INTERPACE DIAGNOSTICS
GUIDING TREATMENT. DELIVERING INNOVATION.

Directory of Laboratory Services

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Interpace Diagnostics 2515 Liberty Avenue | Pittsburgh, PA 15222
800-495-9885 | www.interpacediagnostics.com

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List of Testing Services

Interpace Diagnostics offers multiple tests available in all states unless otherwise mentioned.

ThyGenX®/ThyraMIR™
For Thyroid cytology slides available in all states except NY.
Cytology:
For Thyroid nodule FNA available in all states except RI.
For Pancreatic Cyst FNA available in all states except NY, FL, and RI.
PancraGen™ Molecular Analysis
GNAS Mutation
BarreGen™ Molecular Analysis
Interpace Molecular Analysis
AccuCEA™ and Amylase Chemistry testing

Acceptable specimen criteria for testing:

ThyGenX®/ThyraMIR™
- Dedicated FNA biopsy of the thyroid in RNA*Retain*® only
- Cytology slides with Papanicolaou or Diff-Quik stain

Cytology testing
- All body fluids, masses and ERCP brushes

PancraGen™ Molecular Analysis
- Pancreaticobiliary fluid
- Pancreaticobiliary cytology brushings
- Control: Buccal Brush or Whole Blood in EDTA/ACD

GNAS
- Performed upon request on pancreatic cyst fluid samples only

BarreGen™ Molecular Analysis
- Histology slides with formalin and other routine fixatives
- Paraffin embedded tissue and cell blocks
  - 10% buffered formalin, B6, paraformaldehyde and most common fixatives accepted

Interpace Molecular Analysis
- Cyto-centrifugation supernatants (pancreatic mass or pancreaticobiliary ductal brushing)
- Cytology slides with Papanicolaou or Diff-Quik stain
- Paraffin embedded tissue and cell blocks
  - 10% buffered formalin, B6, paraformaldehyde and most common fixatives accepted
- Other specimen types - contact Interpace Diagnostics' Client Services department if you have a question regarding submission of other specimen types

AccuCEA™ and Amylase Chemistry testing
- All body fluids

Specimen Viability Service (SVS)
- Specimen storage service provided by Interpace Diagnostics at no cost for clients to maintain specimens for possible future testing.

Rejection criteria:

All Tests
- Frozen specimens
- Co-mingled specimens
- Unlabeled or mislabeled specimens
- Missing, incomplete, incorrect or illegible test requisitions
- Leaking or broken specimen vial
- Improper specimen type
- Clotted blood (for controls) in red top tube

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Rejection criteria test specific:

ThyGenX®/ThyraMIR™
- Thyroid specimens in media other than RNA*Retain*® are not acceptable
- FFPE thyroid specimens
- FNA specimens >6 weeks from date of collection

Cytology testing
- Specimens >14 days from date of collection

PancraGen™ Molecular Analysis
- Fluids diluted in any solution.
- Bleached, decalcified or tissue fixed histology slides in Zenker's and Bouin's fixative
- Specimens will be discarded after 45 days from date of collection

BarreGen™ Molecular Analysis
- Bleached, decalcified or tissue fixed histology slides in Zenker's and Bouin's fixative

Interpace Molecular Analysis
- Cytology brushings may be placed in approved preservative or media.
- CytoLyt® and other routine cytology media are acceptable, as per Test Requisition Form.
- CytoRich Red and acetic acid are not acceptable.
- Bleached, decalcified or tissue fixed histology slides in Zenker's and Bouin's fixative

AccuCEA™ and Amylase Chemistry testing
- Specimens >28 days from date of collection

Specimen Collection Requirements

Patient Preparation: No special preparation or timing is required for collection of specimens.

Control Preparation: For pancreas specimens, buccal brushes are required and used to collect normal control samples. For instructions, please refer to the Control Prep section.

If there are any questions regarding specimen collection, handling, or shipping, contact Interpace Diagnostics Client Services at 855-776-6419.

Specimen Labeling Requirement

Complete and correct labeling of specimens ensures proper identification and integrity of patient samples and accurate test reporting.

- All specimen containers must be labeled with at least two patient identifiers. One must be the patient's full name as it appears on the test requisition, and the other identifier may be the date of birth and gender, social security number, medical record number, or specimen accession number (Pathology Department).
- Microscope slides must be labeled with the submitting Pathology Department's accession number. A copy of the pathology or cytology report must be provided for cross-checking the Test Requisition Form with patient name, date of collection and with the Pathology Department's accession number.

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Volume/Specimen Requirements

VOLUME/SPECIMEN REQUIREMENTS FOR ALL SPECIMEN TYPES	
TEST REQUESTED	**SAMPLE VOLUME/REQUIREMENT**
ThyGenX®/ThyraMIR™	1 dedicated FNA pass in RNARetain or cytology slides
Thyroid Cytology***	1 IDX Specimen Collection Kit
AccuCEA™, Amylase*, PancraGen™, Cytology**	800 µl (0.8 ml)
AccuCEA™, Amylase*, PancraGen™	600 µl (0.6 ml)
AccuCEA™, Amylase*, Cytology **	600 µl (0.6 ml)
AccuCEA™* Only	200 µl (0.2 ml)
Amylase* Only	200 µl (0.2 ml)
Cytology**	200 µl (0.2 ml)
PancraGen™ Only	200 µl (0.2 ml)
BarreGen™	1 FFPE block or 1 H&E and 8 unstained recuts
Metastases vs. Primary Tumors (MvP)	1 FFPE block or 1 H&E and 8 unstained recuts
Tissue Identity (TI)	1 FFPE block or 1 H&E and 8 unstained recuts
*Specimens submitted that do not meet volume requirements will be tested using a dilution protocol or the ordering physician may be contacted for testing priority.	
** Cytology testing is not available on pancreatic specimens submitted from NY, FL or RI. *** Cytology testing is not available on thyroid specimens submitted from RI.	
All other testing is accepted for all states unless otherwise stated above.	

Control Prep

A control sample is not required for ThyGenX®/ThyraMIR™ testing. One control sample is required with the submission of a sample for PancraGen™, Cytology, Cyto-centrifugation Supernatant Pancreaticobiliary specimens, and Metastases vs. Primary Tumors (MvP). It is *recommended* for all BarreGen™ and Tissue Identity (TI) specimens.

The following are acceptable controls:

Buccal Brush Scraping

- A buccal brush scraping is used as a control (normal cellular material) for all specimens. These brushes are supplied in the Interpace Specimen Collection Kit in a frosted plastic container, which is to be reused for shipment back to Interpace Diagnostics.
- Preparation of the patient is required for collection of this sample:
  - Scrape superficial layer of buccal mucosa for 10 seconds using the sterile cytology brush provided in the Interpace Specimen Collection Kit.
  - Do not rinse or add preservatives.
  - Place the entire brush back into the container and close.
  - Properly label the container and place in the biohazard bag with the sample to be tested.
  - Ship overnight.

Blood

- Blood may be used as the normal control material if a buccal brush scraping is not available.
- Approximately 1.0mL of anti-coagulated peripheral blood is sufficient for analysis.
- Use one lavender top (EDTA as anticoagulant) blood collection tube or one yellow top (ACD solution A or B) blood collection tube. Mix blood well in tube.
  - Do not use tubes with any other types of additives or anti-coagulants.
- Label tube appropriately with patient identifiers and the date and time of collection.
- Ship overnight

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Histology Slides

- Include one section with non-neoplastic tissue (per shipping instructions) if available.

Thyroid Testing

Specimen Prep for ThyGenX®/ThyraMIR™

- Collect a dedicated FNA biopsy and express it into the provided preservative solution contained in the Interpace Specimen Collection Vials box.
- Invert vial 2-3 times.
- FNAs from the same nodule can be expressed into the same vial of preservative solution.
- FNAs from different nodules needs to be expressed into separate vials, and the location of each nodule should be noted on the requisition form AND labeled on the vial correspondingly.
- If sending cytology slides please marked with areas of interest

Specimen Storage and Packaging

- Specimens may be stored at ambient temperature up to six (6) weeks in RNA*Retain*® (provided preservative) solution until shipped
- Use the Interpace Specimen Transport Kit to ship the specimens

Cytology Testing

Endocrine:

- Thyroid FNA smears and CytoLyt® are accepted for cytology testing.
- Specimens should be collected with the Interpace Cytopathology + Molecular Kit.
- Specimens should be sent to us immediately after collection.
- Cytology testing is performed by one of our renowned affiliates.

GI:

- All body fluids, masses and ERCP brushes are accepted for cytology testing.
- Specimens should be sent in the Interpace Specimen Collection Kit or PreservCyt Collection Kit and shipped with 2 frozen bricks.
- Specimens should be sent to us immediately after collection.
- As with every lab, cytology analysis is affected by the nature of the fluid specimens. Many pancreaticobiliary fluid specimens are acellular or only contain cellular debris. The longer a specimen is stored, the higher the risk of cellular degradation.
- Cytology testing is not available for specimens submitted from New York, Florida and Rhode Island.
- Preparation of fluid cytology specimens is performed at Allegheny General Hospital, Pittsburgh, PA.

Pancreas Testing

Specimen Prep for Pancreatic Cyst Fluid Specimens (PancraGen™)

Collect for pancreatic cyst fluid specimens only.

- Place pancreatic cyst fluid specimen in provided polypropylene 2 mL tubes contained in the Interpace Specimen Collection Kit provided by Interpace Diagnostics.
  - **Important Note:** Preservatives and buffers should not be added to these fluid aspirates.
- If multiple fluid specimens are collected from different lesions/cysts for the same patient:
  - Place specimens in separate tubes and **label properly** (each tube with

corresponding specimen location or pass) so that there is clear distinction between the specimen tubes.
o Aspirated fluid collected at different times should not be placed into the same tube as well.
o Indicate the number of specimen vials and whether vials are from the **same or multiple cyst/s** in the specimen information section on the Test Requisition Form.
o **Testing requires submission of a normal control.**

Specimen Storage

o If there will be a delay in shipping, hold specimens refrigerated at 2-8°C until specimen can be shipped overnight. Do not freeze the aspirate.

Specimen Prep for Cyto-centrifugation Supernatant Pancreaticobiliary Specimens

Collect for cytology, pancreatic mass, or ERCP biliary brush specimens by standard FNA and cytology procedures.

o Place up to 50 ml of either supernatant fluid or residual fluid from a liquid cytology preparation such as ThinPrep® or SurePrep™ into supernatant collection tube provided by Interpace Diagnostics.
o Do not mix supernatants from different specimens in the same shipping tube. Use additional tubes if more than one specimen is submitted and label each tube with specific collection site to distinguish the specimens.
o Place "DO NOT DISCARD" sticker onto vial with cytology specimen (when sending to Cytology Laboratory for processing). Contact Client Services for ordering information.
o **Testing requires submission of a normal control.**

Specimen Storage and Packaging

o Specimens may be stored refrigerated at 2-8°C until shipped.
o Use the Interpace Specimen Collection Kit to ship the specimens.

Specimen Prep for Interpace Molecular Testing

Collect for pancreatic masses, cytology, ERCP biliary or pancreas brush specimens.

Cytology Slides

Cytology slides, including those with little cellular material, are acceptable for analysis.

Acceptable fixatives include ethanol, methanol and most common cytology fixatives.

o Slides stained with Papanicolaou of Diff-Quik with coverslips removed are preferred. Interpace Diagnostics can remove coverslip.
o Hematoxylin/Eosin stained slides are problematic due to interference of the analysis by the Hematoxylin dye. Please contact Interpace Diagnostics if no other materials are available or if there are questions.
o Send slides with most representative cells. Please indicate on the requisition if slide is from a smear, cell block, or ThinPrep®.
o Ensure that slides are labeled for proper identification.
o Pathologist may mark area(s) of interest on the underside of stained slide(s) using a permanent marker.

Specimen Storage

o The slides may be stored at room temperature prior to shipment.

Cytology Brushing

Cellular material remaining on a cytology brush head after preparation of smears should be processed as follows:

o Detach portion of brush head or entire brush head and place into an empty 2 mL polypropylene screw cap tube contained in the Interpace Specimen Collection Kit.
Or
o After brushing has been placed into vial of cytology fixative for cytology evaluation, vigorously agitate for 10 seconds. Aliquot 10-15 mL into empty screw cap vial.

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- For optimal results, it is recommended to use the supplied media from the Interpace PreservCyt Collection kit if using a preservative or buffer. **CytoRich Red and acetic acid are not acceptable**.
- Place one brush head per tube. Use additional tubes if more than one brush head is submitted, and label specifically to distinguish between the collection sites.

Specimen Storage

- Specimens may be stored refrigerated at 2-8°C until shipped.

Histology Testing

Use for PancraGen™, BarreGen™, Metastases vs. Primary Tumors (MvP), and Tissue Identity (TI) specimens

Specimen Prep for Histology

Histology Slides

- Cut nine (9) histology sections (4-5 microns thick) from paraffin blocks. Ribboning (placing serial copies of the same tissue section next to each other) multiple tissue sections onto a single glass slide is encouraged. Positive charged slides not required.
- ***One re-cut per block should be stained with Hematoxylin/Eosin and cover slipped.***
- ***Do not stain or cover slip the remaining 8 re-cut sections.***
- Decalcified, bleached, or Zenker's or Bouin's fixed tissues are not acceptable for testing.
- Pathologist may mark area(s) of interest on the underside of stained slide using permanent marker.
- Unstained slides must be deparaffinized and care should be taken to avoid over-baking the specimen. Interpace Diagnostics can provide this service.

Specimen Storage and Packaging

- The stained and unstained re-cuts may be stored indefinitely at room temperature prior to shipment and may be shipped at ambient (room) temperature.
- Use Interpace Diagnostics Histology/Cytology Collection Kit and contents for packaging and shipment of glass microscope slides of tissue sections or cells for diagnosis.
  Slides should be placed into the provided rigid polypropylene slide holders. Do not use cardboard slide mailers.
  These hold four to five microscope slides. If a lesser amount of slides is packaged, use included materials to reduce movement of slides.
- Do not allow slides to touch.
- **PancraGen™ and BarreGen™ testing requires submission of a normal control.**

Paraffin Blocks

- Paraffin blocks are accepted, but testing will be delayed due to slide processing.
- Interpace Diagnostics can provide this service.
  - Slide processing will entail the following:
    - Nine (9) sections (4 – 5 microns thick). Recuts will be reduced if minimal cells available.
    - One slide will be stained with Hematoxylin/Eosin and cover slipped.

  The remaining re-cuts will not be stained or cover slipped

Specimen Storage and Packaging

The Paraffin blocks may be stored indefinitely at room temperature prior to shipment.

CEA and Amylase Testing

- All body fluids are accepted for AccuCEA™ and Amylase testing
- Do not submit fluids diluted in any solution.
- All specimens for AccuCEA™ and Amylase testing should be sent in the Interpace Specimen Collection Kit and shipped with 2 frozen bricks.
- Frozen specimens are unacceptable for AccuCEA™ and Amylase testing.

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Ordering Tests

Physicians may order ThyGenX®/ThyraMIR™, PancraGen™, AccuCEA™, Amylase, and Cytology, or request specimen storage by completing the appropriate Interpace Diagnostics requisition form. The physician must sign and date the appropriate requisition form and it must be included in the specimen shipment to Interpace Diagnostics. Incomplete information on the form may cause a testing delay. Interpace Diagnostics does not accept standing orders. If you have questions regarding any test ordering, please contact Client Services at 855-776-6419.

Please note: PancraGen™ molecular test requests are not accepted on the fluid chemistry or storage test form.

Test Requisition Forms

Test Requisition Forms are available by contacting Client Services at 855-776-6419 or on the Interpace Diagnostics website at www.interpacediagnostics.com. Completion of all fields is required. Please be sure all fields have been completed prior to submitting to Interpace Diagnostics. Please complete and submit a **separate Test Requisition Form** for each patient.

Required Documents and Reports

Ship specimen(s) with the following documentation:

- Completed Test Requisition Form
- Patient billing demographics
- Imaging or Endoscopy report (when appropriate and if available)
- Cytology/Pathology report (when appropriate and if available)

If Imaging or Endoscopy and Cytology/Pathology report are not available at time of submission, please send as soon as available.

Specimen Packaging

Interpace Specimen Collection/Transport Kits

Interpace Specimen Collection/Transport Kits are provided free of charge for your convenience and to ensure appropriate materials are used for specimen collection and shipping. These are to be used only for submitting specimens to Interpace Diagnostics.

To request an initial or replacement supply of Interpace Specimen Collection/Transport Kits call Client Services at 855-776-6419. Orders are filled and shipped via FedEx Ground (two to-three business days) within one business day of request. Overnight delivery shipping is provided upon request.

Packaging for ThyGenX®/ThyraMIR™ Specimens

- Use Interpace Specimen Transport Kit and contents for packaging and shipment.
  - Place specimen vial in a specimen collection bag and seal. If placing more than one vial in a specimen collection bag please **clearly label each specimen**
  - **If sending cytology collection kit only, use a single kit per nodule sampling.**
  - Refrigeration is not required for storing or shipping specimen.
  - Close kit by tucking flaps into the outer cardboard box.
  - Put collection kit in the FedEx Clinical Pak (shipping bag), remove adhesive strip protector, and seal tightly.
  - Call FedEx at (800) 463-3339 to schedule specimen pickup.

Packaging for Pancreatic Cyst Fluid Specimens (PancraGen™, Cytology, AccuCEA™, Amylase testing)

- Use Interpace Specimen Collection Kit and contents for packaging and shipment.
- Once specimens are in a biohazard bag:

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- Place biohazard bag containing specimens and documentation into the styrofoam shipping container. Up to three (3) biohazard bags from different cases may be shipped in one shipping container.
- Place 2 frozen bricks into the shipping container.
- Place styrofoam lid on the shipping container and close kit by tucking flaps into the outer cardboard box.
- Put collection kit in the FedEx Clinical Pak (shipping bag), remove adhesive strip protector, and seal tightly.

- Call FedEx at (800) 463-3339 to schedule specimen pickup.

Packaging for Cyto-centrifugation Supernatant Pancreaticobiliary Specimens and Cytology Brush Specimens

- Use Interpace Specimen Collection Kit and contents for packaging and shipment.
- Once specimens are in a biohazard bag:
  - Place biohazard bag containing specimens and documentation into the styrofoam shipping container. Up to two (2) biohazard bags from different cases may be shipped in one shipping container.
  - Place 2 frozen bricks into the shipping container.
  - Place styrofoam lid on the shipping container and close kit by tucking flaps into the outer cardboard box.
  - Put collection kit in the FedEx Clinical Pak (shipping bag), remove adhesive strip protector, and seal tightly.
  - Call FedEx at (800) 463-3339 to schedule specimen pickup.

Packaging for BarreGen™, MvP and Tissue Identity Specimens

- Use Interpace Histology/Cytology Collection Kit and contents for packaging and shipment of glass microscope slides of tissue sections or cells for diagnosis.
  - Slides should be placed into the provided rigid polypropylene slide holders. Do not use cardboard slide mailers.
  - These hold five (5) microscope slides.
  - Place slide holders and/or blocks into the foam insert and put back into shipping container.
  - Up to four (4) slide holders (for a total of 20 slides) and three (3) blocks can fit into the foam insert.
  - Do not allow slides to touch.
  - Refrigeration is not required for storing or shipping specimen.
  - Close kit by tucking flaps into the outer cardboard box.
  - Put collection kit in the FedEx Clinical Pak (shipping bag), remove adhesive strip protector, and seal tightly.
- Call FedEx at (800) 463-3339 to schedule specimen pickup.

Shipping Specimens to Interpace Diagnostics

Specimens should be shipped via FedEx Priority Overnight delivery to Interpace Diagnostics using pre-paid, pre-addressed labels provided by Interpace Diagnostics.

Ship To:	Or:
Interpace Diagnostics 2515 Liberty Avenue Pittsburgh, PA 15222 Ph: 412-224-6100	Hold At FedEx Interpace Diagnostics International Dr, Cargo 2 Coraopolis, PA 15108 Ph: 412-224-6100

We accept specimens for testing Monday through Friday from 8:00 AM to 5:00 PM EST. Specimens sent by FedEx on Fridays and **checked on the FedEx Airbill for Saturday Delivery** are received on Saturdays for testing on the next business day. The client is responsible for contacting FedEx to ship the specimens.

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Billing Information

Interpace Diagnostics will bill third party payers directly for insured patients, wherever permitted by government regulations, payer billing policies, or contractual arrangements, as long as the following information is provided:

- o Patient Demographic Information (ie. Name, Date of Birth, Address, etc)
- o Insurance Information (ie. Insurance Name, Policy ID, Group Number, etc)
- o Specimen Collection Location (ie. Outpatient, Inpatient, Ambulatory Surgical Center, etc)
  If the Specimen Collection Location is Inpatient, the Discharge Date must also be provided.
- o Submitting Diagnosis
  The diagnosis code or written narrative provided should be consistent with the patient's medical records.

The information above may be provided on the test requisition or on a patient information sheet (face sheet) or by attaching a good quality photocopy of the patient's insurance cards (front and back). If this information is not provided, it may result in a client bill. Our Client Services Department can assist with questions regarding billing requirements Monday through Friday, 8:00am to 8:00pm EST, and can be reached at 800-495-9885.

Additional Information for Medicare Patients:

If molecular testing is ordered more than 14 days after patient discharge from hospital (or specimen collection date for outpatients) Medicare will be billed. If the test order is PancraGen™ the ordering physician must identify and indicate factor(s) that affected the time of ordering molecular testing. Factors indicated must be consistent with the patient's medical records.

Specimen Viability Service (SVS)

Interpace Diagnostics offers the Specimen Viability Service for the purpose of maintaining pancreaticobiliary fluids, ERCP brush specimens, the accompanying control specimens (buccal brush or whole blood sample) and extracted DNA under appropriate conditions to ensure their viability for analysis by the PancraGen™ molecular test.

Based on the results of an internal stability study of pancreaticobiliary fluids, it was determined that these specimens are only viable for a defined period of time following collection (with storage under the conditions of the Specimen Viability Service).

SVS Specimen Submission

Customers should use an Interpace Specimen Collection Kit to collect and ship the specimens (using prepaid, pre-addressed FedEx™ label) to Interpace Diagnostics.

Specimens must be labeled appropriately as is required for all clinical specimens with at least two patient identifiers to include name, SSN/MRN, gender, and/or date of birth. These specimen label identifiers must match the information on the Requisition for First-Line Testing or Storage Form.

Specimens submitted for 'Storage only' require a completed Storage Form. An aliquot of specimens submitted for Fluid Chemistry testing and/or Cytology will automatically be placed into storage for possible future testing.

SVS Inventory Reports

Client Services will notify each physician on a weekly basis of their current inventory of specimens.

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SVS Specimen Options

The client has the option, at any time, to do one of the following:

- If the customer requests that Interpace Diagnostics perform PancraGen™ testing, a completed Test Requisition must be sent to Interpace Diagnostics prior to the scheduled date of discard (Specimens for PancraGen™ will be discarded after 45 days) as specified by this policy.

- If the customer requests that Interpace Diagnostics forward the specimen to another laboratory for testing, Interpace Diagnostics will forward the specimen upon receipt of the shipping information from the submitting physician at no charge to the customer.

- If the customer requests that Interpace Diagnostics return the specimen, Interpace Diagnostics will return the specimen to the institution from which the specimen was shipped at no charge to the customer.

- If the customer should indicate that the specimen is to be disposed of, Interpace Diagnostics will handle the proper disposal of the specimen. Note: the specimen will be discarded if no instruction is received from the ordering physician prior to Day 45.

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Important Contact Information

General Inquiries: 855-776-6419

PancraGen™: (800) 495-9885

ThyGenX®/ThyraMIR™: (844) 405-9655

BarreGen™: (844) 227-7621

Client Services fax: (412) 224-6425 or (888) 674-6894

Client Services email: client_services@interpacedx.com

Client billing questions: (877) 436-9464 or InterpaceDiagnostics@mylabbill.com

Patient billing questions: (877) 436-9464 or InterpaceDiagnostics@mylabbill.com

Hours of operation: Monday-Friday 8:00am – 8:00pm EST

Website: www.interpacediagnostics.com – blank test requisitions available

Laboratory address: 2515 Liberty Ave., Pittsburgh, PA 15222

To schedule a FedEx pick-up: (800) 463-3339
FedEx Account # 2907-7656-6

Accreditation: CLIA ID# 39D1024654
CAP # 1410260

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