Directory of Lab Services
## Diagnostic Tests Currently Available

<table>
<thead>
<tr>
<th>Indication</th>
<th>Diagnostic Test</th>
<th>Diagnostic Report</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ThyGeNEXT®</strong> Thyroid Oncogene Panel</td>
<td>Thyroid Cancer NGS Panel for Thyroid Cancer</td>
<td>Rules In Thyroid Cancer</td>
</tr>
<tr>
<td><strong>ThyraMIR®</strong> Thyroid miRNA Classifier</td>
<td>Thyroid Cancer microRNA Risk Classifier for Thyroid Cancer</td>
<td>Rules Out Thyroid Cancer</td>
</tr>
<tr>
<td><strong>PancraGEN®</strong> Pancreatic &amp; Biliary Cancer Risk Classifier</td>
<td>Risk-Stratifies, Pancreatic Cysts, Pancreaticobiliary Solid Lesions</td>
<td>Fully Integrated Report That Rules In and Rules Out Pancreatic or Biliary Cancer</td>
</tr>
<tr>
<td><strong>PanDNA®</strong> Pancreatic &amp; Biliary Cancer Molecular Classifier</td>
<td>Risk-Stratifies, Pancreatic Cysts, Pancreaticobiliary Solid Lesions</td>
<td>Molecular-only Results for Pancreatic or Biliary Cancer</td>
</tr>
<tr>
<td>Lung Cancer</td>
<td>Risk of New Primary Cancer Formation vs. Metastases or Recurrence</td>
<td>Rules In and Rules Out New Primary Cancer Formation</td>
</tr>
<tr>
<td><strong>RespriDx®</strong> Lung Cancer Risk Classifier</td>
<td>Risk-Stratifies for Esophageal Cancer</td>
<td>Rules In Higher Risk of Progression of Esophageal Cancer</td>
</tr>
<tr>
<td><strong>SARS-CoV-2 (COVID-19)®</strong></td>
<td>Enzyme-linked immunosorbent assay (ELISA) for the qualitative detection of IgG antibodies</td>
<td>Positive/Negative indication of exposure to SARS-CoV-2 (COVID-19)</td>
</tr>
</tbody>
</table>

See next page for table of contents.
# Table of Contents

Return to this page at any time by clicking the “Table of Contents” link at the top of any page.

- Contact Info .......................................................................................................................... 4
- Website ....................................................................................................................................... 4
- Accreditations and Licensure .................................................................................................... 5
- List of Testing Services and Expected Turnaround Time (TAT) ............................................... 6
- Specimen Collection Requirements .......................................................................................... 7
- Specimen Labeling Requirement .............................................................................................. 7
- Volume/Specimen Requirements For All Specimen Types ....................................................... 8
- Specimen Collection/Transport Kits .......................................................................................... 8
- Test Ordering and Shipping Process .......................................................................................... 9
  - Test Requisition Forms ............................................................................................................. 9
  - Required Documents and Reports to be Shipped with the Specimen ........................................ 9
  - Packaging for Specimens ......................................................................................................... 9
  - Shipping .................................................................................................................................... 9
  - Interpace Diagnostics Specimen Collection/Transport Kits ..................................................... 10
- Cytology with Reflex to ThyGeNEXT®/ThyraMIR® .................................................................... 11
- ThyGeNEXT® ............................................................................................................................ 15
- ThyraMIR® (Ordered as a Reflex Test with ThyGeNEXT®) ........................................................ 19
- AccuCEA™ (Carcinoembryonic Antigen) .................................................................................. 20
- Amylase ...................................................................................................................................... 22
- Cytology (Pancreaticobiliary) .................................................................................................... 24
- PancraGEN® ............................................................................................................................. 26
- PancraGEN® with GNAS .......................................................................................................... 29
- Pancreaticobiliary Molecular Testing ....................................................................................... 33
- PanDNA® ................................................................................................................................. 36
- BarreGEN® ............................................................................................................................... 40
- RespriDX® ................................................................................................................................. 44
- COVIANT™ ............................................................................................................................... 48
- Tissue Identity Testing ............................................................................................................... 51
- Specimen Viability Service ......................................................................................................... 53
Contact Info

Client Services Department
» Phone: 412-224-6900, or toll-free 800-495-9885
» Fax: 412-224-6425, or toll-free 888-674-6894
» Email: clientservices@interpace.com
» Hours of Support Services:
  - Monday to Friday, 8 am – 8 pm EST
  - Closed Saturday, Sunday, and all major holidays

Billing and Reimbursement
» Phone: 888-963-6621
» Fax: 888-963-6627
» Email: reimbursement@interpace.com
» Hours of Support Service:
  - Monday to Friday, 9 am – 5 pm EST
  - Closed Saturday, Sunday and all major holidays

Laboratory Hours of Operation
» Monday to Friday, 8 am – 5 pm EST (open through the lunch hour)
» Closed Saturday, Sunday, and all major holidays

Website
Visit Interpace Diagnostics on the web for more information.
www.interpace.com
Accreditations and Licensure

Copies of our licenses are available on our website.
https://www.interpace.com/labs

Pittsburgh, PA Laboratory Location

» College of American Pathologists.................................................#7186526
» CLIA.................................................................................................#39D1024654
» New York.........................................................................................#8306
» California.........................................................................................#CDS00800224
» Maryland .........................................................................................#1423
» Pennsylvania...................................................................................#29043A
» Rhode Island ...................................................................................#LCO00913

New Haven, CT Laboratory Location

» College of American Pathologists.................................................#7215351
» CLIA.................................................................................................#07D1091103
» New York.........................................................................................#8626
» California.........................................................................................#CDS00800543
» Maryland .........................................................................................#2185
» Pennsylvania...................................................................................#31877
» Rhode Island ...................................................................................#LCO00940
» Connecticut.....................................................................................#CL-0664
# List of Testing Services and Expected Turnaround Time (TAT)

<table>
<thead>
<tr>
<th>Test(s)</th>
<th>Specimen Type Accepted</th>
<th>Turnaround Time (business days, from time of accessioning)</th>
</tr>
</thead>
<tbody>
<tr>
<td>AccuCEA™/Amylase</td>
<td>Pancreatic/pancreaobiliary Fluid</td>
<td>1 to 3</td>
</tr>
<tr>
<td>Cytology (GI)</td>
<td>All Bodily Fluid</td>
<td>3 to 5</td>
</tr>
<tr>
<td>PancraGEN®/PanDNA®</td>
<td>FNA Pancreatic Cyst Fluid (undiluted), Supernatant, Brush Fluid/Dry</td>
<td>10 to 14</td>
</tr>
<tr>
<td></td>
<td>Cytology Slide (PAP, Diff-Quik)</td>
<td>Less than 18</td>
</tr>
<tr>
<td></td>
<td>FFPE Tissue (block or recut slides)</td>
<td>Less than 18</td>
</tr>
<tr>
<td>Cytology (Thyroid)</td>
<td>Thyroid FNA</td>
<td>3 to 5</td>
</tr>
<tr>
<td>ThyGeNEXT®/ThyraMIR®</td>
<td>FNA in RNARetain® Vial</td>
<td>10 to 14</td>
</tr>
<tr>
<td></td>
<td>Cytology Slide (PAP, DiffQuik, Giemsa)</td>
<td>Less than 18</td>
</tr>
<tr>
<td></td>
<td>FFPE Tissue</td>
<td>Less than 18</td>
</tr>
<tr>
<td>RespriDx®</td>
<td>Comparative Tissue Profiling (2 locations minimum—tissue block, FFPE slide or cytology slide)</td>
<td>Less than 18</td>
</tr>
<tr>
<td>BarreGEN®</td>
<td>Esophageal Tissue (tissue block or FFPE slides)</td>
<td>Less than 18</td>
</tr>
<tr>
<td>Pancreatic Storage Viability Service</td>
<td>FNA-pancreatic cyst (undiluted)</td>
<td>Stored for 42 days from date of collection</td>
</tr>
<tr>
<td>COVIANT™</td>
<td>Cell-free plasma (preferred) or cell-free serum</td>
<td>3 or less</td>
</tr>
</tbody>
</table>
Specimen Collection Requirements

Please see each specific test type for more detailed collection requirements.
Patient Preparation: No special preparation or timing is required for collection of specimens.
Control Preparation: For pancreas specimens only, buccal brushes or whole blood 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 800-495-9885 or clientservices@interpace.com.

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 2 patient identifiers. One must be the patient’s 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 with patient name, date of collection, and Pathology Department’s accession number

Failure to label specimens properly will result in delayed testing or specimen rejection.
## Volume/Specimen Requirements For All Specimen Types

<table>
<thead>
<tr>
<th>Test Requested</th>
<th>Sample Volume/Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>ThyGeNEXT®/ThyraMIR®</td>
<td>1 dedicated FNA pass in RNARetain® or cytology slides (PAP, DiffQuik, Geimsa) or 1 FFPE block or 1 H&amp;E and 8 unstained recuts</td>
</tr>
<tr>
<td>Thyroid Cytology**</td>
<td>1 IDX Specimen Cytology Collection Kit</td>
</tr>
<tr>
<td>AccuCEA™<em>, Amylase</em>, PancraGEN®/PanDNA®, Cytology**</td>
<td>800 µl (0.8 mL)</td>
</tr>
<tr>
<td>AccuCEA™<em>, Amylase</em>, PancraGEN®/PanDNA®</td>
<td>600 µl (0.6 mL)</td>
</tr>
<tr>
<td>AccuCEA™<em>, Amylase</em>, Cytology **</td>
<td>600 µl (0.6 mL)</td>
</tr>
<tr>
<td>PancraGEN® Only</td>
<td>200 µl (0.2 mL)</td>
</tr>
<tr>
<td>PanDNA®</td>
<td>200 µl (0.2 mL)</td>
</tr>
<tr>
<td>BarreGEN™</td>
<td>1 FFPE block or 1 H&amp;E and 8 unstained recuts</td>
</tr>
<tr>
<td>RespiDx®</td>
<td>1 FFPE block or 1 H&amp;E and 8 unstained recuts</td>
</tr>
<tr>
<td>COVIANT™</td>
<td>2 mL cell-free plasma or 1 mL cell-free serum</td>
</tr>
<tr>
<td>Tissue Identity</td>
<td>1 FFPE block or 1 H&amp;E and 8 unstained recuts</td>
</tr>
</tbody>
</table>

*S*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 cannot be provided for NY state.**

All other testing is accepted for all states unless otherwise stated above.

## Specimen Collection/Transport Kits

Interpace Diagnostics 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 order for supply of Interpace Diagnostics Specimen Collection/Transport Kits, contact Client Services at 800-495-9885 or clientservices@interpace.com. Orders are filled and shipped via FedEx Ground (2 to 3 business days) within 1 business day of request. Overnight delivery shipping is provided upon request.
Test Ordering and Shipping Process

Physicians may order a test by completing the appropriate Interpace Diagnostics requisition. The physician must sign and date the appropriate requisition 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 800-495-9885 or clientservices@interpace.com.

Test Requisition Forms

Test Requisition Forms are available by contacting Client Services at 800-495-9885 or clientservices@interpace.com, and on the Interpace Diagnostics website at www.interpace.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. Refer to “How to Complete a Test Requisition”.

Required Documents and Reports to be Shipped with the Specimen

*(Failure to submit required documentation may lead to testing delays)*

- Completed Test Requisition
- Patient billing information (full patient address, phone number, insurance information)
- Ultrasound report (if available)
- Cytology/Pathology report (if available)
  - If Ultrasound and/or Cytology/Pathology report are not available at time of submission, please send as soon as available

Packaging for Specimens

Use Interpace Specimen Collection Kit and contents for packaging and shipment (please refer to section below on how to request supplies).

Once specimens are in a biohazard bag:

- Arrange the biohazard bag with specimen(s) material at the bottom of the kit box
- Insert a completed Test Requisition, billing information, face sheet, and any additional medical records in kit box on top of samples
- If applicable, add frozen cold bricks to kit to ensure sample remains cold during shipment
  - Please ensure review of test-specific collection requirements
- Close the kit by tucking flaps into outer cardboard box
- Put collection kit in the FedEx® Clinical Pak, remove adhesive strip protector, and seal tightly. Affix pre-labeled FedEx Airbill to outside of FedEx Clinical Pak

Shipping

Call FedEx at (800) 463-3339 to schedule specimen pickup. Requests for pickup made before 1 pm should be picked up on the same business day.
Specimens should be shipped via FedEx Priority Overnight delivery to Interpace Diagnostics using pre-paid, pre-addressed labels provided by Interpace Diagnostics.

<table>
<thead>
<tr>
<th>Ship To:</th>
<th>Or:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Interpace Diagnostics</td>
<td>Hold At FedEx</td>
</tr>
<tr>
<td>2515 Liberty Avenue</td>
<td>Interpace Diagnostics</td>
</tr>
<tr>
<td>Pittsburgh, PA 15222</td>
<td>International Dr, Cargo 2</td>
</tr>
<tr>
<td>Ph: 412-224-6100</td>
<td>Coraopolis, PA 15108</td>
</tr>
<tr>
<td></td>
<td>Ph: 412-224-6100</td>
</tr>
</tbody>
</table>

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

**Interpace Diagnostics Specimen Collection/Transport Kits**

Interpace Diagnostics 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 order for supply of Interpace Diagnostics Specimen Collection/Transport Kits, contact Client Services at 800-495-9885 or clientservices@interpace.com. Orders are filled and shipped via FedEx Ground (2 to 3 business days) within 1 business day of request. Overnight delivery shipping is provided upon request.
# Cytology with Reflex to ThyGeNEXT®/ThyraMIR®

**CPT:** 81445 / PLA 0081U

Cytology is used to evaluate thyroid fine needle aspirates and categorize into 1 of 6 Bethesda categories, each with implied risk of malignancy. Cytology is ordered, with reflex to ThyGeNEXT and/or ThyraMIR in such cases when cytologic diagnosis is not clearly benign or malignant, but is indeterminate (Bethesda III, IV, or V). When all 3 tests are ordered, this is a full rule-in and rule-out test order. You can find additional information on our website, [www.interpace.com](http://www.interpace.com).

## Accepted Specimens
- Thyroid FNA (in CytoLyt and RNARetain)
- 1-2 ThinPrep or cytospin slides

## Turnaround Time
- 3-5 business days from time of accessioning for cytology report
- 10-14 days for molecular results

## Methodology
- Cytology staining
- Next Gen Sequencing (NGS)

## Specimen Requirements
Collection requirements using Interpace Diagnostics Specimen Collection Kit:

*Note: When more than 1 nodule is present, use separate collection vials.*

- Label each vial with 2 unique patient identifiers (full name, DOB, MRN), collection date, and nodule location
- Collect and express 2-4 FNA passes into the provided CytoLyt™ vial. Be sure to also rinse any residual material in the needle from each pass into the vial
- Obtain a single dedicated pass to express andrin RNARetain® vial
- Invert the RNARetain vial 2-3 times
- Securely tighten all caps and seal all containers to prevent leakage
- Place CytoLyt™ and RNARetain vial back into the biohazard bag with absorbent pad
- No special preparation or timing is required for collection of specimens
- Sample does not need to be refrigerated

## Control Prep
A control sample is not required for ThyGeNEXT®/ThyraMIR® testing.
Specimen Rejection Criteria

» Specimen not originating from thyroid
» Frozen specimen
» Co-mingled specimen (ex: mixing 2 different nodules in 1 vial)
» Unlabeled or mislabeled specimen
» Empty, leaking, or broken specimen vials
» FNA specimens older than 42 days
» Slide Specimens older than 6 months
» Any media other than RNARetain (for molecular testing)

Specimen Storage for Viability

» Store at room temp
» Do not freeze
» FNA specimens viable up to 42 days (6 weeks) in RNARetain

Related Test Orders

» ThyraMIR®
» ThyGeNEXT®

Ordering and Shipping Process

For instructions on how to order this test, see the Interpace Diagnostics “Test Ordering and Shipping Process” on page 9 of this document.

How to Complete a Test Requisition

Testing requisitions can vary. The following are general guidelines to assist in completing the Interpace Diagnostics Testing Requisitions to ensure timely and correct handling of submitted specimens to our laboratory. Please refer to examples below to help answer questions that you may have for completion of the testing requisition. If at any point you have additional questions or need a requisition for specimen submission, please contact Client Services at 800-495-9885 or clientservices@interpace.com. Additionally, blank requisitions can be found on our website, www.interpace.com.
Section 1. Patient Information

All fields are required. Include patient first and last name, date of birth, SSN/MRN code, and sex. A complete patient label can be adhered in this field as long as patient information is complete and includes 2 unique identifiers. Incomplete information will result in testing delays.

Section 2. Physician Information

This section may be pre-filled if an account has been set up with Interpace Diagnostics. If blank, complete each field. Account Number should match your Interpace Diagnostics account number (leave blank if unknown). Complete physician institution contact information. Please avoid Office/Hospital acronym nomenclature and spell out institution to ensure accurate case entry for ordering. Provide institution, full name, and phone/fax number for referring/treating physician if applicable. Leaving contact information incomplete will result in processing delays.

Section 3. Billing Information

Check appropriate box to indicate type of insurance/payor for patient. A copy of the patient’s billing information MUST be submitted with specimen.

Section 4. Specimen & Diagnosis Information

Select box to indicate where procedure was performed (non-hospital affiliated setting, Private Practice, Outpatient, or Inpatient with discharge date). Submitted Specimen(s): Check box off to indicate type of specimen being sent in for testing or indicate number of slides being sent (REQUIRED). If submitting multiple nodules, indicate type and quantity separately. Specimen Collection Date should be date of the procedure when specimen was collected. Indicate key characteristics identified from patient’s medical records for each specimen (cytology diagnosis/Bethesda Category, ultrasound characteristics, location, and size of nodule). Highlight nodule location on thyroid diagram. If submitting more than 1 specimen, provide details for each location. Incomplete or incorrect information will lead to testing delays. Submitting Diagnosis: Write in appropriate ICD-10 code based on the patient’s medical records. The diagnosis code(s) provided should always be supported by documentation within the patient’s medical records. Testing cannot be performed unless ICD-10 code(s) are included.
Section 5. Test Menu

(This section may vary. If you have questions please contact Client Services)

Specimen processing cannot begin until there is a clear indication of type of testing to be performed (check box). Please indicate tests requested for patient specimen. Details of each test can be found on our website and in test details from our Directory of Laboratory Services. Only 1 test should be selected. A copy of the corresponding cytology report is requested to be sent with this specimen as available. If these reports are not available at time of specimen submission please forward to Client Services (fax: 1-888-674-6894 or 412-224-6425) when received.

Section 6. Authorization

The ordering physician is required to sign and date the requisition as authorization for Interpace Diagnostics to perform testing. Only the ordering physician can sign this requisition. Stamped signatures cannot be accepted. An incomplete signature will result in testing delays. Order date cannot precede Collection Date of the specimen. Post-dated requisitions are not accepted.
ThyGeNEXT®

CPT: 81445

ThyGeNEXT is a rule-in test for malignancy. ThyGeNEXT is often ordered in conjunction with ThyraMIR®, and is available for indeterminate cytology results to provide additional risk assessment for clinical management decisions. You can find additional information on our website, www.interpace.com.

Accepted Specimens

» Thyroid FNA in RNARetain®
» 1-2 Thyroid cytology smears (DiffQuick or PAP stained, non-frosted slides)
» 1-2 ThinPrep, or cytospin slides
» Formalin Fixed Paraffin Embedded Tissue/Cell Block (FFPE)
  - whole block that will be recut for testing
  - 8 recut slides, plus 1 H&E slide

Turnaround Time

» 10-14 business days for FNA samples from time of accessioning
» Less than 18 business days for slides or FFPE samples from time of accessioning

Methodology

Next Gen Sequencing (NGS)

Specimen Requirements

RNARetain® (FNA) Collection requirements

» Label vial with 2 unique patient identifiers (full name, DOB, MRN), collection date, and nodule location
» Obtain a single dedicated pass to express and rinse in RNARetain® vial
» Invert the RNARetain® vial 2-3 times
» Securely tighten all caps and seal all containers to prevent leakage
» Place RNARetain® vial back into the biohazard bag with absorbent pad
» No special preparation or timing is required for collection of specimens
» Sample does not need to be refrigerated
Thyroid cytology smear, ThinPrep, Cytospin or FFPE Block Collection Instructions

> 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 with patient name, date of collection, and with the Pathology Department’s accession number.

> On the test requisition, be sure to indicate the slide(s) accession number and appropriate amount of slide(s) being sent for testing.

> Insert slide(s) into provided plastic slide holder, securely snap lid shut.

> Place slide holder with glass slide into padded pouch.

> No special preparation or timing is required for collection of specimens.

> Sample does not need to be refrigerated.

Control Prep

A control sample is not required for ThyGeNEXT®/ThyraMIR® testing.

Specimen Rejection Criteria

> Specimen not originating from thyroid.

> Frozen specimen.

> Slides that are non-diagnostic (lacking cellular material sufficient for diagnosis).

> Co-mingled specimen (i.e. mixing 2 different nodules in 1 vial).

> Unlabeled or mislabeled specimen.

> Specimens submitted on frosted slides.

> Empty, leaking, or broken specimen vials.

> FNA specimens older than age > 42 days.

> Slide Specimens older than age > 6 months.

> Any media other than RNARetain® (for molecular testing).

Specimen Storage for Viability

> Store at room temp.

> Do not freeze.

> FNA specimens viable up to 42 days (6 weeks) in RNARetain®.

Related Test Orders

> Cytology.

> ThyraMIR.

Ordering and Shipping Process

For instructions on how to order this test, see the Interpace Diagnostics “Test Ordering and Shipping Process” on page 9 of this document.
How to Complete a Test Requisition

Testing requisitions can vary. The following are general guidelines to assist in completing the Interpace Diagnostics Testing Requisitions to ensure timely and correct handling of submitted specimens to our laboratory. Please refer to examples below to help answer questions that you may have for completion of the testing requisition. If at any point you have additional questions or need a requisition for specimen submission, please contact Client Services at 800-495-9885 or clientservices@interpace.com. Additionally, blank requisitions can be found on our website, www.interpace.com.

Section 1. Patient Information

All fields are required. Include patient first and last name, date of birth, SSN/MRN code, and sex. A complete patient label can be adhered in this field as long as patient information is complete and includes 2 unique identifiers. Incomplete information will result in testing delays.

Section 2. Physician Information

This section may be pre-filled if an account has been set up with Interpace Diagnostics. If blank, complete each field. Account Number should match your Interpace Diagnostics account number (leave blank if unknown). Complete physician institution contact information. Please avoid Office/Hospital acronym nomenclature and spell out institution to ensure accurate case entry for ordering. Provide institution, full name and phone/fax number for referring/treating physician if applicable. Leaving contact information incomplete will result in processing delays.

Section 3. Billing Information

Check appropriate box to indicate type of insurance/payer for patient. A copy of the patient’s billing information MUST be submitted with specimen.

Section 4. Specimen & Diagnosis Information

Select box to indicate where procedure was performed (non-hospital affiliated setting, Private Practice, Outpatient, or Inpatient with discharge date). Submitted Specimen(s): Check box off to indicate type of specimen being sent in for testing OR indicate number of slides being sent (REQUIRED). If submitting multiple nodules, indicate type and quantity separately. Specimen Collection Date should be the date of the procedure when specimen was collected. Indicate key characteristics identified from patient’s medical records for each specimen (cytology diagnosis/Bethesda Category, ultrasound characteristics, location, and size of nodule). Highlight nodule location.
on thyroid diagram. If submitting more than 1 specimen, provide details for each location. **Incomplete or incorrect information will lead to testing delays.** Submitting Diagnosis: Write in appropriate ICD-10 code based on the patient’s medical records. The diagnosis code(s) provided should always be supported by documentation within the patient’s medical records. **Testing cannot be performed unless ICD-10 code(s) are included.**

**Section 5. Test Menu**

(If you have questions please contact Client Services)

Specimen processing cannot begin until there is a clear indication of type of testing to be performed (check box). Please indicate tests requested for patient specimen. Details of each test can be found on our website and in test details from our Directory of Laboratory Services. Only 1 test should be selected. A copy of the corresponding cytology report is requested to be sent with this specimen as available. If these reports are not available at time of specimen submission please forward to Client Services (fax: 1-888-674-6894 or 412-224-6425) when received.

**Section 6. Authorization**

The ordering physician is required to sign and date the requisition as authorization for Interpace Diagnostics to perform testing. Only the ordering physician can sign this requisition. Stamped signatures cannot be accepted. **An incomplete signature will result in testing delays.** Order date cannot precede Collection Date of the specimen. Post-dated requisitions are not accepted.
ThyraMIR® (Ordered as a Reflex Test with ThyGeNEXT®)

CPT: PLA 0081U

ThyraMIR® is a rule-out test for malignancy. ThyraMIR is available to order in conjunction with ThyGeNEXT® and cannot be ordered as a stand-alone test. Like ThyGeNEXT, this test is available for indeterminate thyroid nodules to provide additional risk assessment for optimum clinical management decisions. You can find additional information on our website, www.interpace.com.

Accepted Specimens

» Thyroid FNA in RNARetain®
» Thyroid cytology smear, ThinPrep, or cytospin
» Formalin Fixed Paraffin Embedded Tissue/Cell Block (FFPE) (8 recut slides plus 1 H&E slide)

Turnaround Time

» 10-14 business days for FNA samples from time of accessioning
» Less than 18 business days for cytology or FFPE samples from time of accessioning

Methodology

» MicroRNA Testing
» Specimen Requirements and Collection requirements are the same as ThyGeNEXT testing. Please refer to ThyGeNEXT for additional details

Related Test Orders:

» Cytology
» ThyGeNEXT

Ordering and Shipping Process

For instructions on how to order this test, see the Interpace Diagnostics “Test Ordering and Shipping Process” on page 9 of this document.

How to Complete a Test Requisition

ThyraMIR is ordered as a reflex test with ThyGeNEXT. To ensure timely and correct handling of submitted specimens to our laboratory, please refer to the requisition completion guidance found on Please see page 17.
AccuCEA™ (Carcinoembryonic Antigen)

CPT: 82378

AccuCEA™ (Carcinoembryonic Antigen) is often ordered in conjunction with Amylase to help characterize cyst type. AccuCEA results should be reviewed in relation to the patient’s medical history and current conditions. AccuCEA is a laboratory developed test (LDT) validated for pancreatic cyst fluids and small volume specimens.

Accepted Specimens

» Pancreaticobiliary cyst fluid, undiluted (1 mL requested)
» All bodily fluids

Turnaround Time

» 1-3 business days from time of accessioning

Methodology

» Immunochemiluminometric assay (ICMA)

Specimen Requirements

Collection requirements:

» Label vial with 2 unique patient identifiers (full name, DOB, MRN), collection date, and sample location
» Express each sample into a sterile DNAse- and RNase-free 2 mL vial (provided with the collection kit)
» Securely tighten all caps and seal all containers to prevent leakage
» Place vial into the biohazard bag with absorbent pad
» No special preparation or timing is required for collection of specimens
» Refrigerate sample(s) until time of shipping
» Specimen must be shipped with completely frozen freezer block (provided with the collection kit)

Control Prep (recommended for potential downstream molecular testing)

Buccal Brush (provided in Collection Kit) 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
» Label swab with 2 patient identifiers (full name, DOB, MRN) and collection date
» Scrape buccal brush firmly on the inside of patient’s cheek 6-8 times (~10 secs)
» Do not rinse or add preservatives
» Place the entire brush back into the container and close
» Place in the biohazard bag with the sample to be tested

Blood
Blood may be used as the normal control material if a buccal brush scraping is not available.
» Label blood vial with 2 patient identifiers (full name, DOB, MRN) and collection date
» Approximately 1.0 mL of anti-coagulated peripheral blood is sufficient for analysis
» Use 1 lavender top (EDTA as anti-coagulant) blood collection tube or 1 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

Rejected Specimen
» Frozen specimen
» Pre-diluted pancreaticobiliary cyst fluid
» Co-mingled specimen
» Unlabeled or mislabeled specimen
» Empty, leaking, or broken specimen vials

Storage Viability
» Store at 2-8°C
» Do not freeze
» Viable up to 28 days from collection

Related Test Orders
» Amylase
» Cytology
» PancraGEN®

Ordering and Shipping Process
For instructions on how to order this test, see the Interpace Diagnostics “Test Ordering and Shipping Process” on page 9 of this document.
**Amylase**

CPT: 82150

Amylase is often ordered in conjunction with AccuCEA™ (Carcinoembryonic Antigen) to help characterize cyst type. Amylase results should be reviewed in relation to the patient’s medical history and current conditions.

### Accepted Specimens

- Pancreaticobiliary cyst fluid, undiluted (1mL requested)
- All bodily fluids

### Turnaround Time

- 1-3 business days from time of accessioning

### Methodology

- Immunochemiluminometric assay (ICMA)

### Specimen Requirements

**Collection requirements**

- Label vial with 2 unique patient identifiers (full name, DOB, MRN), collection date, and sample location
- Express each sample into a sterile DNase- and RNase-free 2 mL vial (provided with the collection kit)
- Securely tighten all caps and seal all containers to prevent leakage
- Place vial into the biohazard bag with absorbent pad
- No special preparation or timing is required for collection of specimens
- Refrigerate sample(s) until time of shipping
- Specimen must be shipped with completely frozen freezer block (provided with the collection kit)

**Control Prep (recommended for potential downstream molecular testing)**

**Buccal Brush (provided in Collection Kit) 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
- Label swab with 2 patient identifiers (full name, DOB, MRN) and collection date
- Scrape buccal brush firmly on the inside of patient’s cheek 6-8 times (~10 secs)
- Do not rinse or add preservatives
- Place the entire brush back into the container and close
» Place in the biohazard bag with the sample to be tested

**Blood**

Blood may be used as the normal control material if a buccal brush scraping is not available.

» Label blood vial with 2 unique patient identifiers (full name, DOB, MRN) and collection date

» Approximately 1.0 mL of anti-coagulated peripheral blood is sufficient for analysis

» Use 1 lavender top (EDTA as anti-coagulant) blood collection tube or 1 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

**Rejected Specimen**

» Frozen specimen

» Pre-diluted pancreaticobiliary cyst fluid

» Co-mingled specimen

» Unlabeled or mislabeled specimen

» Empty, leaking, or broken specimen vials

**Storage Viability**

» Store at 2-8°C

» Do not freeze

» Viable up to 28 days from collection

**Related Test Orders:**

» AccuCEA™

» Cytology

» PancraGEN®

**Ordering and Shipping Process**

For instructions on how to order this test, see the Interpace Diagnostics “Test Ordering and Shipping Process” on page 9 of this document.
Cytology (Pancreaticobiliary)

CPT: 88173, 88305, 88342

Cytology can provide a definitive diagnosis of the pancreatic cystic lesion, and is often ordered in addition to AccuCEA™ (Carcinoembryonic Antigen) and Amylase. Cytology analysis is affected by the nature of the fluid specimens and often pancreatic cyst fluid lacks adequate cellular material for diagnosis. In such cases, absence of definitive malignant cells does not alone rule out malignancy, and all clinical features must be considered.

Accepted Specimens

» Pancreaticobiliary cyst or mass fluid, undiluted (1 mL requested)
» Pancreaticobiliary solid masses and ERCP brushes, in transport media
» All bodily fluids

Turnaround Time

» 3-5 business days from time of accessioning

Methodology

» Cytology staining

Specimen Requirements

Collection requirements

» Label vial with 2 unique patient identifiers (full name, DOB, MRN), collection date, and sample location
» Express each sample into a sterile DNase- and RNase-free 2 mL vial (provided with the collection kit)
» Securely tighten all caps and seal all containers to prevent leakage
» Place vial into the biohazard bag with absorbent pad
» No special preparation or timing is required for collection of specimens
» Refrigerate sample(s) until time of shipping
» Specimen must be shipped with completely frozen freezer block (provided with the collection kit)

Control Prep (recommended for potential downstream molecular testing)

Buccal Brush (provided in Collection Kit) 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
» Label swab with 2 unique patient identifiers (full name, DOB, MRN) and collection date
» Scrape buccal brush firmly on the inside of patient’s cheek 6-8 times (~10 secs)
» Do not rinse or add preservatives
» Place the entire brush back into the container and close
» Place in the biohazard bag with the sample to be tested

Blood

Blood may be used as the normal control material if a buccal brush scraping is not available.

» Label blood vial with 2 unique patient identifiers (full name, DOB, MRN) and collection date
» Approximately 1.0 mL of anti-coagulated peripheral blood is sufficient for analysis
» Use 1 lavender top (EDTA as anti-coagulant) blood collection tube or 1 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

Rejected Specimen:

» Frozen specimen
» Pre-diluted pancreaticobiliary cyst fluid
» Co-mingled specimen
» Unlabeled or mislabeled specimen
» Empty, leaking, or broken specimen vials

Storage Viability:

» Store at 2-8°C
» Do not freeze
» Viable up to 14 days

Related Test Orders:

» Amylase
» AccuCEA™
» PancraGEN®

Ordering and Shipping Process

For instructions on how to order this test, see the Interpace Diagnostics “Test Ordering and Shipping Process” on page 9 of this document.
PancraGEN®

CPT: 81479

PancraGEN is a molecular panel test based on 4 components (Quality and Quantity of DNA, Oncogene point mutations (KRAS only), and Tumor Suppressor Gene Mutations) that integrates clinical features and provides risk stratification of a patient’s pancreaticobiliary sample. This test is ordered after evaluation of first-line results such as endoscopic ultrasound (EUS), Carcinoembryonic Antigen (CEA) or AccuCEA™, Amylase, and Cytology, when additional detail of risk may help clarify patient management. You can find additional information on our website, www.interpace.com.

The GNAS oncogene point mutation is ordered separately. Please see page 29.

Accepted Specimens

» Pancreaticobiliary cyst or mass fluid, undiluted (1 mL requested)
» Pancreaticobiliary solid masses and ERCP brushes, in transport media
» Pancreaticobiliary solid masses and ERCP brushes, dry

Turnaround Time

» 10-14 business days from time of accessioning

Methodology

» Loss of Heterozygosity (LOH) through Fragment Analysis
» Sanger Sequencing

Specimen Requirements

Collection requirements

» Label vial with 2 unique patient identifiers (full name, DOB, MRN), collection date, and sample location
» Express each sample into a sterile DNAse- and RNase-free 2 mL vial (provided with the collection kit)
» Securely tighten all caps and seal all containers to prevent leakage
» Place vial into the biohazard bag with absorbent pad
» No special preparation or timing is required for collection of specimens
» Refrigerate sample(s) until time of shipping
» Specimen must be shipped with completely frozen freezer block (provided with the collection kit)
Control Prep (required)

**Buccal Brush (provided in Collection Kit) 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
- Label swab with 2 unique patient identifiers (full name, DOB, MRN) and collection date
- Scrape buccal brush firmly on the inside of patient’s cheek 6-8 times (~10 secs)
- Do not rinse or add preservatives
- Place the entire brush back into the container and close
- Place in the biohazard bag with the sample to be tested

**Blood**

Blood may be used as the normal control material if a buccal brush scraping is not available.

- Label blood vial with 2 unique patient identifiers (full name, DOB, MRN) and collection date
- Approximately 1.0 mL of anti-coagulated peripheral blood is sufficient for analysis
- Use 1 lavender top (EDTA as anti-coagulant) blood collection tube or 1 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

**Rejected Specimen:**

- Non-pancreaticobiliary samples
- Frozen specimen
- Pre-diluted cyst fluid
- Co-mingled specimen
- Unlabeled or mislabeled specimen
- Empty, leaking, or broken specimen vials

**Storage Viability:**

- Store at 2-8°C
- Do not freeze
- Viable up to 45 days

**Related Test Orders**

- Amylase
- AccuCEA™
- Cytology
Ordering and Shipping Process
For instructions on how to order this test, see the Interpace Diagnostics “Test Ordering and Shipping Process” on page 9 of this document.

How to Complete a Test Requisition
To ensure timely and correct handling of submitted specimens to our laboratory, please refer to the requisition completion guidance found on Please see page 31.
PancraGEN® with GNAS

CPT: 81479

PancraGEN with GNAS is a molecular panel test based on 4 components (Quality and Quantity of DNA, Oncogene point mutations (KRAS and GNAS), Tumor Suppressor Gene Mutations) that integrates clinical features and provides risk stratification of a patient’s pancreaticobiliary sample. This test is ordered after evaluation of first-line results such as endoscopic ultrasound (EUS), Carcinoembryonic Antigen (CEA) or AccuCEA™, Amylase, and Cytology, when additional detail of risk may help clarify patient management. GNAS is highly specific for Intraductal papillary mucinous neoplasm (IPMN) lesions. You can find additional information on our website, www.interpace.com.

Accepted Specimen:
- Pancreaticobiliary cyst or mass fluid, undiluted (1 mL requested)

Turnaround Time:
- 10-14 business days from time of accessioning

Methodology:
- Loss of Heterozygosity (LOH) through Fragment Analysis
- Sanger Sequencing

Specimen Requirements

Collection requirements
- Label vial with 2 unique patient identifiers (full name, DOB, MRN), collection date, and sample location
- Express each sample into a sterile DNAse- and RNase-free 2 mL vial (provided with the collection kit)
- Securely tighten all caps and seal all containers to prevent leakage
- Place vial into the biohazard bag with absorbent pad
- No special preparation or timing is required for collection of specimens
- Refrigerate sample(s) until time of shipping
- Specimen must be shipped with completely frozen freezer block (provided with the collection kit)
Control Prep (required)

Buccal Brush (provided in Collection Kit) 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
- Label swab with 2 unique patient identifiers (full name, DOB, MRN) and collection date
- Scrape buccal brush firmly on the inside of patient’s cheek 6-8 times (~10 secs)
- Do not rinse or add preservatives
- Place the entire brush back into the container and close
- Place in the biohazard bag with the sample to be tested

Blood

Blood may be used as the normal control material if a buccal brush scraping is not available.

- Label blood vial with 2 unique patient identifiers (full name, DOB, MRN) and collection date
- Approximately 1.0 mL of anti-coagulated peripheral blood is sufficient for analysis
- Use 1 lavender top (EDTA as anti-coagulant) blood collection tube or 1 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

Rejected Specimen:

- Non-pancreaticobiliary samples
- Frozen specimen
- Pre-diluted cyst fluid
- Co-mingled specimen
- Unlabeled or mislabeled specimen
- Empty, leaking, or broken specimen vials

Storage Viability:

- Store at 2-8°C
- Do not freeze
- Viable up to 45 days

Related Test Orders:

- Amylase
- AccuCEATM
- Cytology
Ordering and Shipping Process

For instructions on how to order this test, see the Interpace Diagnostics “Test Ordering and Shipping Process” on page 9 of this document.

How to Complete a Test Requisition

Testing requisitions can vary. The following are general guidelines to assist in completing the Interpace Diagnostics Testing Requisitions to ensure timely and correct handling of submitted specimens to our laboratory. Please refer to examples below to help answer questions that you may have for completion of the testing requisition. If at any point you have additional questions or need a requisition for specimen submission, please contact Client Services at 800-495-9885 or clientservices@interpace.com. Additionally, blank requisitions can be found on our website, www.interpace.com.

Section 1. Patient Information

All fields are required. Include patient first and last name, date of birth, SSN/MRN, and sex. A complete patient label can be adhered in this field as long as patient information is complete and includes 2 unique identifiers. Incomplete information will result in testing delays.

Section 2. Physician Information

Submitting Physician—this section may be pre-filled if an account has been set up with Interpace Diagnostics. If blank, complete each field. Account Number should match your Interpace Diagnostics account number (leave blank if unknown). Complete physician institution contact information. Please avoid Office/Hospital acronym nomenclature and spell out institution to ensure accurate case entry for ordering. Staff Contact—provide contact information for appropriate person to provide information should any questions or issues arise for specimen testing. Leaving contact information incomplete will result in testing delays.

Section 3. Billing Information

Check appropriate box to indicate type of insurance/payor for patient. A copy of the patient’s billing information MUST be submitted with specimen. Select box to indicate where procedure was performed (inpatient with discharge date (required), outpatient, or non-hospital/freestanding clinic). Write in appropriate ICD-10 code based on the patient’s medical records. The diagnosis code(s) provided should always be supported by documentation within the patient’s medical records. Testing cannot be performed unless ICD-10 code(s) are included.
Section 4. Specimen Information

*Specimen Collection Date* should be the date the specimen was collected. Check box to indicate type of specimen being sent in for testing (REQUIRED). *Submitted Control:* Refer to details in test descriptions above for collection process. Indicate type of control being submitted. *Specimen Location:* If submitting more than 1 specimen, provide details for each location. Please check/write in specimen location. Please indicate the number of vials being submitted for that location. Repeat for additional specimens in spaces provided. **Incomplete or incorrect information will lead to testing delays.**

**For pancreatic masses or ERCP brush specimens, indicate if media is contained with specimen or if specimen is undiluted. (If media was used, please indicate type). Pancreatic Cyst FNA specimens must be UNDILUTED**

Section 5. Test Menu

(This may vary per account and preference. If you have questions please contact Client Services.)

Specimen processing cannot begin until there is a clear indication of type of testing to be performed. Please indicate tests needed for patient specimen. Details of each test can be found on our website and in test details from our Directory of Laboratory Services. When ordering PancraGEN or PancraGEN plus GNAS testing, copies of EUS/Cytology reports are required. If these reports are not available at time of specimen submission please forward to Client Services (fax: 1-888-674-6894 or 412-224-6425) when received.

Section 6. Authorization

The ordering physician is required to sign and date the requisition as authorization for Interpace Diagnostics to perform testing. Only the ordering physician can sign this requisition. Stamped signatures cannot be accepted. **An incomplete signature will result in testing delays.** Order date cannot precede Collection Date of the specimen. Post-dated requisitions are not accepted.
Pancreaticobiliary Molecular Testing
(Cyto-centrifugation Supernatant, Biliary Brushings, Cytology Slide Specimens)

CPT: N/A

Molecular panel, powered by PathfinderTG®, based on 4 components (Quality and Quantity of DNA, Oncogene point mutations (KRAS and GNAS), and Tumor Suppressor Gene Mutations) that integrates clinical features and provides risk stratification of a patient’s pancreaticobiliary sample.

Accepted Specimen
- Pancreaticobiliary cyst or mass fluid, undiluted (1 mL requested)
- Pancreaticobiliary solid masses and ERCP brushes, in preservative solution
- Pancreaticobiliary solid masses and ERCP brushes, dry

Turnaround Time
- 10-14 business days from time of accessioning

Methodology
- Loss of Heterozygosity (LOH) through Fragment Analysis
- Sanger Sequencing

Specimen Requirements
Collection requirements:

Cyto-centrifugation Supernatant Collection
- Label specimen collection container(s) with 2 unique patient identifiers (full name, DOB, MRN), collection date, and sample location
- Place up to 50 mL of supernatant fluid or residual fluid from a liquid cytology preparation (such as ThinPrep® or SurePrep®) in to the supernatant collection tube provided with the collection kit
- Do not mix supernatants from multiple specimens. Each specimen should be collected in designated collection tube and clearly labeled to indicate specimen location/type
- Securely tighten all caps and seal all containers to prevent leakage
- Place vial into the biohazard bag with absorbent pad
- No special preparation or timing is required for collection of specimens
- Refrigerate sample(s) until time of shipping
- Specimen must be shipped with completely frozen freezer block (provided with the collection kit)
- Indicate type of media used on requisition
- NOTE: If sending to local cytology laboratory for processing, please label supernatant tubes as “DO NOT DISCARD”
**ERCP Biliary Brushing Specimen Collection**

- Label specimen collection container(s) with 2 unique patient identifiers (full name, DOB, MRN), collection date, and sample location
- Prepare brush (either below are acceptable for testing):
  - Detach portion of brush head or entire brush head and place into an empty 2 mL polypropylene screw cap tube (provided in collection kit)
  - Place brush into a vial of cytology fixative (recommendations are to use provided solution from collection kit, PreservCyt), vigorously agitate solution with brush for 10 seconds (vortex). Aliquot 10 mL to 15 mL of specimen solution into empty screw cap vial (provided in collection kit). **CytoRich Red and acetic acid are rejected media and will not be accepted for testing**
- If sending multiple specimens, place 1 brush head per collection vial. Each specimen should be collected in designated collection tube and clearly labeled to indicate specimen location/type
- Securely tighten all caps and seal all containers to prevent leakage
- Place vial into the biohazard bag with absorbent pad
- Refrigerate sample(s) until time of shipping
- Specimen must be shipped with completely frozen freezer block (provided with the collection kit)
- Indicate type of media (if applicable) used on requisition

**Cytology Slide Specimen Collection**

- Slides stained with Papanicolaou (PAP) or Diff-Quik, with coverslips removed, are preferred for testing
- Hematoxylin/Eosin stained slides are NOT accepted
- Selected slides should be most representative of diagnosis with adequate cellularity (smear, cell block, or ThinPrep® accepted)
- 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-reference of patient name, date of collection, and Pathology accession number
- On the test requisition, be sure to indicate the slide(s) accession number and number of slide(s) submitted for testing. Indicate on requisition type of cytology slide (smear, cell block, ThinPrep®)
- Insert slide(s) into provided plastic slide holder, securely snap lid shut
- Place slide holder with glass slide into padded pouch
- Sample does not need to be refrigerated
Control Prep (required)

**Buccal Brush (provided in Collection Kit) 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.

- Label swab with 2 unique patient identifiers (full name, DOB, MRN) and collection date
- Scrape buccal brush firmly on the inside of patient’s cheek 6-8 times (~10 secs)
- Do not rinse or add preservatives
- Place the entire brush back into the container and close
- Place in the biohazard bag with the sample to be tested

**Blood**
Blood may be used as the normal control material if a buccal brush scraping is not available.

- Label blood vial with 2 unique patient identifiers (full name, DOB, MRN) and collection date
- Approximately 1.0 mL of anti-coagulated peripheral blood is sufficient for analysis
- Use 1 lavender top (EDTA as anti-coagulant) blood collection tube or 1 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

**Rejected Specimen:**
- Non-pancreaticobiliary samples
- Frozen specimen
- Co-mingled specimen
- Unlabeled or mislabeled specimen
- Empty, leaking, or broken specimen vials

**Storage Viability:**
- Store at 2-8°C (cytology slides can be stored at room temperature)
- Do not freeze
- Viable up to 45 days

**Related Test Orders:**
- Amylase
- AccuCEA™
- Cytology

**Ordering and Shipping Process**
For instructions on how to order this test, see the Interpace Diagnostics “Test Ordering and Shipping Process” on page 9 of this document.
PanDNA®

CPT: 81479

PanDNA® is a molecular panel test based on 2 molecular components (Oncogene point mutations (KRAS and GNAS) and Tumor Suppressor Gene Mutations) for use by practitioners to assist in patient management when assessing risk for a patient’s pancreaticobiliary sample. This test is ordered after evaluation of first-line results such as endoscopic ultrasound (EUS), Carcinoembryonic Antigen (CEA) or AccuCEA™, Amylase, and Cytology, when additional detail of risk may help clarify patient management. GNAS is highly specific for Intraductal papillary mucinous neoplasm (IPMN) lesions. You can find additional information on our website, www.interpace.com.

Accepted Specimen:

» Pancreaticobiliary cyst or mass fluid, undiluted (1 mL requested)

Turnaround Time:

» 10-14 business days from time of accessioning

Methodology:

» Loss of Heterozygosity (LOH) through Fragment Analysis
» Sanger Sequencing

Specimen Requirements

Collection requirements

» Label vial with 2 unique patient identifiers (full name, DOB, MRN), collection date, and sample location
» Express each sample into a sterile DNase- and RNase-free 2 mL vial (provided with the collection kit)
» Securely tighten all caps and seal all containers to prevent leakage
» Place vial into the biohazard bag with absorbent pad
» No special preparation or timing is required for collection of specimens
» Refrigerate sample(s) until time of shipping
» Specimen must be shipped with completely frozen freezer block (provided with the collection kit)
Control Prep (required)

**Buccal Brush (provided in Collection Kit) 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
- Label swab with 2 unique patient identifiers (full name, DOB, MRN) and collection date
- Scrape buccal brush firmly on the inside of patient’s cheek 6-8 times (~10 secs)
- Do not rinse or add preservatives
- Place the entire brush back into the container and close
- Place in the biohazard bag with the sample to be tested

**Blood**
Blood may be used as the normal control material if a buccal brush scraping is not available.

- Label blood vial with 2 unique patient identifiers (full name, DOB, MRN) and collection date
- Approximately 1.0 mL of anti-coagulated peripheral blood is sufficient for analysis
- Use 1 lavender top (EDTA as anti-coagulant) blood collection tube or 1 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

**Rejected Specimen**
- Non-pancreaticobiliary samples
- Frozen specimen
- Pre-diluted cyst fluid
- Co-mingled specimen
- Unlabeled or mislabeled specimen
- Empty, leaking, or broken specimen vials

**Storage Viability**
- Store at 2-8°C
- Do not freeze
- Viable up to 45 days

**Related Test Orders**
- Amylase
- AccuCEATM
- Cytology
Ordering and Shipping Process

For instructions on how to order this test, see the Interpace Diagnostics “Test Ordering and Shipping Process” on page 9 of this document.

How to Complete a Test Requisition

Testing requisitions can vary. The following are general guidelines to assist in completing the Interpace Diagnostics Testing Requisitions to ensure timely and correct handling of submitted specimens to our laboratory. Please refer to examples below to help answer questions that you may have for completion of the testing requisition. If at any point you have additional questions or need a requisition for specimen submission, please contact Client Services at 800-495-9885 or clientservices@interpace.com. Additionally, blank requisitions can be found on our website, www.interpace.com.

Section 1. Patient Information

All fields are required. Include patient first and last name, date of birth, SSN/MRN, and sex. A complete patient label can be adhered in this field as long as patient information is complete and includes 2 unique identifiers. Incomplete information will result in testing delays.

Section 2. Physician Information

Submitting Physician—this section may be pre-filled if an account has been set up with Interpace Diagnostics. If blank, complete each field. Account Number should match your Interpace Diagnostics account number (leave blank if unknown). Complete physician institution contact information. Please avoid Office/Hospital acronym nomenclature and spell out institution to ensure accurate case entry for ordering. Staff Contact—provide contact information for appropriate person to provide information should any questions or issues arise for specimen testing. Leaving contact information incomplete will result in testing delays.

Section 3. Billing Information

Check appropriate box to indicate type of insurance/payor for patient. A copy of the patient’s billing information MUST be submitted with specimen. Select box to indicate where procedure was performed (inpatient with discharge date (required), outpatient, or non-hospital/freestanding clinic). Write in appropriate ICD-10 code based on the patient’s medical records. The diagnosis code(s) provided should always be supported by documentation within the patient’s medical records. Testing cannot be performed unless ICD-10 code(s) are included.
Section 4. Specimen Information
Specimen Collection Date should be the date the specimen was collected. Check box to indicate type of specimen being sent in for testing (REQUIRED). Submitted Control: Refer to details in test descriptions above for collection process. Indicate type of control being submitted. Specimen Location: If submitting more than 1 specimen, provide details for each location. Please check/write in specimen location. Please indicate the number of vials being submitted for that location. Repeat for additional specimens in spaces provided. Incomplete or incorrect information will lead to testing delays.

For pancreatic masses or ERCP brush specimens, indicate if media is contained with specimen or if specimen is undiluted. (If media was used, please indicate type). Pancreatic Cyst FNA specimens must be UNDILUTED

Section 5. Reasons for Ordering
If this test is ordered 14 or more days after collection, you must identify factors that affected the time of ordering PanDNA®. (This information is required for Medicare).

Section 6. Attestation
This section advises that by signing the requisition, the ordering physician attests that PanDNA® is medically reasonable and necessary, first-line evaluation was not clearly malignant or clearly benign, and a decision for treatment has not already been made based on existing information.

Section 7. Test Menu
(This may vary per account and preference. If you have questions please contact Client Services.) Specimen processing cannot begin until there is a clear indication of type of testing to be performed. Please indicate tests needed for patient specimen. Details of each test can be found on our website and in test details from our Directory of Laboratory Services.

Section 8. Authorization
The ordering physician is required to sign and date the requisition as authorization for Interpace Diagnostics to perform testing. Only the ordering physician can sign this requisition. Stamped signatures cannot be accepted. An incomplete signature will result in testing delays. Order date cannot precede Collection Date of the specimen. Post-dated requisitions are not accepted.
BarreGEN® testing is a detailed risk classifier summary of a patient’s esophageal sample. This test is ordered after indeterminate pathology or cytology results from biopsies or IHC staining where no patient treatment has been decided upon. You can find additional information on our website, www.interpace.com.

Accepted Specimen
Esophageal Biopsies; Formalin Fixed Paraffin Embedded Tissue/Cell Block (FFPE)

» Whole block that will be recut for testing
» 8 recut slides, plus 1 H&E slide
   - Positive charged slides not required
   - Ribboning is encouraged

Turnaround Time
» Less than 18 business days from time of accessioning

Methodology
» Loss of Heterozygosity (LOH) through Fragment Analysis
» Sanger Sequencing

Specimen Requirements

Collection requirements

Slide Recuts from an FFPE Tissue Block
» Recut 9 sections (4-5 microns thick) form each tissue block of interest
   - 1 slide must be stained with H&E and cover slip (do not send original)
   - 8 slides unstained and no coverslip
» All blocks 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 with patient name, date of collection, and with the Pathology Department’s accession number
» Select most representative sections including 1 section that contains non-neoplastic tissue (control)
On the test requisition, be sure to indicate the slide(s) accession number and appropriate amount of slide(s) being sent for testing

- Insert slide(s) into provided plastic slide holder, securely snap lid shut
- Place slide holder with glass slide into padded pouch
- No special preparation or timing is required for collection of specimens
- Sample does not need to be refrigerated

**FFPE Block Collection**

- All blocks 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 with patient name, date of collection, and with the Pathology Department’s accession number
- On the test requisition, be sure to indicate the block(s) accession number and appropriate amount of block(s) being sent for testing
- Insert block(s) into provided plastic zip-lock bag, securely snap shut
- Place sealed bag into the foam insert of the collection kit to prevent damage
- In warm weather, a frozen freezer brick (or equivalent) can be placed above the foam insert
- No special preparation or timing is required for collection of specimens
- Sample does not need to be refrigerated

**Control Prep**

- If sending slide recuts from an FFPE block, include 1 slide section that contains non-neoplastic tissue

**Rejected Specimen**

- Unlabeled or mislabeled specimen
- Empty, leaking, or broken specimen
- Bleached, decalcified, or tissue fixed histology slides in Zenker’s and Bouin’s fixative

**Storage Viability**

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

**Related Test Orders**

- None

**Ordering and Shipping Process**

For instructions on how to order this test, see the Interpace Diagnostics “Test Ordering and Shipping Process” on page 9 of this document.

**How to Complete a Test Requisition**

Testing requisitions can vary. The following are general guidelines to assist in completing the Interpace Diagnostics Testing Requisitions to ensure timely and correct handling of submitted
specimens to our laboratory. Please refer to examples below to help answer questions that you may have for completion of the testing requisition. If at any point you have additional questions or need a requisition for specimen submission, please contact Client Services at 800-495-9885 or clientservices@interpace.com. Additionally, blank requisitions can be found on our website, www.interpace.com.

Section 1. Patient Information

All fields are required. Include patient first and last name, date of birth, SSN/MRN, and sex. A complete patient label can be adhered in this field as long as patient information is complete and includes 2 unique identifiers. Incomplete information will result in testing delays.

Section 2. Physician Information

This section may be pre-filled if an account has been set up with Interpace Diagnostics. If blank, complete each field. Account Number should match your Interpace Diagnostics account number (leave blank if unknown). Complete physician institution contact information. Please avoid Office/Hospital acronym nomenclature and spell out institution to ensure accurate case entry for ordering. Provide institution, full name, and phone/fax number for referring/treating physician if applicable. Leaving contact information incomplete will result in processing delays.

Section 3. Billing Information

Check appropriate box to indicate type of insurance/payor for patient. A copy of the patient’s billing information MUST be submitted with specimen. Select box to indicate where procedure was performed (inpatient with discharge date (required), outpatient, or non-hospital/freestanding clinic). Write in appropriate ICD-10 code based on the patient’s medical records. The diagnosis code(s) provided should always be supported by documentation within the patient’s medical records. Testing cannot be performed unless ICD-10 code(s) are included.

Section 4. Specimen Information

Specimen Collection Date should be the date specimen was collected. Complete type of specimen being sent in for testing with corresponding pathology accession number from the slides (REQUIRED). Check appropriate box for slides being submitted and enter number of slides included for testing. If submitting more than 1 specimen, provide details for each location. Please check/write in specimen descriptions. Incomplete or incorrect information will lead to testing delays.
Section 5. Reasons for Ordering (Required for Medicare if ordering 14 days or more after collection)

This section pertains only to patients with Medicare insurance. A reason code is required for medicare patients if testing is being order 14 days (or more) after collection. It is required that a Reason Code be selected to proceed with testing. **Leaving this section incomplete for those patients with Medicare will delay testing.**

Section 6. Clinical Reports

Indicate test reports being sent with specimen for review. If reports are not available at the time of submission, please fax to 888-674-6894 or 412-224-6425 upon completion.

Section 7. Authorization

The ordering physician is required to sign and date the requisition as authorization for Interpace Diagnostics to perform testing. Only the ordering physician can sign this requisition. Stamped signatures cannot be accepted. **An incomplete signature will result in testing delays.** Order date cannot precede Collection Date of the specimen. Post-dated requisitions are not accepted.
RespriDX®

CPT: 81479

RespriDX® is a comparative mutational profile test. This test is ordered to help decide the treatment course for possible metastatic cancers, and to determine if the tumors are recurrent or a new primary tumor. You can find additional information on our website, www.interpace.com.

Accepted Specimen

Formalin Fixed Paraffin Embedded Tissue/Cell Block (FFPE)

- Whole block that will be recut for testing
- 8 recut slides, plus 1 H&E slide 2 different cancers:
  - Positive charged slides not required
  - Ribboning is encouraged
- 1-2 representative cytology smears (DiffQuick or PAP stained, non-frosted slides)
- 1-2 representative ThinPrep, or cytospin slides

Turnaround Time

- Less than 18 business days from time of accessioning

Methodology

- Loss of Heterozygosity (LOH) through Fragment Analysis
- Sanger Sequencing

Specimen Requirements

Collection requirements

Slide Recuts from an FFPE Tissue Block

- Recut 9 sections (4-5 microns thick) form each tissue block of interest
  - 1 slide must be stained with H&E and cover slip (do not send original)
  - 8 slides unstained and no coverslip
- All blocks 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 with patient name, date of collection, and with the Pathology Department’s accession number
Select **most representative sections** including 1 section that contains non-neoplastic tissue (control)

- On the test requisition, be sure to indicate the slide(s) accession number and appropriate amount of slide(s) being sent for testing
- Insert slide(s) into provided plastic slide holder, securely snap lid shut
- Place slide holder with glass slide into padded pouch
- No special preparation or timing is required for collection of specimens
- Sample does not need to be refrigerated

**FFPE Block Collection**

- All blocks 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 with patient name, date of collection, and with the Pathology Department’s accession number
- On the test requisition, be sure to indicate the block(s) accession number and appropriate amount of block(s) being sent for testing
- Insert block(s) into provided plastic zip-lock bag, securely snap shut
- Place sealed bag into the foam insert of the collection kit to prevent damage
- In warm weather, a frozen freezer brick (or equivalent) can be placed above the foam insert
- No special preparation or timing is required for collection of specimens. Sample does not need to be refrigerated

**Cytology smear or ThinPrep Collection**

- 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 with patient name, date of collection, and the Pathology Department’s accession number
- On the test requisition, be sure to indicate the slide(s) accession number and appropriate amount of slide(s) being sent for testing
- Insert slide(s) into provided plastic slide holder, securely snap lid shut
- Place slide holder with glass slide into padded pouch
- No special preparation or timing is required for collection of specimens
- Sample does not need to be refrigerated

**Control Prep:**

*If sending slide recuts from an FFPE block*, include 1 slide section that contains non-neoplastic tissue.

**Rejected Specimen:**
- Unlabeled or mislabeled specimen
- Empty, leaking, or broken specimen
» Bleached, decalcified, or tissue fixed histology slides in Zenker’s and Bouin’s fixative

**Storage Viability:**

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

**Related Test Orders:**

» None

**Ordering and Shipping Process**

For instructions on how to order this test, see the Interpace Diagnostics “Test Ordering and Shipping Process” on page 9 of this document.

**How to Complete a Test Requisition**

Testing requisitions can vary. The following are general guidelines to assist in completing the Interpace Diagnostics Testing Requisitions to ensure timely and correct handling of submitted specimens to our laboratory. Please refer to examples below to help answer questions that you may have for completion of the testing requisition. If at any point you have additional questions or need a requisition for specimen submission, please contact Client Services at 800-495-9885 or clientservices@interpace.com. Additionally, blank requisitions can be found on our website, www.interpace.com.

### Section 1. Patient Information

All fields are required. Include patient first and last name, date of birth, SSN/MRN, and sex. A complete patient label can be adhered in this field as long as patient information is complete and includes 2 unique identifiers. **Incomplete information will result in testing delays.**

### Section 2. Physician Information

This section may be pre-filled if an account has been set up with Interpace Diagnostics. If blank, complete each field. Account Number should match your Interpace Diagnostics account number (leave blank if unknown). Complete physician institution contact information. Please avoid Office/Hospital acronym nomenclature and spell out institution to ensure accurate case entry for ordering. Provide institution, full name, and phone/fax number for referring/
treatings physician if applicable. **Leaving contact information incomplete will result in processing delays.**

**Section 3. Billing Information**

Check appropriate box to indicate type of insurance/payor for patient. **A copy of the patient’s billing information MUST be submitted with specimen.** Select box to indicate where procedure was performed (inpatient with discharge date (required), outpatient, or non-hospital/freestanding clinic). Write in appropriate ICD-10 code based on the patient’s medical records. The diagnosis code(s) provided should always be supported by documentation within the patient’s medical records. **Testing cannot be performed unless ICD-10 code(s) are included.**

**Section 4. Specimen Information**

*Specimen Collection Date* should be the date specimen was collected. Complete type of specimen being sent in for testing with corresponding pathology accession number from the slides (REQUIRED). Check appropriate box for slides being submitted and enter number of slides included for testing, or if submitting paraffin embedded tissue block. Complete the same information for the second specimen. **Incomplete or incorrect information will lead to testing delays.**

**Section 5. Reasons for Ordering (Required for Medicare if ordering 14 days or more after collection)**

This section pertains only to patients with Medicare insurance. A reason code is required for medicare patients if testing is being ordered 14 days (or more) after collection. It is required that a Reason Code be selected to proceed with testing. **Leaving this section incomplete for those patients with Medicare will delay testing.**

**Section 6. Clinical Reports**

Indicate test reports being sent with specimen for review. Each submitted specimen should have supporting documentation submitted. If reports are not available at time of submission, please fax to 888-674-6894 or 412-224-6425 upon completion.

**Section 7. Authorization**

The ordering physician is required to sign and date the requisition as authorization for Interpace Diagnostics to perform testing. Only the ordering physician can sign this requisition. Stamped signatures cannot be accepted. **An incomplete signature will result in testing delays.** Order date cannot precede Collection Date of the specimen. Post-dated requisitions are not accepted.
COVIANT™ provides qualitative detection of IgG antibodies to the novel coronavirus SARS-CoV-2 in human serum. The assay is based on the capacity to distinguish between relatively high and low levels of antibody. The presence of the IgG antibody to the SARS-CoV-2 antigen is an indication that the patient has been exposed to the SARS-CoV-2 virus, which is responsible for COVID-19 disease. You can find additional information on about COVIANT at www.coviant.com.

Accepted Specimen
- Cell-free EDTA plasma (lavender cap) is the preferred specimen type. Cell-free serum (red or gold cap) can also be accommodated for testing

Turnaround Time
- Less than 3 days

Methodology
- Enzyme-linked immunosorbent assay (ELISA)
- The test kit for antibody assessment is manufactured by EUROIMMUN US, Mountain Lakes, NJ, and has been awarded an Emergency Use Authorization (EUA) from the United States Food and Drug Association (FDA)

Specimen Requirements

Collection requirements
- Cell-free EDTA plasma (lavender cap) is the preferred specimen type. Cell-free serum (red or gold cap) can also be accommodated for testing
- A minimum of 2 mL cell-free EDTA plasma or 1 mL cell-free serum is needed to run the assay
- Specimens must be refrigerated (2-8°C) until shipping
- Samples should be shipped for overnight delivery using the FedEx® label provided

Rejected Specimen
- Severely hemolyzed specimens

Storage Viability
- Store at 2-8°C until shipping
- Do not freeze specimen
Ordering and Shipping Process
For instructions on how to order this test, see the Interpace Diagnostics “Test Ordering and Shipping Process” on page 9 of this document.

How to Complete a Test Requisition
Testing requisitions can vary. The following are general guidelines to assist in completing the Interpace Diagnostics Testing Requisitions to ensure timely and correct handling of submitted specimens to our laboratory. Please refer to examples below to help answer questions that you may have for completion of the testing requisition. If at any point you have additional questions or need a requisition for specimen submission, please contact Client Services at 800-495-9885 or clientservices@interpace.com. Additionally, blank requisitions can be found on our website, www.interpace.com.

Section 1. Patient Information
All fields are required. Include patient first and last name, date of birth, SSN/MRN code, and sex. A complete patient label can be adhered in this field as long as patient information is complete and includes 2 unique identifiers. Incomplete information will result in testing delays.

Section 2. Physician Information
Submitting Physician—this section may be pre-filled if an account has been set up with Interpace Diagnostics. If blank, complete each field. Account Number should match your Interpace Diagnostics account number (leave blank if unknown). Complete physician institution contact information. Please avoid Office/Hospital acronym nomenclature and spell out institution to ensure accurate case entry for ordering. Staff Contact—provide contact information for appropriate person to provide information should any questions or issues arise for specimen testing. Leaving contact information incomplete will result in testing delays.

Section 3. Billing Information
COVIANT is direct-billed. Please ensure appropriate billing contact information is provided.

Section 4. Specimen Information
Select boxes to indicate where the procedure was performed and all diagnostic questions. Write in appropriate ICD-10 code based on the patient’s medical records. The diagnosis code(s) provided
should always be supported by documentation within the patient’s medical records. **Testing cannot be performed unless ICD-10 code(s) are included.**

**Section 5. Test Menu**
Order Covid-19 IgG testing by completing, signing and dating the authorization in section 6 of this requisition.

**Section 6. Authorization**
The ordering physician is required to sign and date the requisition as authorization for Interpace Diagnostics to perform testing. Only the ordering physician can sign this requisition. Stamped signatures cannot be accepted. **An incomplete signature will result in testing delays.** Order date cannot precede Collection Date of the specimen. Post-dated requisitions are not accepted.

**Section 7. Patient Authorization**
The patient should review this section of the requisition with the physician. If they choose, the patient should sign and date as acknowledgement and authorization of testing.
Tissue Identity Testing

CPT: N/A

Tissue Identity Testing is offered to institutions for confirmatory testing when a patient sample’s identity is of concern or when metastases versus primary solid tumor analysis is desired.

Accepted Specimen:
Formalin Fixed Paraffin Embedded Tissue/Cell Block (FFPE)
  » Whole block that will be recut for testing
  » 8 recut slides, plus 1 H&E slide:
    - Positive charged slides not required
    - Ribboning is encouraged

Turnaround Time:
  » Less than 18 business days from time of accessioning

Methodology:
  » Loss of Heterozygosity (LOH) through Fragment Analysis
  » Sanger Sequencing

Specimen Requirements

Collection requirements

Slide Recuts from an FFPE Tissue Block
  » Recut 9 sections (4-5 microns thick) form each tissue block of interest
    - 1 slide must be stained with H&E and cover slip (do not send original)
    - 8 slides unstained and no coverslip
  » All blocks 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 with patient name, date of collection, and with the Pathology Department’s accession number
  » On the test requisition, be sure to indicate the slide(s) accession number and appropriate amount of slide(s) being sent for testing
  » Insert slide(s) into provided plastic slide holder, securely snap lid shut
  » Place slide holder with glass slide into padded pouch
  » No special preparation or timing is required for collection of specimens
  » Sample does not need to be refrigerated
FFPE Block Collection

» All blocks 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 with patient name, date of collection, and with the Pathology Department’s accession number.

» On the test requisition, be sure to indicate the block(s) accession number and appropriate amount of block(s) being sent for testing.

» Insert block(s) into provided plastic zip-lock bag, securely snap shut.

» Place sealed bag into the foam insert of the collection kit to prevent damage.

» In warm weather, a frozen freezer brick (or equivalent) can be placed above the foam insert.

» No special preparation or timing is required for collection of specimens.

» Sample does not need to be refrigerated.

Control Prep

Normal control from known patient is required.

Rejected Specimen

» Unlabeled or mislabeled specimen

» Empty, leaking, or broken specimen

» Bleached, decalcified, or tissue fixed histology slides in Zenker’s and Bouin’s fixative

Storage Viability

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

Related Test Orders

» Pathology

Ordering and Shipping Process

For instructions on how to order this test, see the Interpace Diagnostics “Test Ordering and Shipping Process” on page 9 of this document.
Interpace Diagnostics offers the Specimen Viability Service for the purpose of maintaining pancreaticobiliary fluids, ERCP brush specimens, and the accompanying control specimens (buccal brush or whole blood sample) 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 2 patient identifiers to include name, SSN/MRN, gender, and/or date of birth. These specimen label identifiers must match the information on the Requisition.

Specimens submitted for ‘Storage only’ require a completed Requisition with “Storage Only” selected. 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 bi-weekly basis of their current inventory of specimens

**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