Emeritus
MEDICAL TECHNOLOGY

Client Resource Guide

EmeritusDX
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Email: contact@emeritusdx.com

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Our Mission

EmeritusDX is a cancer diagnostics and information company that is dedicated to patient care. Within our world-class CAP accredited and CLIA certified laboratory, our mission is to save lives through providing better diagnostics and actionable clinical information. We solve medical, scientific, and logistical issues in order to improve patient care, diagnosis and treatment. Our customer and partner relationships are important to us in achieving our vision that,

"Together, we save lives."

Contact Information

EmeritusDx
12 Spectrum Pointe Dr, Lake Forest, California 92630
Monday-Saturday 9:00am to 6:00pm

Freedom Pathology
524 East Elm Street, Conshohocken, Pennsylvania 19428
Monday – Saturday 9:00am-6:00pm

Phone 800-959-2846
Fax 610-465-8962
contact@emeritusdx.com

About Our Quality Assurance

EmeritusDX has a robust end-to-end quality assurance program. Our quality measures include many unique activities:

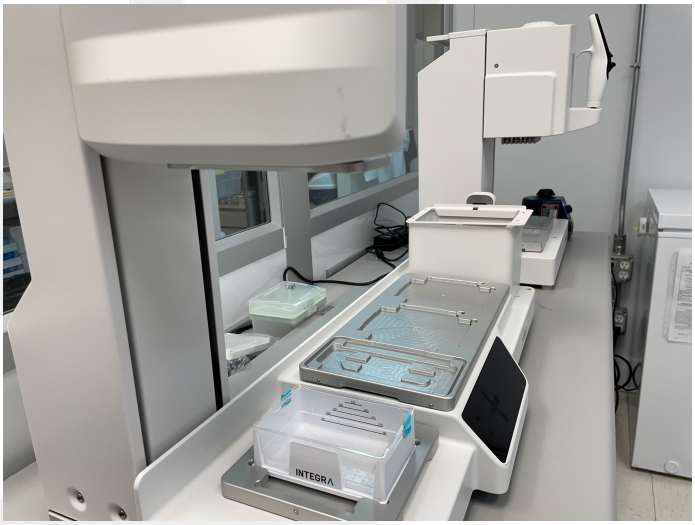
- Emeritrak, an electronic point-to-point tracking service for couriered samples
- Barcodes for all specimens
- Video recording of package opening and specimen grossing
- Secured work area
- Click-seal specimen jars to help reduce specimen leakage
- Random retrospective reviews of pathologists' cases to check accuracy
- Collaboration by pathologists to set consistent criteria, terminology, and evaluation protocols
- Secured shipping boxes to reduce specimen damage during transit

General Information

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 EmeritusDX.

Medical Necessity



The Centers for Medicare and Medicaid Services (CMS) is responsible for administering Medicare and other federally funded 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 EmeritusDX only to perform tests that are medically necessary for the diagnosis and treatment of the patient.

(Medical Necessity con't)

Some insurance carriers request additional medical information in order to approve medically necessary tests. In most cases, the information required and/or requested on the pathology requisition is sufficient to demonstrate medically necessity to most insurance carriers. EmeritusDX requires a completed pathology requisition for each specimen submitted. Refer to "Requisition Requirements" for more information.

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 some adjunct services beyond immunohistochemistry, the client may be contacted for approval. In some circumstances, EmeritusDX may contact your office to request additional patient information in order to submit or re-submit a claim to 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 have additional requirements, and we will contact you accordingly.

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

**EmeritusDX may be able to offer payment plans or other arrangements to patients. Please instruct patients to contact EmeritusDX directly at our toll-free number.*

Patient Privacy/HIPAA

EmeritusDX 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).

Patient Requests for Pathology Reports

Patients have the right to request their pathology report directly from EmeritusDX. They also may direct EmeritusDX to transmit copies of their pathology report to persons or entities of their choosing.

Licensure, Certifications and Credentialing

EmeritusDX maintains appropriate and required licensure for all locations. Current licensure information can be found on our website at: https://emeritusdx.com/licensure

If you require information about credentialing for our pathologists, please contact us directly.

Testing 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.

EmeritusDX is unable to provide services to any clients that do not meet regulatory requirements. It is the responsibility of the client to be aware of and meet all federal and state regulations that apply.

Proficiency Testing/Peer Review

EmeritusDX does not perform CAP proficiency testing for clients. However, EmeritusDX does provide peer-review contracted services for CLIA-accredited TC/PC clients.

The fee for this peer-review service will be billed to your office.

Billing Information

EmeritusDX is currently contracted with several U.S. payors.

Each pathology requisition must include patient insurance information or other billing instructions, as well as 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 permitted to order laboratory testing. We require the ordering physician/clinician NPI number in order to properly identify all authorized providers.

Patients should remember an Explanation of Benefits (EOB) received from an insurer is not an invoice.

Reflex Testing

EmeritusDX recognizes the ability of clinicians to order testing believed to be medically necessary for the diagnosis and/or treatment of patients.

Reflex testing is that which is subsequently ordered when the results of the initial testing meet certain established criteria. For Urology, Dermatology, and Gastroenterology clients, EmeritusDX requires an Approved Protocol Form in order to authorize reflex testing in advance when established criteria is met. If an Approved Protocol Form is not file with EmeritusDX, our pathologists may order reflex testing based on best practices and defined standards of care.

Send-Out Testing

In some instances, specimens may require additional specialized testing performed by an outside laboratory. Outside laboratories maintain their own billing practices and policies and may bill directly for testing performed.

Turnaround Time

EmeritusDX provides rapid turnaround time without compromising quality. In general, anatomic pathology and cytopathology reports will be generated within 48 hours of being received at the lab. Any subsequent testing or additional immunohistochemistry stains may cause a delay.

Transportation or additional testing may impact turnaround time. For urgent cases, please contact Client Services and identify the case as **STAT**. EmeritusDX uses the term **STAT** to identify any case where it is medically necessary to receive expedited pathology results.

Pathology Orders and Report Delivery

Pathology orders may be sent via either of the following:

- Interface to your EHR/ERW
- Paper requisition

Pathology results can be delivered using any of the following methods:

- Fax
- Email
- Interface to your EHR/ERW
- Our web-based VitalDx portal

EmeritusDX may provide software, equipment, or services to clients for installation of an interface. Equipment and supplies provided by EmeritusDX must be used exclusively for transmitting pathology requests and results with EmeritusDX.

(Pathology Orders and Report Delivery con't)

EmeritusDX maintains ownership of all provided hardware and supplies. This equipment must be returned to EmeritusDX should pathology services no longer be needed. In addition, printer toner will be provided based on actual use. Use is estimated from typical toner usage based on the efficiency of the equipment provided and the exclusive use of equipment based on your case volume with EmeritusDX.

EmeritusDX reserves the right to discontinue the use of equipment at any time.

Medical Records/Slide Release

For the release of medical records, EmeritusDX requires a signed Release of Medical Records. EmeritusDX 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, EmeritusDX 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 EmeritusDX pathologist.

Allow 48 hours for laboratory processing before materials are shipped. All materials must be returned intact within 30 days unless expressly allowed by EmeritusDX in advance.

The slides/blocks cannot be released to a third party without prior permission from the patient and/or ordering physician. The recipient must agree to take full responsibility and assume chain of custody of the requested materials until returned to EmeritusDX.

Specimens Requiring Cultures/Microbiologic Testing

Specimens for cultures should be referred to a clinical reference laboratory. EmeritusDX does not accept specimens requiring cultures, including stool samples and sputum.

EmeritusDX does not perform microbial cultures or antimicrobial sensitivity testing. Specimens requiring microbiologic cultures and/or antimicrobial sensitivity testing must be referred to a local clinical laboratory or reference laboratory specializing in microbiologic testing to assure optimal specimen viability.

Accidental Receipt of Specimens

EmeritusDX occasionally receives specimens for tests not performed at EmeritusDX, such as Stone Analysis and Urine Culture. Client Services will attempt to contact the sender for direction. The specimen will either be returned to the sender or forwarded to an alternate laboratory.

Radioactive Materials

EmeritusDX does not accept tissue containing radioactive materials.

Sharps

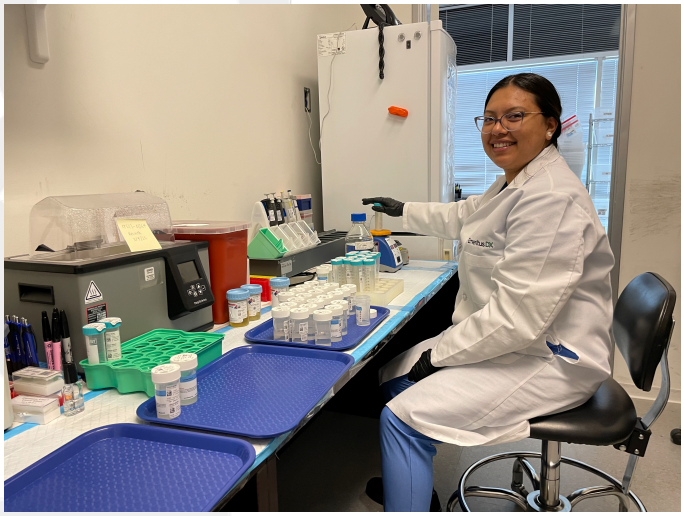
Specimens including blades and needles will not be accepted.

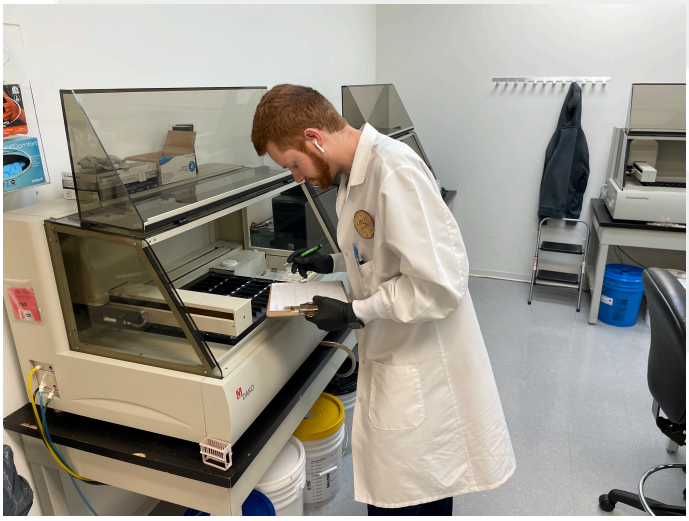
Consultations

The pathologists at EmeritusDX 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.

Delivery of Services

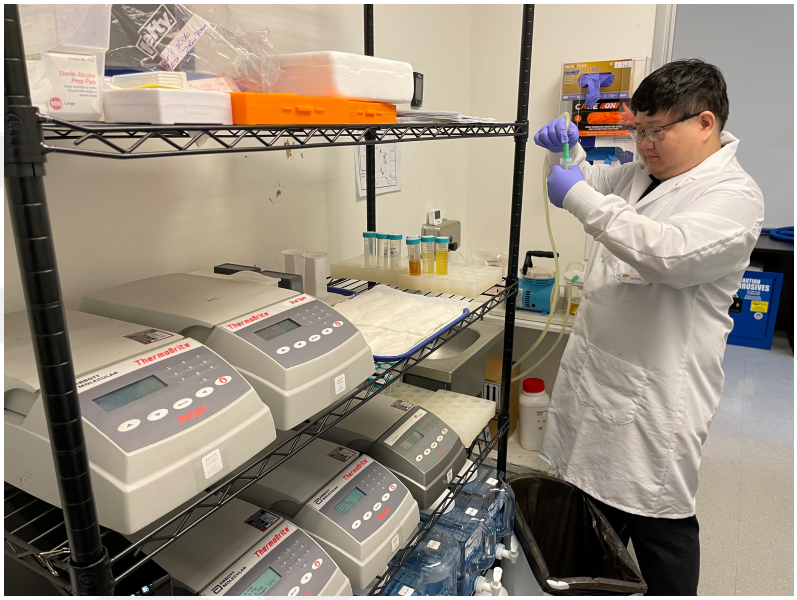
EmeritusDX endeavors to provide reliable and valued services to our clients. However, EmeritusDX reserves the right to add or discontinue services to correspond with changing business needs. Please note that inclusion in this Client Resource Guide is not a guarantee that all listed services and tests will continue to be offered in the future.





Specimen Collection, Labeling and Submission

EmeritusDX is committed to providing clients and patients with high-quality service through all phases of the laboratory experience. To assist us in providing exceptional service, we ask all clients to use supplies provided by EmeritusDX and to follow certain general guidelines.



Items Supplied to Clients

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

Supplies

- Urine Collection Cups
- Biohazard Bags
- Fedex Shipping Supplies
- 10mL Biopsy Containers
- Prostate Biopsy Kits
- Requisitions
- Vacutainers (UTI Collection Kits)
- Lockbox

Professional Component Supplies

- Slide folders/trays

Contact Client Services to obtain a Supply Order Form.

Requisitions for All Specimens

Certain elements are required under the CLIA (Clinical Laboratory Improvement Amendments) requisition requirements 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. Patient's first and last name (no nicknames, no initials)
2. Date of birth
3. Patient gender
4. Address, including apartment # if applicable
5. Patient insurance information or other billing instructions, with an attached copy of the front and back of the patient's insurance card
6. Date of collection
7. Specimen source
8. 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)
9. Test requested
10. ICD-10 code(s)
11. Name and address of ordering clinician
12. Authorized ordering provider

Tissue Collection Instructions

- Tissues should be placed in 10% neutral 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 types of toweling as they absorb the fixative. 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.).
- 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 (should hear a click).

Acceptable Transport Media

- FFPE Block
- Histopathology - Formalin-fixed tissue
- Urine - >30mL urine in PreservCyt solution
- UTI – BD Gray Top Vacutainer or Sterile Urine

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. An Additional Information Required Form may be necessary to complete specimen processing.

Additional Container Labeling

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

Labeling and Preparing Slides

- Each slide must be marked with two patient identifiers, per CAP requirements. Use a 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.
- Place specimen on the same side as the label. If multiple specimen sources are sent on the same patient, identify specimen source on each slide. (For example, for right Vas Deferens, mark “R” on slide, and for left Vas Deferens, mark “L” on slide).
- Place slides into a slide holder.
- Wrap slides securely with bubble wrap or rubber bands to ensure that slides do not shift or break during transit.
- 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 delayed processing. An Additional Information Required Form may be necessary to complete processing.

DOT Packaging

This guide outlines the requirements for shipping biological specimens. In addition, all shipments must comply with applicable local, state, and federal laws governing the packing, marking, and labeling of shipments containing biological specimens. Blood, urine, other body fluids, and other specimens containing or suspected to contain infectious substances must be shipped according to applicable government, International Air Transport Association (IATA), and International Civil Aviation Organization (ICAO) regulations. Per federal regulations, these are classified as Dangerous Goods under UN3373, Category B, Infectious Substance. All packaging must include the UN3373 mark and the wording BIOLOGICAL SUBSTANCE, CATEGORY B.

General Packaging Requirements

- **Specimen Container:** Use watertight containers with a positive closure (ClikSeal™cup). *Take special care to secure the lid tightly.* If multiple fragile primary containers are placed into a single secondary container, each must be individually wrapped or separated to prevent contact between them during shipping.
- **Sealed Plastic Bag:** Place specimen along with absorbent material into biohazard bags. Note that biohazard bags available from EmeritusDX include absorbent material and have an outer sleeve where corresponding paperwork can be inserted.
- **Sturdy Outer Packaging:** The rigid outer box is the carrier package designed for transit and shipping. This rigid outer box must be a new box provided by EmeritusDX. Do not re-use any box, including boxes sent from EmeritusDX to transport supplies. Couriers picking up for Fedex service are instructed not to pick up any box that has the appearance of being re-used. Chipboard or paperboard boxes are unacceptable.

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 before a holiday. If you are unsure which location to send a specimen, please contact Client Services.
With your specimens, include a Specimen Log/Manifest that lists all enclosed specimens. These logs can be faxed or emailed in advance and will assist in notifying the lab of expected incoming samples. If expected specimens are not received, we will notify you. Contact Client Services for a Specimen Log template.

Sending via Fedex

EmeritusDX provides pre-labeled boxes for shipping to our labs. When you request shipping materials for Freedom Pathology (specifically Fedex Clinical Boxes), the return service label (RSL) will be affixed to the package. For unlabeled boxes, RSL receipt tickets are found at the top of the tracking labels. To remove, pull the receipt ticket until it detaches from the backing. It is recommended to use these stickers in client offices to track outbound packages.

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Fedex Boxes

If you ship via FedEx, please use a FedEx Clinical Box, which provides higher visibility to FedEx employees. These labels can be ordered from EmeritusDX.

Specimen Storage

All specimens in fixatives (other than DNA Extraction) can be stored at room temperature.

During hot summer months - May 1 to September 30 - store and ship all specimens, blocks and slides on ice, particularly paraffin blocks.

Be mindful of freezing temperatures during cold months (November – April). If placed in lockboxes in non-climate-controlled areas, specimens can freeze affecting viability. If lockboxes must be stored outdoors, place samples outside as close to your pickup window as possible.

Specimens not in fixative must be refrigerated.

On rare occasions, weather or other extenuating circumstances may probity routine transport of specimens. The same store requirements would apply until routine transportation resumes.

Specimen Pick Up

Specimens from clinicians will be arranged for pick up by Fedex or local courier. Contact Client Services for more information.

If you wish to change your pickup details (ex. Day(s) of the week, time of day, or pick up location), contact Client Services immediately. Please DO NOT give instructions directly to the courier or carrier driver. “Will-Call” pickups are available as an exception to your regular service schedule and can be arranged through Client Services. Please provide at least three hours for before your desired pickup time.

Dermatopathology

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

Tissue Types Accepted and Not Accepted

Specimen Types Accepted:

- Skin
- Oral, vulvar and penile mucosa
- Conjunctiva
- Nail Clippings
- Sentinel lymph notes

Specimen Types 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.
- Nail clippings and skin scrapings should be placed in a dry container.
- Specimens sent with a needle attached to the syringe will be sent back to the client.

Additional Diagnostic Offerings

- Melanoma FISH
- 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 stating and examination

- Note: The treating clinician may be required to appeal their services with the insurance provider.

WoundDX™

PCR can be employed to detect the presence of specific microorganisms, such as bacteria or fungi, in a wound. PCR can aid in the diagnosis of certain conditions that may affect wound healing, such as underlying genetic disorders and autoimmune diseases.

Recognizing that each patient is unique, we develop personalized treatment plans based on a thorough assessment of your wound, medical history, and overall health, ensuring the best possible outcomes.

Specimen Type

- Swab

Container

- Copan eSwab w/Amies, 1mL of eSwab Fluid (pre packaged) with swab collected from patient, labeled with two unique patient identifiers

Podiatry Services

EmeritusDX offers comprehensive menu of industry-leading diagnostics using:

- Histology
- Immunohistochemistry
- PCR testing for –
  - Skin disorders
  - Nail disorders
  - Soft tissue injuries
  - Tumors neuropathies
  - Arthritic conditions

Sample Types Accepted and Not Accepted

- Skin
- Nail
- Soft Tissue
- Bone
- Bacteriology/Swab (See pg. 18 for information on WoundDX™)

Gastrointestinal Pathology

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
- Cytologic specimens of the GI tract, including brushings, washings and fine needle aspirates
- Previously prepared slides for second opinion (consultation)
- Tissue blocks

Specimen Types Not Accepted

- Any specimen that does not appropriately fit into the provided specimen jar
- Specimens requiring cultures
- Specimens for CLO testing

Fixative

- Biopsies and excisions for routine histologic examination: 10% neutral buffered formalin
- Colonic, esophageal, gastric washings, and brushings: 95% ethanol

Insurance Information

- General rules for screening colonoscopies to be covered under preventive benefits:
  - The patient must be 45 years of age or older and be asymptomatic for signs or symptoms of colon cancer.
  - If a polyp is biopsies on an asymptomatic patient, most commercial payors will cover pathology services under preventive benefits. However, Medicare will still require patient coinsurance for pathology services.

BE FISH & BE FISH +

Specimen Type

- FFPE Block
- Biopsy Tissue
- Unstained Slides

FFPE Block

- Must be labeled with two patient identifiers, if unable to mark block with identifiers, container must be labeled instead

Biopsy Tissue

- Refer to Gastrointestinal Pathology for further instructions
- Tissue should be submitted in 10mL formalin container with two unique patient identifiers

Unstained Slides

- BE FISH : 5-6 Unstained slides, 4 microns, each slide should be labeled with two unique patient identifiers. If unable to mark slides with identifiers, slide holder must labeled instead
- BE FISH+ : 10 Unstained slides, 4 microns, each slide should be labeled with two unique patient identifiers. If unable to mark slides with identifiers, slide holder must labeled instead

Urologic Pathology

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/Specimen Types NOT Accepted:

- Kidney biopsy performed for renal disease
- Kidney/renal stones*

*Stones received at EmeritusDX are forwarded to Dianon/LabCorp for processing. Dianon/LabCorp is responsible for reporting results directly to ordering physicians. Results will **not** be sent from EmeritusDX.

Standard Processing

- EmeritusDX will provide 14-part kits. Best practice is 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.**
- 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 be sure to use a Fedex label with Saturday delivery indicated.

Collection Instructions for Urine Cytology and Bladder FISH Requests

- Collect urine specimens for cytology evaluation and Bladder FISH examination in provided kit maintaining 2:1 ratio (2 parts urine, 1 part fixative). Use only collection materials provided by EmeritusDX.
- If Bladder FISH is requested, preferred volume is at least 33mL. If the urine volume is less than 33mL, the assay will be attempted, however the cell yield may be insufficient for analysis. If insufficient for analysis, a new specimen may be requested.
- In general, catheterized and neobladder specimens are not optimal for Bladder test as they may have an insufficient quantity of urothelial cells.
- Best practice and preferred range for urine specimens requiring Bladder is 72 hours. However, the specimen may still be viable for up to three weeks after receipt at EmeritusDX if

(Collection Instructions for Urine Cytology and Bladder FISH Requests con't)

the recommended collection method was followed. EmeritusDX cannot guarantee viability after 72 hours, but will keep all specimens on site for three weeks after receipt.

- 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 Bladder FISH testing, select ICD10 codes as required on the requisition.
- Cytology and Bladder FISH turnaround time: 96 to 144 hours

Additional Requirements for Bladder FISH Payor Coverage

- Initial diagnosis: Bladder FISH may be performed based on atypical cytology results. Hematuria is not considered a medically necessary condition for Bladder FISH testing.
- Surveillance (previous diagnosis of bladder cancer): Order must indicate personal history of bladder cancer and/or ICD10 code Z85.51.
- Bladder FISH may be performed based on:
    - Equivocal cytology results (for low-grade bladder cancer)
    - Negative or equivocal cytology results (for high-grade bladder cancer)

Voided Urine Specimen Collection and Handling

- Refer to the Specimen Collection, Labeling and Submission section for labeling details.
- Use the provided urine collection cup.
- Collect 30 cc urine into white cap specimen jar.
- Add 2:1 ratio of preservative solution to the urine in the specimen jar for a total of approximately 45 cc.
- If volume of urine is less than 30 cc, attempt to keep a 2:1 ratio of urine and fixative.
- Tighten the white cap on the specimen jar until it clicks, then continue tightening another quarter turn to complete the seal.

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 fixative keeping at 2:1 ratio.
- Tighten the white cap on the specimen jar until it clicks, then continue tightening another quarter turn to complete the seal.

MetaDX™

Specimen Type
- FFPE Block
- Biopsy Tissue
- Unstained Slides

FFPE Block
- Must be labeled with two patient identifiers, if unable to mark block with identifiers, container must be labeled instead

Biopsy Tissue
- Tissue should be submitted in 10mL formalin container with two unique patient identifiers

Unstained Slides
- 10 Unstained slides, 4 microns, each slide should be labeled with two unique patient identifiers. If unable to mark slides with identifiers, slide holder must labeled instead

UTIDX™ & UTIDX™ F-AST

Specimen Type
- Urine: Voided (clean catch midstream) or catheterized

Container
- 1 gray top Vacutainer with preservative, minimum volume to fill line (4mL), labeled with two unique patient identifiers

STIDX™

Specimen Type
- Urine: Voided (First Void) or catheterized

Container
- 1 gray top Vacutainer with preservative, minimum volume to fill line (4mL), labeled with two unique patient identifiers

Prostatitis

Specimen Type

- Post Prostate Massage (DRE) Urine or Semen Sample

Post Prostate Massage Urine

- 1 gray top Vacutainer with preservative, minimum volume to fill line (4mL), labeled with two unique patient identifiers

Semen

- 1 sterile cup with boric acid liquid, minimum 2mL of sample added to 8mL preservative. Sample must be labeled with two unique patient identifiers

Urinalysis

Specimen Type

- Urine: Voided (clean catch midstream) or catheterized

Container

- 1 Tiger top Vacutainer, minimum volume to fill line (4mL), labeled with two unique patient identifiers

Bladder17™

Specimen Type

- Urine: Voided, bladder or catheterized

Container

- 1 specimen container with PreservCyt solution, 30mL urine mixed with 15mL PreservCyt solution (2:1 ratio), labeled with two unique patient identifiers

Pre-Prostate Biopsy Rectal Swab (PPBRS)

Specimen Type

- Rectal Swab

Container

- Copan eSwab w/Amies, 1mL of eSwab Fluid (pre packaged) with swab collected from patient, labeled with two unique patient identifiers

Additional Diagnostic Offerings

Additional diagnostic offers are available on the Urology Requisition. Advanced Protocols can be setup for reflex testing.

- **Urine UroVysion™ FISH** assay is available as a standalone test or reflex test with urine cytology. This test enhances the detection of urothelial carcinoma. UroVysion FISH can be performed as a standalone only when the patient has a prior history of bladder cancer. All other UroVysion FISH testing will require positive cytology results, excluding hematuria only.
- **ERG** is available as a reflex test on prostate biopsies with HGPIN. This test predicts the risk of prostate cancer at re-biopsy.
- **Prolaris®** is available as a send-out reflex test upon the diagnosis of localized prostate cancer, to personalize risk stratification.
- **ConfirmMDx™** 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.
- **Decipher®** is available as a send-out reflex test on prostate biopsies.

General Surgical Pathology

Accepted

- Gynecology
  - Cervical biopsy
  - Endometrial biopsy
  - Endocervical curettage/curetting
  - LEEP biopsy
  - CONE biopsy
  - Fallopian tubes
- Oral and laryngeal tumors
- Sino nasal polyps and mucosa
- Fine Needle Aspirations
- Lymph node Mediastinum Pancreas Parotid
- Soft tissue Thyroid
- Cytologic Brushings
  - Esophageal Bronchial
- Fluids
  - Bladder washings
  - Bronchial washings and lavage fluid
  - Joint fluid
  - Pleural and ascitic fluid
  - Pelvic and abdominal fluid

Not Accepted

- Any specimen that does not fit easily in 240ml or 500 ml containers (provided)
- Products of conception (with identifiable fetus)
- Kidney biopsy for non-neoplastic disease
- Tissue for culture
- Known of suspected CJD/Prion samples

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. EmeritusDX 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 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.
3. If multiple specimen sources are sent on the same patient, identify the specimen source on each slide.
4. Place slides into slide holder.

Improperly labeled slides will result in a delay of specimen processing. An AIR form may be necessary to complete specimen processing.

Cytologic Brushings -*Esophageal, Bronchial, Colon, Rectum, Anal*

- Refer to Specimen Collection, Labeling and Submission section for specimen-labeling details.
- Immediately after collection, place each brush into a separate vial of PreservCyt fixative that is labeled with patient ID and area brushed (nodular or pan).
- Free cells from brush into PreservCyt as quickly as possible by rotating the brush in the solution 10 times and then swirling the brush vigorously.
- Snip off the brush in the PreservCyt solution and tighten the cap.

Cytology Fluids – *Bladder Washings*

- Refer to Specimen Collection, Labeling and Submission section for specimen-labeling details.
- Submit sample in vial of PreservCyt fixative that is labeled with patient ID.
- Refer to Specimen Packaging and Submission section for further details.

Women's Health

Sample Types

- PAP and HPV
- Cervical FISH
- Her2 FISH

Brushing

- Refer to Specimen Collection, Labeling and Submission section for specimen-labeling details.
- Immediately after collection, place each brush into a separate vial of PreservCyt fixative that is labeled with patient ID and area brushed (nodular or pan).
- Free cells from brush into PreservCyt as quickly as possible by rotating the brush in the solution 10 times and then swirling the brush vigorously.
- Snip off the brush in the PreservCyt solution and tighten the cap.

Biopsy Tissue

- Tissue should be submitted in 10mL formalin container with two unique patient identifiers

Unstained Slides

- 5-6 Unstained slides, 4 microns, each slide should be labeled with two unique patient identifiers. If unable to mark slides with identifiers, slide holder must labeled instead