
- Esophageal
- Bronchial
- Colon
- Rectum
- Anal
- Tzanck/skin

Collection Instructions
- Refer to Labeling and Preparing Slides in this section for slide-labeling details.
- Refer to the Specimen Collection, Labeling, and Submission section for specimen-labeling details.
- Prepare smears and put them immediately in a labeled tube/container containing alcohol fixative or spray fix.
- Put the brush (cut off the handle if necessary) immediately in a labeled tube/container containing alcohol fixative (not formalin). Placing the brush in a dry container will limit the number of viable cells due to the cells degenerating without fixative.
- Refer to the Specimen Packaging and Submission section for further instructions.

Bile Aspirates for Cholesterol Crystals

Collection Instructions
- Refer to the Specimen Collection, Labeling, and Submission section for specimen-labeling details.
- Add fresh aspirate to dry collection container. Note: The entire collected specimen should be submitted for cytological processing. It is the opinion of Inform Diagnostics’ pathologists that the yield and diagnostic sensitivity is increased when the entire specimen is received for cytological reparation and interpretation.
- DO NOT add fixative. The water content in the fixative will destroy any crystals that may be present.
- Refer to the Specimen Packaging and Submission section for further instructions.

Cytology Fluids

Fluids Accepted
- Bladder washings
- Bronchial washing and lavage fluid
- Joint fluid
- Pleural and ascitic fluid
- Pelvic and abdominal fluid

Collection Instructions
- Refer to the Specimen Collection, Labeling, and Submission section for specimen-labeling details.
- Fix fluid by mixing with equal amounts of 50% ethanol or 70% isopropyl alcohol (available in the hospital surgical area). Submit joint fluid in 10 ml purple-top tube containing anti-coagulant EDTA (provided by Inform Diagnostics). Mix well by inverting tube several times.
- Refer to the Specimen Packaging and Submission section for further instructions.
## Revisions

<table>
<thead>
<tr>
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<th>Effective Date</th>
<th>Reason for Change</th>
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<tr>
<td>0</td>
<td>05/09/2012</td>
<td>This document replaces the previously uncontrolled Client Resource Guide. Complete rewrite to conform to regulations and clarification.</td>
</tr>
<tr>
<td>1</td>
<td>08/20/2014</td>
<td>Changed document # from MLS-19-0100 to MLS-20-0100 to align with current numbering scheme. Added clarification to document.</td>
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<tr>
<td>2</td>
<td>07/31/2016</td>
<td>Added sections on Baylor Genetics and Breast pathology; revised all other sections. Created MLS-20-0100F1.0 for Test Menu.</td>
</tr>
<tr>
<td>3</td>
<td>05/07/2019</td>
<td>Changed branding to Inform Diagnostics. Added section on Flow Cytometry. Added neuropathology offerings from Therapath. Updated other sections throughout document.</td>
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Appendix: Test Menu
Inform Diagnostics offers anatomic pathology, therapeutic drug monitoring, genomic testing, and non-gynecological cytopathology services.

### Special Stains
- AFB (Kinyoun’s)
- Alcian Blue
- Alcian Blue PAS
- CAE (Leder)
- Collodial Iron
- Congo Red
- Copper
- Crystal Violet (Lieb’s)
- Elastic
- Fite
- Fontana
- Giemsa
- GMS
- Gram
- Iron
- Melanin Bleach
- Mucin
- PAS
- PAS with Diastase
- Reticulin
- Steiner
- Thioflavin T
- Trichrome
- Von Kossa

### Antibodies, continued

<table>
<thead>
<tr>
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<tbody>
<tr>
<td>CD15</td>
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<td>Granzyeme B</td>
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### Antibodies, continued

<table>
<thead>
<tr>
<th>Antibodies, continued</th>
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<tbody>
<tr>
<td>HCG</td>
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<tr>
<td><em>Helicobacter pylori</em></td>
</tr>
<tr>
<td>Hepatocyte</td>
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<tr>
<td>HER2/Neu</td>
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<tr>
<td>HHV8</td>
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<tr>
<td>HMB45</td>
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<tr>
<td>HSV I</td>
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<tr>
<td>HSV II</td>
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<td>IgD</td>
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<td>IgM</td>
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<tr>
<td>Inhibin, Alpha</td>
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<tr>
<td>KBA62</td>
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<tr>
<td>Ki-67</td>
</tr>
<tr>
<td>Lysozyme</td>
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<tr>
<td>Mammaglobin</td>
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<tr>
<td>MART-1/Melan-A</td>
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<tr>
<td>MiTF</td>
</tr>
<tr>
<td>MLH1</td>
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<tr>
<td>MSH 2</td>
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<td>MUC2</td>
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<td>MUM-1</td>
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<tr>
<td>NKX3.1</td>
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<td>NSE</td>
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<td>p504s</td>
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<td>p53</td>
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<td>p63</td>
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<tr>
<td>Pan Keratin (mnf116)</td>
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<tr>
<td>PanKeratin (OSCAR)</td>
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<td>PAX-5</td>
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<td>Perforin</td>
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<td>PLAP</td>
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<tr>
<td>PMS 2</td>
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<td>PSMA</td>
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<td>PTEN</td>
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<td>RCC</td>
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</tbody>
</table>
**Antibodies, continued**

S100
Smooth Muscle Myosin
Synaptophysin
T Paliidum (Spirochete)
TCR BF1
TDT
TIA-1
Tryptase
TTF-1
Tyrosinase
Uroplakin
Varicella Zoster
Villin
Vimentin
WT-1

**Antibody Cocktails**
Basal Cell Cocktail
Harmony Cockail (MART-1/Tyrosinase)
HSV I/II
Melanoma Cocktail/Tyrosinase
PIN-4
PIN-4/ERG

**Double-Stain IHC**
CD3/CDX2
CD31 & AE1/AE3
CD56/Synaptophysin
CD8/CDX2
CYCLIN D1/CD138
CYCLIN D1/CD20
D2-40/AE1-AE3
HMW/p63
HMW/S100
Ki-67/CD20
Ki-67/MART-1
PAX5/CD5

**ISH Antibodies**
EBER
Kappa
Lambda

**Direct Immunofluorescent Stains**
Albumin
IgA
IgG
IgM
C3
Fibrin

**Additional Tests**

**For Breast pathology:**
ER/PR/HER2/Ki-67/p53 (IHC)
HER2 FISH
HER2 CISH
BRCA1 and BRCA2 Screening
High-Risk Hereditary Breast Cancer Panel
OncAware Complete

**For GI pathology:**
Therapeutic Drug Monitoring for IBD patients

**For Uropathology:**
Urinary UroVysion™ FISH assay
PINgenius® for HGPIN
PTEN & ERG IHC
PTEN IHC only
Confirm MDx™ epigenetic assay (send-out test)
KnowError® (send-out test)
Oncotype DX® (send-out test)
Prolaris® (send-out test)
Decipher® (send-out test)

*Contact Client Services for questions about new or discontinued tests.*