Emeritus
MEDICAL TECHNOLOGY

Client Resource Guide

EmeritusDX
12 Spectrum Pointe Drive
Lake Forest | CA | 92630
Phone: 800-959-2846
Email: cs@emeritusdx.com

Table of Contents

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 Drive, Lake Forest, CA 92630
Monday-Saturday 9:00am to 6:00pm

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

Phone 800-959-2846
Billing 949-374-5019
Fax 949-418-7287
Client Services cs@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.

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 medical 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.

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 via Interface or paper requisition.

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

- Fax
- Email
- Interface via EHR/ERW
- 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.

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.

Accidental Receipt of Specimens

EmeritusDX occasionally receives specimens for tests not performed at EmeritusDX. 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

- Collection Cups
- Biohazard Bags
- FedEx Shipping Supplies
- Biopsy Containers
- Prostate Biopsy Kits
- Requisitions
- Vacutainers
- Swabs
- 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:

- Patient's first and last name (no nicknames, no initials)
- Date of birth
- Patient gender
- Address, including apartment # if applicable
- Patient insurance information or other billing instructions, with an attached copy of the front and back of the patient's insurance card
- Date of collection
- Specimen source
- 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)
- Test requested
- ICD-10 code(s)
- Name and address of ordering clinician

- 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 Preservative solution
- UTI – BD Gray Top Vacutainer or Sterile Urine
- UA – Tiger Top Vacutainer or Sterile Urine
- Swab
- Brushings (with preservative)
- PAPs (ThinPrep)

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.

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 with an ice pack, 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 prohibit routine transport of specimens. The same storage 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

For dermatology cases, please send detailed patient history, office visit notes, and a clinical photo via your EHR with the electronic order or requisition. This information helps our pathologists make a more accurate diagnosis, as histologic patterns can match multiple conditions.

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 Wound
- Skin disorders
- Nail disorders
- Soft tissue injuries
- Tumors neuropathies
- Arthritic conditions

Sample Types Accepted and Not Accepted

- Skin
- Nail
- Soft Tissue
- Bacteriology/Swab (See WoundDX)

Sample Types Not Accepted

- Bone

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
- Brushings (with preservative)

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

KRAS therascreen®

KRAS is a real-time, qualitative in vitro diagnostic test for the detections of 7 somatic mutations in the KRAS oncogene. Therascreen KRAS is an FDA-approved companion diagnostic PCR Test intended to aid in the identification of NSCLC patients for treatment.

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

- 5-6 Unstained slides at 4-5 µM. One matching H&E-stained slide. Each slide should be labeled with two unique patient identifiers. If unable to mark the slides with identifiers, slide holder must be labeled instead.

BRAF therascreen®

The therascreen BRAF test enables qualitative detection of V600E mutations in the BRAF gene. It is an FDA-approved CDx assay to identify patients with cases of metastatic colorectal cancer for whom treatment with BRAFTOVI in combination with cetuximab may be appropriate.

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

- 5-6 Unstained slides at 4-5 µM. One matching H&E-stained slide. Each slide should be labeled with two unique patient identifiers. If unable to mark the slides with identifiers, slide holder must be labeled instead.

GI Detect™

GI Detect™ is a revolutionary diagnostic test that swiftly identifies a broad spectrum of pathogenic organisms that can affect gastrointestinal health. This test leverages advanced molecular diagnostics to detect bacteria, viruses, and parasites that are often the culprits behind common and complex gastrointestinal disorders.

Specimen Type

- Stool

Container

- Copan FecalSwab

Requirements

- Samples must be received by the lab within 3 days of collection.

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 30mL. If the urine volume is less than 30mL, 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 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: 72 to 120 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 30mL urine into cap specimen jar.
- Add 2:1 ratio of preservative solution to the urine in the specimen jar for a total of approximately 45mL..
- If volume of urine is less than 30mL, attempt to keep a 2:1 ratio of urine and fixative.
- Tighten the 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.

UTIDX® & UTIDX®F-AST

UTIDX® is a urine based test designed to identify pathogens commonly associated with recurrent or persistent urinary tract infections while determining the best treatment options for the patient.

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

STIDX is a urine based test designed to identify pathogens commonly associated with sexually transmitted infections.

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

ViralDX

ViralDX is a urine test aimed at detecting pathogens typically linked to sexually transmitted infections, along with testing for additional viruses, including JC and BK Virus.

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

Our Prostatitis tests is a post-massage urine and/or semen based test designed to identify pathogens commonly associated with acute or chronic prostatitis while determining the best treatment options for the patient.

Specimen Type

- Post Prostate Massage (DRE) Urine
- 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

Quantitative Urinalysis*/Urinalysis

The Automated Urinalysis test is a user-friendly, automated analyzing system for the quantitative analysis of fifteen analytes in human urine.

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

*Not available for New York practitioners.

Bladder17®

Bladder17® provides sensitivity and specificity to significantly improve the diagnosis and treatment of bladder cancer patients and is compatible with all standard immunohistochemistry systems. With 100% Sensitivity and 96% Specificity, current data suggests Bladder17® is the most sensitive/specific test for bladder cancer.

Specimen Type

- Urine: Voided, bladder or catheterized

Container

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

Pre-Prostate Biopsy Rectal Swab (PPBRS)

PPBRS is a rectal-swab based test designed to identify the presence of pathogens commonly associated with infection post-surgery.

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

Women's Health

PAP and HPV

While squamous cell carcinoma has steadily decreased since the introduction on the Pap smear, adenocarcinoma remains an area of great concern. The ability to detect adenocarcinoma is an essential part of comprehensive cervical cancer screening.

Specimen Type

- Cervical Brushing

Container

- ThinPrep

Brushing

- Refer to Specimen Collection, Labeling and Submission section for specimen-labeling details.
- Immediately after collection, place each brush into a separate vial of preservative that is labeled with patient ID and area brushed (nodular or pan).
- Free cells from brush into preservative 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 preservative solution and tighten the cap.

CT/NG/BV/CV/TV/MGen

Specimen Type

- Vaginal Swab

Container

- Aptima® Tube

Brushing

- Refer to Specimen Collection, Labeling and Submission section for specimen-labeling details.
- Immediately after collection, place swab into a separate vial of preservative that is labeled with patient ID and area swabbed.
- Break shaft of swab at the score line and discard top portion.
- Close tube and tighten the cap.

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

- 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.

- Place specimen on the same side as the label.
- If multiple specimen sources are sent on the same patient, identify the specimen source on each slide.
- 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 preservative that is labeled with patient ID and area brushed (nodular or pan).
- Free cells from brush into preservative 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 preservative 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 preservative that is labeled with patient ID.
- Refer to Specimen Packaging and Submission section for further details

Therapeutic Offerings

MMR

IHC can be used to detect MMR deficiency ((MLH1, MSH2, MSH6, and PMS2) in bladder cancer. Tumors with MMR deficiency are often high-grade and invasive. They may also be more likely to occur in males and be located in the bladder or ureters. Pembrolizumab and nivolumab are approved for treating certain tumors with MMR deficiency or MSI-H. MMR status is a promising predictive biomarker for immunotherapy.

PDL-1

Programmed death ligand 1 (PD-L1) is a protein that can be expressed on tumor cells or immune cells in bladder cancer. PD-L1 expression is associated with poor responsiveness to bacillus Calmette–Guérin (BCG) immunotherapy. PD-L1–positive tumors are associated with improved prognosis among patients with metastatic urothelial carcinoma who receive Immune check point inhibitors.

FGFR3

Fibroblast growth factor receptor 3 (FGFR3) is an actionable prognostic and therapeutic target in bladder cancer (BC). FGFR3 mutations are common in noninvasive BC and associated with favorable BC prognosis. About 75% of low-grade papillary bladder tumors have activating mutations of FGFR3. About 20% of muscle-invasive bladder tumors have FGFR3 mutations, and about half of cases overexpress FGFR3. Overexpression and or mutations were reported in up to 40% of FGFR3 wild-type muscle-invasive BC. **Erdafitinib (Balversa) targets FGFR3 mutations in bladder cancer which regulates cell growth and** division, it has been shown to be at least as effective as chemotherapy without the toxic side effects. **R3Mab**, a monoclonal antibody that targets FGFR3 has been shown to inhibit tumor growth in preclinical studies.

Her2

IHC testing for HER2 is a useful tool for assessing bladder cancer (BC) and can help with diagnosis, prognosis, and treatment. IHC can help identify flat and inverted urothelial lesions, provide prognostic information for both non-muscle invasive and muscle invasive tumors, and guide treatment by identifying effective therapies, including the exploration of anti-HER2 targeted therapy for bladder cancer. HER2 over expression in bladder cancer has been shown to correlate well with response to Antibody drug conjugates approved by the FDA. In General, HER2-targeted therapies include monoclonal antibodies, tyrosine-kinase inhibitors, and antibody-drug conjugates (ADCs):

- **Monoclonal antibodies**: The FDA has not yet approved HER2 monoclonal antibodies for urothelial carcinoma treatment.
- **Tyrosine-kinase inhibitors**: These have been used in clinical trials as a second-line treatment for advanced or metastatic bladder cancer.
- **Antibody-drug conjugates**: These are considered the most promising therapeutic strategy for HER2-targeted therapy in bladder cancer. Disitamab vedotin (DV, or RC48-

ADC) and Enhertu are ADC FDA approved therapies that have shown promising efficacy in patients with advanced urothelial carcinoma who have failed chemotherapy.

Nectin4

Nectin-4 is detectable on the surface of almost all urothelial cancer cells. High Expression of Nectin has shown to increase efficacy of the drug. The EV/pembro combination outperformed cisplatin-based chemotherapy, reducing the risk of disease progression or death by 55%. The FDA approved a combination of enfortumab vedotin (EV) and pembrolizumab (pembro) as a first-line treatment for locally advanced or metastatic urothelial bladder cancer in December 2023: The FDA granted full approval to the combination, regardless of cisplatin eligibility. Enfortumab vedotin-ejf (EV), an antibody drug conjugate that targets nectin-4, has shown efficacy in platinum- and immunotherapy refractory bladder cancer.

- *Patient profiles eligible for both Immunotherapy and targeted therapies have been shown to be more effective in combination than by themselves.*

Additional Diagnostic Offerings

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

- 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.