Interpace Diagnostics®

Directory of Lab Services

Diagnostic Tests Currently Available

	Indication	Diagnostic Test	Diagnostic Report
ThyGeNEXT® THYROID ONCOGENE PANEL	Thyroid Cancer	NGS Panel for Thyroid Cancer	Rules In Thyroid Cancer
ThyraMIR® v2 THYROID miRNA RISK CLASSIFIER	Thyroid Cancer	microRNA Risk Classifier for Thyroid Cancer	Rules Out Thyroid Cancer
PANCRAGEN® PANCREATIC CANCER RISK CLASSIFIER	Pancreatic & Biliary Cancer	Risk-Stratifies Pancreatic Cysts and Pancreaticobiliary Solid Lesions	Fully Integrated Report That Rules In and Rules Out Pancreatic or Biliary Cancer
PANDNA® PANCREATIC CYST MOLECULAR CLASSIFIER	Pancreatic & Biliary Cancer	Risk-Stratifies Pancreatic Cysts and Pancreaticobiliary Solid Lesions	Molecular-only Results for Pancreatic or Biliary Cancer
RespriDx®	Lung Cancer	Risk of New Primary Cancer Formation vs. Metastases or Recurrence	Rules In and Rules Out New Primary Cancer Formation
BARREGEN® ESOPHAGEAL CANCER RISK CLASSIFIER	Esophageal Cancer	Risk-Stratifies for Esophageal Cancer	Rules In Higher Risk of Progression of Esophageal Cancer

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

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

Navigator Patient Support Team

- Phone: 866-316-0020
- Email: navigator@interpace.com
- Hours of Support
  - 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

List of Testing Services and Expected Turnaround Time (TAT)

Test(s)	Specimen Type(s) Accepted	Turnaround Time (business days, from time of accessioning)
Point2™ Fluid Chemistries » CEA » Glucose » Amylase	Pancreatic/Pancreaticobiliary Fluid	1 to 3
Cytology (GI)	All Bodily Fluids	3 to 5
PancraGEN® PanDNA®	FNA Pancreatic Cyst Fluid (undiluted), Supernatant, Brush Fluid/Dry	10 to 14
Cytology (Thyroid)	Thyroid FNA	3 to 5
ThyGeNEXT®/ ThyraMIR®v2	FNA in provided collection buffer vial	10 to 14
	Cytology Slide (PAP, DiffQuik, Giemsa)	Less than 18
	FFPE Tissue	Less than 18
RespriDx®	Comparative Tissue Profiling (2 locations minimum—tissue block, FFPE slide or cytology slide)	Less than 18
BarreGEN®	Esophageal Tissue (tissue block or FFPE slides)	Less than 18
Pancreatic Storage Viability Service	FNA Pancreatic Cyst Fluid (undiluted)	Stored for 45 days from date of collection

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 Requirements

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

Test Requested	Sample Volume/Requirement
ThyGeNEXT®/ThyraMIR®v2	1 dedicated FNA pass in provided collection buffer vial or cytology slides with at least 80 follicular cells (PAP, DiffQuik, Geimsa), or 1 FFPE block, or 1 H&E and 8 unstained recuts
Thyroid Cytology**	1 IDX Specimen Cytology Collection Kit
Point2™CEA†, Point2™Glucose, Point2™Amylase*, PancraGEN®/PanDNA®, Cytology**	800 µl (0.8 mL)
Point2™CEA†, Point2™Glucose, Point2™Amylase*, PancraGEN®/PanDNA®	600 µl (0.6 mL)
Point2™CEA†, Point2™Glucose, Point2™Amylase*, Cytology **	600 µl (0.6 mL)
PancraGEN® Only	200 µl (0.2 mL)
PanDNA®	200 µl (0.2 mL)
BarreGEN™	1 FFPE block or 1 H&E and 8 unstained recuts
RespriDx®	1 FFPE block or 1 H&E and 8 unstained recuts
Tissue Identity	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 cannot be provided for NY state.

†Point2™CEA was previously AccuCEA™.

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 form. 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 and can be customized to an account, as possible, by contacting Client Services at 800-495-9885 or clientservices@interpace.com. Test Requisition Forms are also available 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" if you have any questions.

Required Documents and Reports to be Shipped with the Specimen

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

- Completed Test Requisition Form
- 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 Form, 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
  - **Freezer bricks should be frozen for at least 24 hours before use**
- Please ensure to review and follow the test-specific collection requirements found within each test section
- 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.

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 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.

ThyGeNEXT® THYROID ONCOGENE PANEL ThyraMIR®v2 THYROID miRNA RISK CLASSIFIER

Cytology with Reflex to ThyGeNEXT®/ThyraMIR®v2

ThyGeNEXT: PLA 0245U
ThyraMIRv2: PLA 0018U

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 ThyraMIRv2 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.

Accepted Specimens

- Thyroid FNA in provided collection buffer vial
  - FNA specimens cannot exceed 6 weeks (42 days) from date of collection
- 1-2 Thyroid cytology smears (DiffQuik or PAP stained, non-frosted slides)
- 1-2 ThinPrep, or cytospin slides
  - Slide specimens cannot exceed 6 months from date of collection
- 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

- Cytology staining
- Next-Generation 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 and rinse in provided collection buffer vial

Specimen Requirements (continued)

- Invert the collection buffer vial 2-3 times
- Securely tighten all caps and seal all containers to prevent leakage
- Place CytoLyt™ or provided collection buffer 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®v2 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 14 days when ordering cytology
- FNA specimens older than 42 days for molecular testing
- FNA specimens submitted within an expired collection buffer vial
- Slide Specimens older than 6 months for molecular testing
- Any media other than the provided collection buffer (for molecular testing)

Specimen Storage for Viability

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

Related Test Orders

- ThyraMIR®v2
- 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 Requisition to ensure timely and correct handling of submitted specimens to our laboratory. Please refer to the examples below to help answer questions you may have about completing 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.

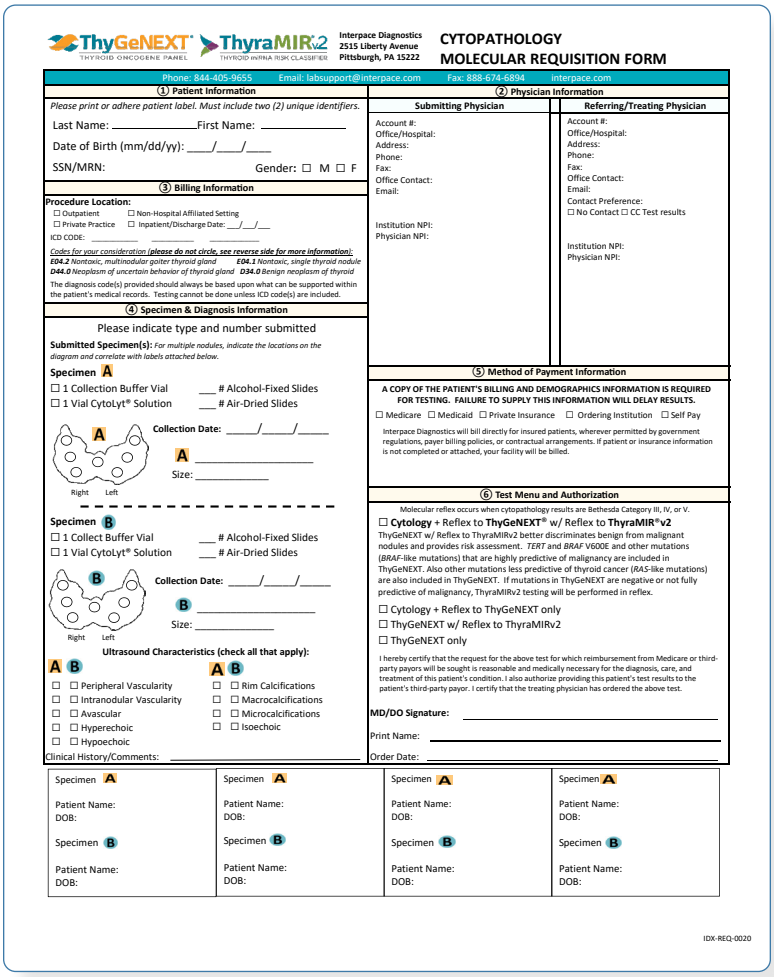
Section 1. Patient Information

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 the 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 the physician institution contact information. Please avoid Office/Hospital acronyms or abbreviations and spell out the institution name.


ThyGeNEXT® THYROID ONCOGENE PANEL ThyraMIR®v2 THYROID miRNA RISK CLASSIFIER

Interpace Diagnostics
2515 Liberty Avenue
Pittsburgh, PA 15222

CYTOPATHOLOGY
MOLECULAR REQUISITION FORM

Phone: 844-405-9655 Email: labsupport@interpace.com Fax: 888-674-6894 interpace.com

① Patient Information

Please print or adhere patient label. Must include two (2) unique identifiers.

Last Name: _____ First Name: _____

Date of Birth (mm/dd/yy): ___/___/___

SSN/MRN: Gender: ☐ M ☐ F

② Physician Information

Submitting Physician

Account #:
Office/Hospital:
Address:
Phone:
Fax:
Office Contact:
Email:

Institution NPI:
Physician NPI:

Referring/Treating Physician

Account #:
Office/Hospital:
Address:
Phone:
Fax:
Office Contact:
Email:
Contact Preference:
☐ No Contact ☐ CC Test results

Institution NPI:
Physician NPI:

③ Billing Information

Procedure Location:
☐ Outpatient ☐ Non-Hospital Affiliated Setting
☐ Private Practice ☐ Inpatient/Discharge Date: ___/___/___
ICD CODE: _____ _____ _____

Codes for your consideration (please do not circle, see reverse side for more information):
E04.2 Nontoxic, multinodular goiter thyroid gland E04.1 Nontoxic, single thyroid nodule
D44.0 Neoplasm of uncertain behavior of thyroid gland D34.0 Benign neoplasm of thyroid

The diagnosis code(s) provided should always be based upon what can be supported within the patient's medical records. Testing cannot be done unless ICD code(s) are included.

④ Specimen & Diagnosis Information

Please indicate type and number submitted

Submitted Specimen(s): For multiple nodules, indicate the locations on the diagram and correlate with labels attached below.

Specimen A
☐ 1 Collection Buffer Vial ___ # Alcohol-Fixed Slides
☐ 1 Vial CytoLyt® Solution ___ # Air-Dried Slides

Collection Date: ___/___/___
A _____
Size: _____

Right Left

Specimen B
☐ 1 Collect Buffer Vial ___ # Alcohol-Fixed Slides
☐ 1 Vial CytoLyt® Solution ___ # Air-Dried Slides

Collection Date: ___/___/___
B _____
Size: _____

Right Left

Ultrasound Characteristics (check all that apply):

A	B		A	B	
☐	☐	Peripheral Vascularity	☐	☐	Rim Calcifications
☐	☐	Intranodular Vascularity	☐	☐	Macrocalcifications
☐	☐	Avascular	☐	☐	Microcalcifications
☐	☐	Hyperechoic	☐	☐	Isoechoic
☐	☐	Hypoechoic			

Clinical History/Comments: _____

⑤ Method of Payment Information

A COPY OF THE PATIENT'S BILLING AND DEMOGRAPHICS INFORMATION IS REQUIRED FOR TESTING. FAILURE TO SUPPLY THIS INFORMATION WILL DELAY RESULTS.

☐ Medicare ☐ Medicaid ☐ Private Insurance ☐ Ordering Institution ☐ Self Pay

Interpace Diagnostics will bill directly for insured patients, wherever permitted by government regulations, payer billing policies, or contractual arrangements. If patient or insurance information is not completed or attached, your facility will be billed.

⑥ Test Menu and Authorization

Molecular reflex occurs when cytopathology results are Bethesda Category III, IV, or V.

☐ Cytology + Reflex to ThyGeNEXT® w/ Reflex to ThyraMIR®v2
ThyGeNEXT w/ Reflex to ThyraMIRv2 better discriminates benign from malignant nodules and provides risk assessment. *TERT* and *BRAF* V600E and other mutations (*BRAF*-like mutations) that are highly predictive of malignancy are included in ThyGeNEXT. Also other mutations less predictive of thyroid cancer (*RAS*-like mutations) are also included in ThyGeNEXT. If mutations in ThyGeNEXT are negative or not fully predictive of malignancy, ThyraMIRv2 testing will be performed in reflex.

☐ Cytology + Reflex to ThyGeNEXT only
☐ ThyGeNEXT w/ Reflex to ThyraMIRv2
☐ ThyGeNEXT only

I hereby certify that the request for the above test for which reimbursement from Medicare or third-party payors will be sought is reasonable and medically necessary for the diagnosis, care, and treatment of this patient's condition. I also authorize providing this patient's test results to the patient's third-party payor. I certify that the treating physician has ordered the above test.

MD/DO Signature: _____
Print Name: _____
Order Date: _____

Specimen A Patient Name: DOB: Specimen B Patient Name: DOB:	Specimen A Patient Name: DOB: Specimen B Patient Name: DOB:	Specimen A Patient Name: DOB: Specimen B Patient Name: DOB:	Specimen A Patient Name: DOB: Specimen B Patient Name: DOB:

IDX-REQ-0020

Referring/Treating Physician:

Please provide full name and phone/fax number for the referring/treating physician, if applicable. Check the box to indicate if you would like the referring/treating physician to receive a copy of the results.

Leaving contact information incomplete will result in processing delays.

Section 3. Billing Information

Check the box to indicate where procedure was performed (Non-hospital affiliated setting, Private Practice, Outpatient, or Inpatient with discharge date).

Testing cannot be performed unless ICD-10 code(s) are included.

Write in the appropriate ICD-10 code based on the patient's medical records. The ICD diagnosis code must be defined by the most detailed level of specificity available. If a diagnosis code cannot be supported by the patient's medical record, then the code should not be used for ordering laboratory services. The list of common ICD diagnosis codes for the characterization of thyroid nodules shown below is not complete. Please refer to the ICD manual for a complete listing.

Common ICD-10 Diagnosis Codes:

- D34.0- Benign neoplasm of thyroid gland
- D44.0-Neoplasm of uncertain behavior of thyroid gland

- D44.9-Neoplasm of uncertain behavior of unspecified endocrine gland
- E01.0-Iodine-deficiency related diffuse (endemic) goiter
- E01.1 Iodine-deficiency related multinodular (endemic) goiter
- E01.2-Iodine-deficiency related (endemic) goiter, unspecified
- E04.0-Nontoxic diffuse goiter
- E04.1-Nontoxic single thyroid nodule
- E04.2-Nontoxic multinodular goiter
- E04.8-Other, specified nontoxic goiter
- E04.9-Nontoxic goiter, unspecified

Section 4. Specimen & Diagnosis Information

Submitted Specimen(s)

Check the box to indicate the type of specimen being sent for testing OR indicate the number of slides being sent (REQUIRED). If submitting multiple nodules, indicate type and quantity separately.

Specimen Collection Date

Enter the date of the procedure when the specimen was collected. Mark the circle on the thyroid diagram to indicate location of the nodule. The requisition can be used to submit specimens for up to 2 locations. Use letter A for the first specimen and letter B for the second specimen. Provide a descriptive name for each location on the line provided, along with the size of each nodule.

Ultrasound Characteristics

Indicate key characteristics identified from the patient's medical records & ultrasound report. Provide relevant clinical history for the patient. Please provide relevant medical records at no cost when requested by the patient's insurance carrier for reimbursement.

Section 5. Method of Payment Information

Check the box indicating how the testing should be billed. Interpace Diagnostics will submit claims to all private insurance, Medicare, and other government plans for insured patients.

Patient Contact Information

Please provide a copy of the patient's face sheet or demographics page to include the patient's full name, gender, date of birth, address, and phone number.

A copy of the patient's billing information MUST be submitted with the specimen.

Medicare/Medicaid/Private Insurance

Provide a clear copy of the front and back of the patient's primary insurance/Medicaid/other payer card. If the patient has a secondary insurance please provide a clear copy of the front and back of the secondary insurance card.

Ordering Institution

Check this box if Interpace Diagnostics is to bill the ordering institution for the ordered testing.

Patient Self-Pay (no insurance)

Check this box if the patient has no insurance.

Section 6. Test Menu and Authorization

Specimen processing cannot begin until there is a clear indication of the type of testing to be performed (check box). Please indicate the tests requested for the patient's 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 (duplicate test selections within a Test Requisition Form cannot be processed and can delay testing).

The ordering physician is required to sign and date the requisition as authorization for Interpace Diagnostics to perform testing. Stamped signatures or physician initials 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®
THYROID ONCOGENE PANEL

ThyGeNEXT®

PLA 0245U

ThyGeNEXT is a rule-in test for malignancy. ThyGeNEXT is often ordered in conjunction with ThyraMIR®v2, 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 provided collection buffer vial
  - FNA specimens cannot exceed 6 weeks (42 days) from date of collection
- 1-2 Thyroid cytology smears (DiffQuik or PAP stained, non-frosted slides)
- 1-2 ThinPrep, or cytospin slides
  - Slide specimens cannot exceed 6 months from date of collection
- 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-Generation Sequencing (NGS)

Specimen Requirements

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 provided collection buffer vial
- Invert the collection buffer vial 2-3 times
- Securely tighten all caps and seal all containers to prevent leakage
- Place collection buffer 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®v2 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 (ie, 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 14 days when ordering cytology
- FNA specimens older than 42 days for molecular testing
- FNA specimens submitted within an expired collection buffer vial
- Slide Specimens older than 6 months for molecular testing
- Any media other than the provided collection buffer (for molecular testing)

Specimen Storage for Viability

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

Related Test Orders

- Cytology
- ThyraMIRv2

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 Requisition to ensure timely and correct handling of submitted specimens to our laboratory. Please refer to the examples below to help answer questions you may have about completing 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 the 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 the physician institution contact information. Please avoid Office/Hospital acronyms or abbreviations and spell out the institution name.

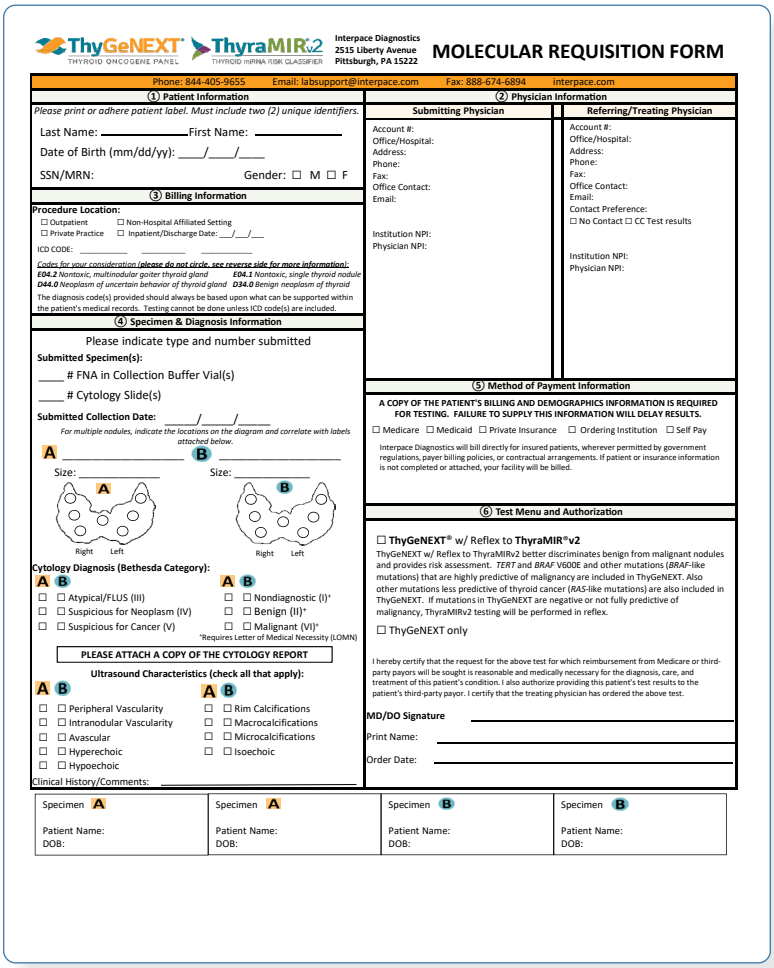
Referring/Treating Physician:

Please provide full name and phone/fax number for the referring/treating physician, if applicable. Check the box to indicate if you would like the referring/treating physician to receive a copy of the results.

Leaving contact information incomplete will result in processing delays.

Section 3. Billing Information

Check the box to indicate where procedure was performed (Non-hospital affiliated setting, Private Practice, Outpatient, or Inpatient with discharge date).



ThyGeNEXT® THYROID ONCOGENE PANEL ThyraMIR®v2 THYROID miRNA RISK CLASSIFIER

Interpace Diagnostics
2515 Liberty Avenue
Pittsburgh, PA 15222

MOLECULAR REQUISITION FORM

Phone: 844-405-9655 Email: labsupport@interpace.com Fax: 888-674-6894 interpace.com

① Patient Information

Please print or adhere patient label. Must include two (2) unique identifiers.

Last Name: _____ First Name: _____

Date of Birth (mm/dd/yy): ___/___/___

SSN/MRN: Gender: ☐ M ☐ F

② Physician Information

Submitting Physician

Account #:
Office/Hospital:
Address:
Phone:
Fax:
Office Contact:
Email:

Institution NPI:
Physician NPI:

Referring/Treating Physician

Account #:
Office/Hospital:
Address:
Phone:
Fax:
Office Contact:
Email:
Contact Preference:
☐ No Contact ☐ CC Test results

Institution NPI:
Physician NPI:

③ Billing Information

Procedure Location:

☐ Outpatient ☐ Non-Hospital Affiliated Setting
☐ Private Practice ☐ Inpatient/Discharge Date: __/__/__

ICD CODE: _____ _____

Codes for your consideration (please do not circle, see reverse side for more information):
E04.2 *Nontoxic, multinodular goiter thyroid gland* ***E04.1*** *Nontoxic, single thyroid nodule*
D44.0 *Neoplasm of uncertain behavior of thyroid gland* ***D34.0*** *Benign neoplasm of thyroid*

The diagnosis code(s) provided should always be based upon what can be supported within the patient's medical records. Testing cannot be done unless ICD code(s) are included.

④ Specimen & Diagnosis Information

Please indicate type and number submitted

Submitted Specimen(s):

____ # FNA in Collection Buffer Vial(s)

____ # Cytology Slide(s)

Submitted Collection Date: ___/___/___

For multiple nodules, indicate the locations on the diagram and correlate with labels attached below.

A _____ B _____

Size: _____ Size: _____

Cytology Diagnosis (Bethesda Category):

A	B		A	B	
☐	☐	Atypical/FLUS (III)	☐	☐	Nondiagnostic (I)*
☐	☐	Suspicious for Neoplasm (IV)	☐	☐	Benign (II)*
☐	☐	Suspicious for Cancer (V)	☐	☐	Malignant (VI)*

*Requires Letter of Medical Necessity (LOMN)

PLEASE ATTACH A COPY OF THE CYTOLOGY REPORT

Ultrasound Characteristics (check all that apply):

A	B		A	B	
☐	☐	Peripheral Vascularity	☐	☐	Rim Calcifications
☐	☐	Intranodular Vascularity	☐	☐	Macrocalcifications
☐	☐	Avascular	☐	☐	Microcalcifications
☐	☐	Hyperechoic	☐	☐	Isoechoic
☐	☐	Hypoechoic			

Clinical History/Comments: _____

⑤ Method of Payment Information

A COPY OF THE PATIENT'S BILLING AND DEMOGRAPHICS INFORMATION IS REQUIRED FOR TESTING. FAILURE TO SUPPLY THIS INFORMATION WILL DELAY RESULTS.

☐ Medicare ☐ Medicaid ☐ Private Insurance ☐ Ordering Institution ☐ Self Pay

Interpace Diagnostics will bill directly for insured patients, wherever permitted by government regulations, payer billing policies, or contractual arrangements. If patient or insurance information is not completed or attached, your facility will be billed.

⑥ Test Menu and Authorization

☐ **ThyGeNEXT® w/ Reflex to ThyraMIR®v2**

ThyGeNEXT w/ Reflex to ThyraMIRv2 better discriminates benign from malignant nodules and provides risk assessment. *TERT* and *BRAF* V600E and other mutations (*BRAF*-like mutations) that are highly predictive of malignancy are included in ThyGeNEXT. Also other mutations less predictive of thyroid cancer (*RAS*-like mutations) are also included in ThyGeNEXT. If mutations in ThyGeNEXT are negative or not fully predictive of malignancy, ThyraMIRv2 testing will be performed in reflex.

☐ ThyGeNEXT only

I hereby certify that the request for the above test for which reimbursement from Medicare or third-party payors will be sought is reasonable and medically necessary for the diagnosis, care, and treatment of this patient's condition. I also authorize providing this patient's test results to the patient's third-party payor. I certify that the treating physician has ordered the above test.

MD/DO Signature _____

Print Name: _____

Order Date: _____

Specimen A	Specimen A	Specimen B	Specimen B
Patient Name:	Patient Name:	Patient Name:	Patient Name:
DOB:	DOB:	DOB:	DOB:

Testing cannot be performed unless ICD-10 code(s) are included.

Write in the appropriate ICD-10 code based on the patient's medical records. The ICD diagnosis code must be defined by the most detailed level of specificity available. If a diagnosis code cannot be supported by the patient's medical record, then the code should not be used for ordering laboratory services. The list of common ICD diagnosis codes for the characterization of thyroid nodules shown below is not complete. Please refer to the ICD manual for a complete listing.

Common ICD-10 Diagnosis Codes:

- D34.0- Benign neoplasm of thyroid gland
- D44.0-Neoplasm of uncertain behavior of thyroid gland
- D44.9-Neoplasm of uncertain behavior of unspecified endocrine gland
- E01.0-Iodine-deficiency related diffuse (endemic) goiter
- E01.1 Iodine-deficiency related multinodular (endemic) goiter
- E01.2-Iodine-deficiency related (endemic) goiter, unspecified
- E04.0-Nontoxic diffuse goiter
- E04.1-Nontoxic single thyroid nodule
- E04.2-Nontoxic multinodular goiter
- E04.8-Other, specified nontoxic goiter
- E04.9-Nontoxic goiter, unspecified

Section 4. Specimen & Diagnosis Information

Submitted Specimen(s)

Check the box to indicate the type of specimen being sent for testing OR indicate the number of slides being sent (REQUIRED). If submitting multiple nodules, indicate type and quantity separately.

Specimen Collection Date

Enter the date of the procedure when the specimen was collected. Mark the circle on the thyroid diagram to indicate location of the nodule. The requisition can be used to submit specimens for up to 2 locations. Use letter A for the first specimen and letter B for the second specimen. Provide a descriptive name for each location on the line provided, along with the size of each nodule.

Cytology Diagnosis (Bethesda Category)

Check the box that corresponds with the patient's medical records to indicate the cytology diagnosis. A copy of the corresponding cytology report is requested to be sent with this specimen, as available. If these reports are not available at the time of specimen submission, please forward to Client Services (fax: 1-888-674-6894 or 412-224-6425) when received.

Please note that for Bethesda I, II, and VI categories a Letter of Medical Necessity is required to start testing.

Ultrasound Characteristics

Indicate key characteristics identified from the patient's medical records & ultrasound report. Provide relevant clinical history for the patient. Please provide relevant medical records at no cost when requested by the patient's insurance carrier for reimbursement.

Section 5. Method of Payment Information

Check the box indicating how the testing should be billed. Interpace Diagnostics will submit claims to all private insurance, Medicare, and other government plans for insured patients.

Patient Contact Information

Please provide a copy of the patient's face sheet or demographics page to include the patient's full name, gender, date of birth, address, and phone number.

A copy of the patient's billing information MUST be submitted with the specimen.

Medicare/Medicaid/Private Insurance

Provide a clear copy of the front and back of the patient's primary insurance/Medicaid/other payer card. If the patient has a secondary insurance please provide a clear copy of the front and back of the secondary insurance card.

Ordering Institution

Check this box if Interpace Diagnostics is to bill the ordering institution for the ordered testing.

Patient Self-Pay (no insurance)

Check this box if the patient has no insurance.

Section 6. Test Menu and Authorization

Specimen processing cannot begin until there is a clear indication of the type of testing to be performed (check box). Please indicate the tests requested for the patient's 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 (duplicate test selections within a Test Requisition Form cannot be processed and can delay testing).

The ordering physician is required to sign and date the requisition as authorization for Interpace Diagnostics to perform testing. Stamped signatures or physician initials 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®v2
THYROID miRNA RISK CLASSIFIER

ThyraMIR®v2 (Ordered as a Reflex Test with ThyGeNEXT®)

PLA 0018U

ThyraMIR®v2 is a rule-out test for malignancy. ThyraMIRv2 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 provided collection buffer (FNA specimens submitted within an expired collection buffer vial will be rejected)
- 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

ThyraMIRv2 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 page 18.

Point2™CEA (Carcinoembryonic Antigen)—Previously AccuCEA™

CPT: 82378

Point2™CEA (Carcinoembryonic Antigen) is often ordered in conjunction with Amylase to help characterize cyst type. Point2™CEA results should be reviewed in relation to the patient's medical history and current conditions. Point2™CEA 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

Buccal Brush Scraping (continued)

- 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 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.

Point2™Glucose

CPT: 82945

Glucose is often ordered on pancreatic cyst or duct fluid in conjunction with CEA (Carcinoembryonic Antigen) and Amylase to help characterize cyst type. Pancreatic cyst fluid glucose results should be reviewed in relation to the patient's medical history and current conditions. Point2Glucose is a laboratory developed test (LDT) validated for pancreatic cyst fluids and small volume specimens.

Accepted Specimens

- Pancreaticobiliary cyst fluid, **undiluted** (200 µL requested)

Turnaround Time

- 1-3 business days from time of accessioning

Methodology

- Enzyme activity

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 overnight with a completely frozen freezer block—provided with the collection kit (bricks must be frozen for a minimum of 24 hours ahead of shipping)

Rejected Specimen

- Frozen specimen
- Pre-diluted pancreaticobiliary cyst fluid
- Co-mingled specimen
- Unlabeled or mislabeled specimen
- Empty, leaking, or broken specimen vials
- Samples stored or shipped at prolonged exposure to high temperatures
- Specimens not shipped overnight will be rejected

Storage Viability

- Store at 2-8°C
- Do not freeze
- Viable up to 28 days from collection with storage at 2-8°C

Related Test Orders

- Point2™CEA (Carcinoembryonic Antigen)
- Point2™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.

- Frozen cold bricks must be used to ensure sample remains cold during shipment
- Freezer bricks are provided with shipping kit and **should be frozen for at least 24 hours before use**
- Must utilize Priority Overnight shipping (FedEx Shipping label included)
- Improper shipping of specimen for Glucose testing is known to cause false positive results for mucinous detection if samples have prolonged exposure to high temperatures

Point2™ Amylase

CPT: 82150

Point2™ Amylase is often ordered in conjunction with Point2™ CEA (Carcinoembryonic Antigen)—previously AccuCEA™—to help characterize cyst type. Point2 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)
  - Freezer block should be frozen for at least 24 hours before use

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

Buccal Brush Scraping (continued)

- 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 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:

- Point2 CEA (Previously 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 Point2™CEA (Carcinoembryonic Antigen)—Previously AccuCEA™— and Point2™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 blocks (provided with the collection kit). **Blocks should be frozen for at least 24 hours before use**

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

Buccal Brush Scraping (continued)

- 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 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:

- Point2™Amylase
- Point2™CEA (Previously 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®
PANCREATIC CANCER RISK CLASSIFIER

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 Point2™CEA (previously AccuCEA™), Point2™Amylase, Point2™Glucose, 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 33.

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 blocks (provided with the collection kit). **Blocks should be frozen for at least 24 hours before use**

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 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

- Point2™Amylase
- Point2™CEA (Previously AccuCEA™)
- Point2™Glucose
- 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 page 35.

PANCRAGEN®
PANCREATIC CANCER RISK CLASSIFIER

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), 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 Point2™CEA (previously AccuCEA™), Point2™Amylase, Point2™Glucose, 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)
- 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 blocks (provided with the collection kit). **Blocks should be frozen for at least 24 hours before use**

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 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:

- Point2™Amylase
- Point2™CEA (Previously AccuCEA™)
- Point2™Glucose
- 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 Requisition 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.

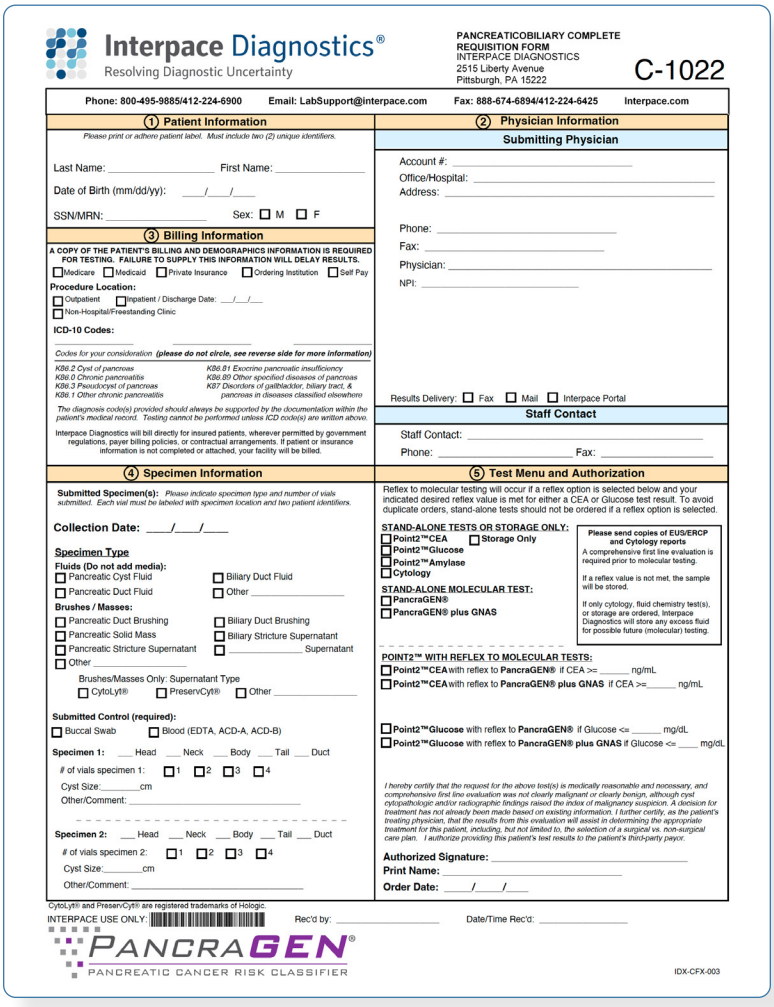
Section 1. Patient Information

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 section if the 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). Ensure physician/institution contact information is completed. Do not use an office/hospital acronyms. Spell out institution name to help ensure accurate case entry.

Staff Contact—provide contact information for an appropriate person to address any questions or issues regarding specimen testing. **Leaving contact information incomplete will result in testing delays.**



Interpace Diagnostics®
Resolving Diagnostic Uncertainty

PANCREATICOBILIARY COMPLETE REQUISITION FORM
INTERPACE DIAGNOSTICS
2515 Liberty Avenue
Pittsburgh, PA 15222
C-1022

Phone: 800-495-9885/412-224-6900 Email: LabSupport@interpace.com Fax: 888-674-6894/412-224-6425 Interpace.com

① Patient Information
Please print or adhere patient label. Must include two (2) unique identifiers.
Last Name: First Name:
Date of Birth (mm/dd/yy): ___/___/___
SSN/MRN: Sex: ☐ M ☐ F

② Physician Information
Submitting Physician
Account #:
Office/Hospital:
Address:
Phone:
Fax:
Physician:
NPI:
Results Delivery: ☐ Fax ☐ Mail ☐ Interpace Portal

Staff Contact
Staff Contact:
Phone: Fax:

③ Billing Information
A COPY OF THE PATIENT'S BILLING AND DEMOGRAPHICS INFORMATION IS REQUIRED FOR TESTING. FAILURE TO SUPPLY THIS INFORMATION WILL DELAY RESULTS.
☐ Medicare ☐ Medicaid ☐ Private Insurance ☐ Ordering Institution ☐ Self Pay
Procedure Location:
☐ Outpatient ☐ Inpatient / Discharge Date: ___/___/___
☐ Non-Hospital/Freestanding Clinic
ICD-10 Codes:
Codes for your consideration (please do not circle, see reverse side for more information)
K86.2 Cyst of pancreas
K86.0 Chronic pancreatitis
K86.3 Pseudocyst of pancreas
K86.1 Other chronic pancreatitis
K86.81 Exocrine pancreatic insufficiency
K86.89 Other specified diseases of pancreas
K87 Disorders of gallbladder, biliary tract, & pancreas in diseases classified elsewhere
The diagnosis code(s) provided should always be supported by the documentation within the patient's medical record. Testing cannot be performed unless ICD code(s) are written above.
Interpace Diagnostics will bill directly for insured patients, wherever permitted by government regulations, payer billing policies, or contractual arrangements. If patient or insurance information is not completed or attached, your facility will be billed.

④ Specimen Information
Submitted Specimen(s): Please indicate specimen type and number of vials submitted. Each vial must be labeled with specimen location and two patient identifiers.
Collection Date: ___/___/___
Specimen Type
Fluids (Do not add media):
☐ Pancreatic Cyst Fluid ☐ Biliary Duct Fluid
☐ Pancreatic Duct Fluid ☐ Other
Brushes / Masses:
☐ Pancreatic Duct Brushing ☐ Biliary Duct Brushing
☐ Pancreatic Solid Mass ☐ Biliary Stricture Supernatant
☐ Pancreatic Stricture Supernatant ☐ _____ Supernatant
☐ Other
Brushes/Masses Only: Supernatant Type
☐ CytoLyt® ☐ PreservCyt® ☐ Other
Submitted Control (required):
☐ Buccal Swab ☐ Blood (EDTA, ACD-A, ACD-B)
Specimen 1: ___ Head ___ Neck ___ Body ___ Tail ___ Duct
# of vials specimen 1: ☐1 ☐2 ☐3 ☐4
Cyst Size:_____cm
Other/Comment:
Specimen 2: ___ Head ___ Neck ___ Body ___ Tail ___ Duct
# of vials specimen 2: ☐1 ☐2 ☐3 ☐4
Cyst Size:_____cm
Other/Comment:

⑤ Test Menu and Authorization
Reflex to molecular testing will occur if a reflex option is selected below and your indicated desired reflex value is met for either a CEA or Glucose test result. To avoid duplicate orders, stand-alone tests should not be ordered if a reflex option is selected.
STAND-ALONE TESTS OR STORAGE ONLY:
☐ Pointz™CEA ☐ Storage Only
☐ Pointz™Glucose
☐ Pointz™Amylase
☐ Cytology
STAND-ALONE MOLECULAR TEST:
☐ PancraGEN®
☐ PancraGEN® plus GNAS
Please send copies of EUS/ERCP and Cytology reports
A comprehensive first line evaluation is required prior to molecular testing.
If a reflex value is not met, the sample will be stored.
If only cytology, fluid chemistry test(s), or storage are ordered, Interpace Diagnostics will store any excess fluid for possible future (molecular) testing.
POINT2™ WITH REFLEX TO MOLECULAR TESTS:
☐ Point2™CEA with reflex to PancraGEN® if CEA >= _____ ng/mL
☐ Point2™CEA with reflex to PancraGEN® plus GNAS if CEA >=_____ ng/mL
☐ Point2™Glucose with reflex to PancraGEN® if Glucose <= _____ mg/dL
☐ Point2™Glucose with reflex to PancraGEN® plus GNAS if Glucose <= ____ mg/dL
I hereby certify that the request for the above test(s) is medically reasonable and necessary, and comprehensive first line evaluation was not clearly malignant or clearly benign, although cyst cytopathologic and/or radiographic findings raised the index of malignancy suspicion. A decision for treatment has not already been made based on existing information. I further certify, as the patient's treating physician, that the results from this evaluation will assist in determining the appropriate treatment for this patient, including, but not limited to, the selection of a surgical vs. non-surgical care plan. I authorize providing this patient's test results to the patient's third-party payor.
Authorized Signature:
Print Name:
Order Date: ___/___/___

CytoLyt® and PreservCyt® are registered trademarks of Hologic.
INTERPACE USE ONLY:
Rec'd by:
Date/Time Rec'd:
PANCRAGEN®
PANCREATIC CANCER RISK CLASSIFIER
IDX-CFX-003

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 (a discharge date is required), outpatient, or nonhospital/freestanding clinic. Write in an appropriate ICD-10 code based upon 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. The ICD diagnosis code must be

defined by the most detailed level of specificity available and should always be based on what has been documented in the patient's medical record. If a diagnosis code cannot be supported by the patient's medical record, then the code should not be used for ordering laboratory services. The list of common ICD diagnosis codes shown within this section of the test requisition is not complete. Please refer to the ICD manual for a complete listing. **Testing cannot be performed unless ICD-10 code(s) are included.**

Section 4. Specimen Information

The Specimen Collection Date should be the date the specimen was collected. Ensure that the Submitted Control box is checked to indicate type of specimen being sent in for testing (REQUIRED). If submitting more than 1 specimen, provide details for each location within the specimen location section of the form by fully completing the location information. 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.**

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

Section 5. Test Menu and Authorization

This section may be customized based on account preference. If you have questions please contact Client Services at 1-800-495-9885.

A clear indication of the requested test must be provided in writing before testing can occur. If selecting a reflex test option, please ensure that only the reflex test option is selected within the requisition for each test type (e.g., "Point2™CEA with reflex...", "Point2™Glucose with reflex..."). If reflex testing is indicated, a written reflex value must be provided—if not provided, then follow-up will be required and may delay testing. A reflex to molecular testing will occur if a reflex option is selected and the indicated desired reflex value is met for either a CEA or Glucose test result, if both tests are ordered. When ordering GNAS, please ensure that the "PancraGEN® plus GNAS" or "PanDNA® plus GNAS" test option is selected.

Duplicate test selections within a Test Requisition Form cannot be processed and can delay testing.

When ordering molecular testing please provide EUS and Cytology reports. If not provided, they will be requested. If these reports are not available at the time of specimen submission, please forward as soon as possible.

The ordering physician is required to sign and date the requisition as authorization for Interpace Diagnostics to perform testing. **An incomplete signature will result in testing delays.**

Interpace Testing Descriptions

Point2™ tests for CEA, glucose, and amylase are laboratory-developed tests (LDT) validated specifically for pancreatic cyst fluids and small volume specimens. Point2 tests are often ordered to help characterize cyst type. All Point2 test results should be reviewed in relation to the patient's medical history and current conditions.

PancraGEN® and PanDNA® are report options of PathFinderTG®, a multi-variate assay that combines molecular analysis with first-line test results (ie, cytology, fluid chemistry, and imaging). PancraGEN and PanDNA are not indicated for cases where the cytology is positive for malignancy. A comprehensive first-line evaluation is required prior to molecular testing.

The intended use of Point2 tests are limited to pancreatic and pancreaticobiliary specimens. PancraGEN and PanDNA are validated on pancreatic and pancreaticobiliary specimens only.

For additional information please visit www.pancragen.com

Local Coverage Determination (LCD)

Covered Indications

- PathfinderTG will be considered medically reasonable and necessary when selectively used as an occasional second-line diagnostic supplement:
  - only where there remains clinical uncertainty as to either the current malignancy or the possible malignant potential of the pancreatic cyst based upon a comprehensive first-line evaluation; AND
  - a decision regarding treatment (e.g. surgery) has NOT already been made based on existing information

Criteria for Coverage

The specific requirements for medical necessity involve:

- Highly concise affirmation, documented in the medical record, that a decision regarding treatment has not already been made and that the results of the molecular evaluation will assist in determining if more aggressive treatment than what is being considered is necessary.
- Previous first-line diagnostics, such as, but not restricted to, the following have demonstrated:
  - A pancreatic cyst fluid carcinoembryonic antigen (CEA), which is greater than or equal to 200 ng/ml, suggesting a mucinous cyst, but is not diagnostic.
  - Cyst cytopathologic or radiographic findings, which raise the index of malignancy suspicion, but where second-line molecular diagnostics is expected to be more compelling in the context of a surgical vs. non-surgical care plan.

Limitations

All PathfinderTG indications other than pancreatic cyst fluid evaluation are considered investigational and are therefore not considered medically reasonable and necessary due to insufficient data on both analytical and clinical validity.

Specific criteria of Non-coverage to include either:

- Image guided needle aspiration of the pancreatic cyst or cystic component of a mass lesion or dilated duct demonstrate definitive diagnosis of malignancy by cytology; OR
- Cytology not showing malignancy but meets AGA guidelines to reach a definitive diagnosis of benign disease. Lesions must be:
  - Under 1 cm
  - Lack a solid component
  - Lack concerning cytology features
  - Lack main pancreatic duct dilatation of >1 cm in diameter with absence of abrupt change in duct diameter

Limitations (continued)

- Have fluid CEA level not exceeding 5 ng/mL

https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?LCDId=34864

Pancreaticobiliary Molecular Testing
(Cyto-centrifugation Supernatant, Biliary Brushings)

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 supernantant collection tube provided with the collection kit
- Do not mix supernatants from multiple specimens. Each specimen should be collected in the 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)
  - Freezer block should be frozen for at least 24 hours before use
- Indicate type of media used on requisition

Cyto-centrifugation Supernatant Collection (continued)

- 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 method below is 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 (recommend using 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)
  - **Freezer blocks should be frozen for at least 24 hours before use**
- Indicate type of media (if applicable) used on requisition

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 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:

- Point2™Amylase
- Point2™AccuCEA (Previously AccuCEA™)
- Point2™Glucose
- 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®
PANCREATIC CYST
MOLECULAR CLASSIFIER

PanDNA®

CPT: 81479

PanDNA® is a molecular panel test based on 2 molecular components (Oncogene point mutations (KRAS) 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 Point2™CEA (previously AccuCEA™), Point2™Amylase, Point2™Glucose, 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 45.

Accepted Specimen:

- 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

Collection requirements (continued)

- Specimen must be shipped with completely frozen freezer block (provided with the collection kit)
  - **Freezer blocks should be frozen for at least 24 hours before use**

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 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

- Point2™Amylase
- Point2™AccuCEA (Previously 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 page 47.

PANCREATIC CYST MOLECULAR CLASSIFIER

PanDNA® with GNAS

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 Point2™CEA (previously AccuCEA™), Point2™Amylase, Point2™Glucose, 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)
- 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)
  - **Freezer blocks should be frozen for at least 24 hours before use**

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 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

- Point2™Amylase
- Point2™AccuCEA (Previously AccuCEA™)
- Point2™Glucose
- 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 Requisition 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.

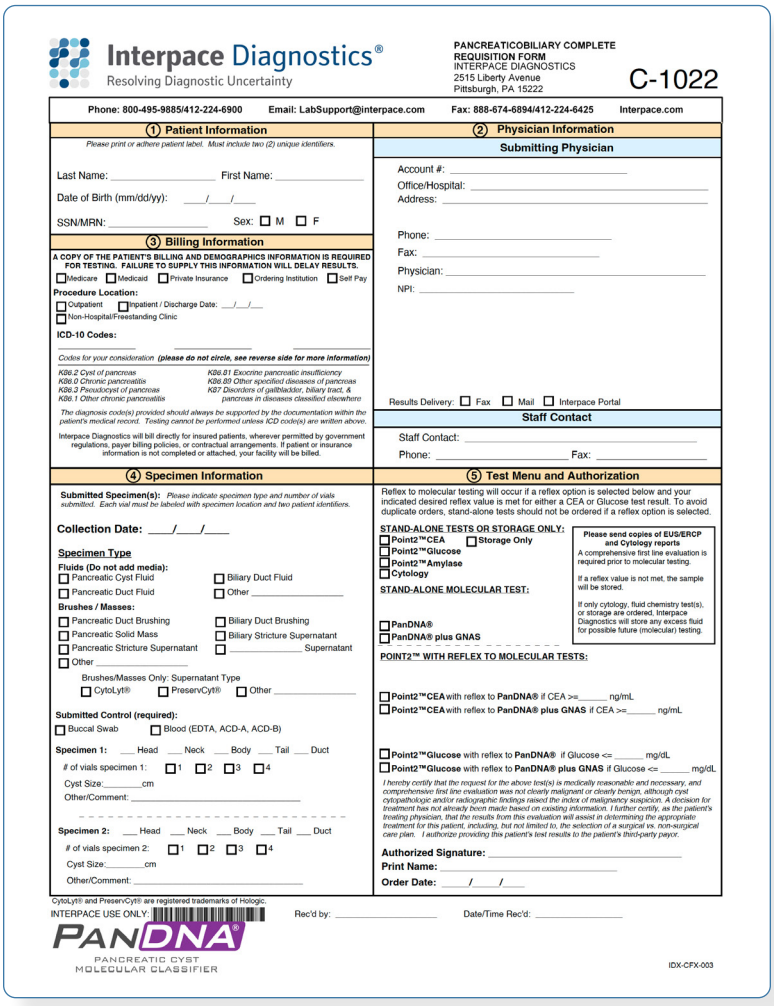
Section 1. Patient Information

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 section if the 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). Ensure physician/institution contact information is completed. Do not use an office/hospital acronyms. Spell out institution name to help ensure accurate case entry.

Staff Contact—provide contact information for an appropriate person to address any questions or issues regarding specimen testing. **Leaving contact information incomplete will result in testing delays.**



Interpace Diagnostics®
Resolving Diagnostic Uncertainty

PANCREATICOBILIARY COMPLETE REQUISITION FORM
INTERPACE DIAGNOSTICS
2515 Liberty Avenue
Pittsburgh, PA 15222

C-1022

Phone: 800-495-9885/412-224-6900 Email: LabSupport@interpace.com Fax: 888-674-6894/412-224-6425 Interpace.com

① Patient Information
Please print or adhere patient label. Must include two (2) unique identifiers.
Last Name: First Name:
Date of Birth (mm/dd/yy): ___/___/___
SSN/MRN: Sex: ☐ M ☐ F

② Physician Information
Submitting Physician
Account #:
Office/Hospital:
Address:
Phone:
Fax:
Physician:
NPI:
Results Delivery: ☐ Fax ☐ Mail ☐ Interpace Portal

Staff Contact
Staff Contact:
Phone: Fax:

③ Billing Information
A COPY OF THE PATIENT'S BILLING AND DEMOGRAPHICS INFORMATION IS REQUIRED FOR TESTING. FAILURE TO SUPPLY THIS INFORMATION WILL DELAY RESULTS.
☐ Medicare ☐ Medicaid ☐ Private Insurance ☐ Ordering Institution ☐ Self Pay
Procedure Location:
☐ Outpatient ☐ Inpatient / Discharge Date: ___/___/___
☐ Non-Hospital/Freestanding Clinic
ICD-10 Codes:
Codes for your consideration (please do not circle, see reverse side for more information)
K86.2 Cyst of pancreas
K86.0 Chronic pancreatitis
K86.3 Pseudocyst of pancreas
K86.1 Other chronic pancreatitis
K86.81 Exocrine pancreatic insufficiency
K86.89 Other specified diseases of pancreas
K87 Disorders of gallbladder, biliary tract, & pancreas in diseases classified elsewhere
The diagnosis code(s) provided should always be supported by the documentation within the patient's medical record. Testing cannot be performed unless ICD code(s) are written above.
Interpace Diagnostics will bill directly for insured patients, wherever permitted by government regulations, payer billing policies, or contractual arrangements. If patient or insurance information is not completed or attached, your facility will be billed.

④ Specimen Information
Submitted Specimen(s): Please indicate specimen type and number of vials submitted. Each vial must be labeled with specimen location and two patient identifiers.
Collection Date: ___/___/___
Specimen Type
Fluids (Do not add media):
☐ Pancreatic Cyst Fluid ☐ Biliary Duct Fluid
☐ Pancreatic Duct Fluid ☐ Other
Brushes / Masses:
☐ Pancreatic Duct Brushing ☐ Biliary Duct Brushing
☐ Pancreatic Solid Mass ☐ Biliary Stricture Supernatant
☐ Pancreatic Stricture Supernatant ☐ Supernatant
☐ Other
Brushes/Masses Only: Supernatant Type
☐ CytoLyt® ☐ PreservCyt® ☐ Other
Submitted Control (required):
☐ Buccal Swab ☐ Blood (EDTA, ACD-A, ACD-B)
Specimen 1: ☐ Head ☐ Neck ☐ Body ☐ Tail ☐ Duct
# of vials specimen 1: ☐1 ☐2 ☐3 ☐4
Cyst Size:_____cm
Other/Comment:
Specimen 2: ☐ Head ☐ Neck ☐ Body ☐ Tail ☐ Duct
# of vials specimen 2: ☐1 ☐2 ☐3 ☐4
Cyst Size:_____cm
Other/Comment:

⑤ Test Menu and Authorization
Reflex to molecular testing will occur if a reflex option is selected below and your indicated desired reflex value is met for either a CEA or Glucose test result. To avoid duplicate orders, stand-alone tests should not be ordered if a reflex option is selected.
STAND-ALONE TESTS OR STORAGE ONLY:
☐ Point2™CEA ☐ Storage Only
☐ Point2™Glucose
☐ Point2™Amylase
☐ Cytology
Please send copies of EUS/ERCP and Cytology reports
A comprehensive first line evaluation is required prior to molecular testing.
If a reflex value is not met, the sample will be stored.
If only cytology, fluid chemistry test(s), or storage are ordered, Interpace Diagnostics will store any excess fluid for possible future (molecular) testing.
STAND-ALONE MOLECULAR TEST:
☐ PanDNA®
☐ PanDNA® plus GNAS
POINT2™ WITH REFLEX TO MOLECULAR TESTS:
☐ Point2™CEA with reflex to PanDNA® if CEA >=_____ ng/mL
☐ Point2™CEA with reflex to PanDNA® plus GNAS if CEA >=_____ ng/mL
☐ Point2™Glucose with reflex to PanDNA® if Glucose <= _____ mg/dL
☐ Point2™Glucose with reflex to PanDNA® plus GNAS if Glucose <= _____ mg/dL
I hereby certify that the request for the above test(s) is medically reasonable and necessary, and comprehensive first line evaluation was not clearly malignant or clearly benign, although cyst cytopathologic and/or radiographic findings raised the index of malignancy suspicion. A decision for treatment has not already been made based on existing information. I further certify, as the patient's treating physician, that the results from this evaluation will assist in determining the appropriate treatment for this patient, including, but not limited to, the selection of a surgical vs. non-surgical care plan. I authorize providing this patient's test results to the patient's third-party payor.
Authorized Signature:
Print Name:
Order Date: ___/___/___

CytoLyt® and PreservCyt® are registered trademarks of Hologic.
INTERPACE USE ONLY:
Rec'd by: Date/Time Rec'd:
PANDNA® PANCREATIC CYST MOLECULAR CLASSIFIER
IDX-CFX-003

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 (a discharge date is required), outpatient, or nonhospital/freestanding clinic. Write in an appropriate ICD-10 code based upon 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. The ICD diagnosis code must be defined by the most detailed level of specificity available and should always be based on what has been documented in the patient's medical record. If a diagnosis code cannot be supported by the patient's medical record, then the code should not be used for ordering laboratory services. The list of common ICD diagnosis codes shown within this section of the test requisition is not complete. Please refer to the ICD manual for a complete listing. **Testing cannot be performed unless ICD-10 code(s) are included.**

Section 4. Specimen Information

The Specimen Collection Date should be the date the specimen was collected. Ensure that the Submitted Control box is checked to indicate type of specimen being sent in for testing (REQUIRED). If submitting more than 1 specimen, provide details for each location within the specimen location section of the form by fully completing the location information. 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.**

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

Section 5. Test Menu and Authorization

This section may be customized based on account preference. If you have questions please contact Client Services at 1-800-495-9885.

A clear indication of the requested test must be provided in writing before testing can occur. If selecting a reflex test option, please ensure that only the reflex test option is selected within the requisition for each test type (e.g., "Point2™CEA with reflex...", "Point2™Glucose with reflex..."). If reflex testing is indicated, a written reflex value must be provided—if not provided, then follow-up will be required and may delay testing. A reflex to molecular testing will occur if a reflex option is selected and the indicated desired reflex value is met for either a CEA or Glucose test result, if both tests are ordered. When ordering GNAS, please ensure that the "PancraGEN® plus GNAS" or "PanDNA® plus GNAS" test option is selected.

Duplicate test selections within a Test Requisition Form cannot be processed and can delay testing.

When ordering molecular testing please provide EUS and Cytology reports. If not provided, they will be requested. If these reports are not available at the time of specimen submission, please forward as soon as possible.

The ordering physician is required to sign and date the requisition as authorization for Interpace Diagnostics to perform testing. **An incomplete signature will result in testing delays.**

Interpace Testing Descriptions

Point2™ tests for CEA, glucose, and amylase are laboratory-developed tests (LDT) validated specifically for pancreatic cyst fluids and small volume specimens. Point2 tests are often ordered to help characterize cyst type. All Point2 test results should be reviewed in relation to the patient's medical history and current conditions.

PancraGEN® and PanDNA® are report options of PathFinderTG®, a multi-variate assay that combines molecular analysis with first-line test results (ie, cytology, fluid chemistry, and imaging). PancraGEN and PanDNA are not indicated for cases where the cytology is positive for malignancy. A comprehensive first-line evaluation is required prior to molecular testing.

The intended use of Point2 tests are limited to pancreatic and pancreaticobiliary specimens. PancraGEN and PanDNA are validated on pancreatic and pancreaticobiliary specimens only.

For additional information please visit www.pancragen.com

Local Coverage Determination (LCD)

Covered Indications

- PathfinderTG will be considered medically reasonable and necessary when selectively used as an occasional second-line diagnostic supplement:
  - only where there remains clinical uncertainty as to either the current malignancy or the possible malignant potential of the pancreatic cyst based upon a comprehensive first-line evaluation; AND
  - a decision regarding treatment (e.g. surgery) has NOT already been made based on existing information

Criteria for Coverage

The specific requirements for medical necessity involve:

- Highly concise affirmation, documented in the medical record, that a decision regarding treatment has not already been made and that the results of the molecular evaluation will assist in determining if more aggressive treatment than what is being considered is necessary.
- Previous first-line diagnostics, such as, but not restricted to, the following have demonstrated:
  - A pancreatic cyst fluid carcinoembryonic antigen (CEA), which is greater than or equal to 200 ng/mL, suggesting a mucinous cyst, but is not diagnostic.
  - Cyst cytopathologic or radiographic findings, which raise the index of malignancy suspicion, but where second-line molecular diagnostics is expected to be more compelling in the context of a surgical vs. non-surgical care plan.

Limitations

All PathfinderTG indications other than pancreatic cyst fluid evaluation are considered investigational and are therefore not considered medically reasonable and necessary due to insufficient data on both analytical and clinical validity.

Specific criteria of Non-coverage to include either:

- Image guided needle aspiration of the pancreatic cyst or cystic component of a mass lesion or dilated duct demonstrate definitive diagnosis of malignancy by cytology; OR
- Cytology not showing malignancy but meets AGA guidelines to reach a definitive diagnosis of benign disease. Lesions must be:
  - Under 1 cm
  - Lack a solid component
  - Lack concerning cytology features
  - Lack main pancreatic duct dilatation of >1 cm in diameter with absence of abrupt change in duct diameter
  - Have fluid CEA level not exceeding 5 ng/mL

https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?LCDId=34864

BARREGEN®
ESOPHAGEAL CANCER RISK CLASSIFIER

BarreGEN®

CPT: 81479

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) from 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)

Slide Recuts from an FFPE Tissue Block (continued)

- 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

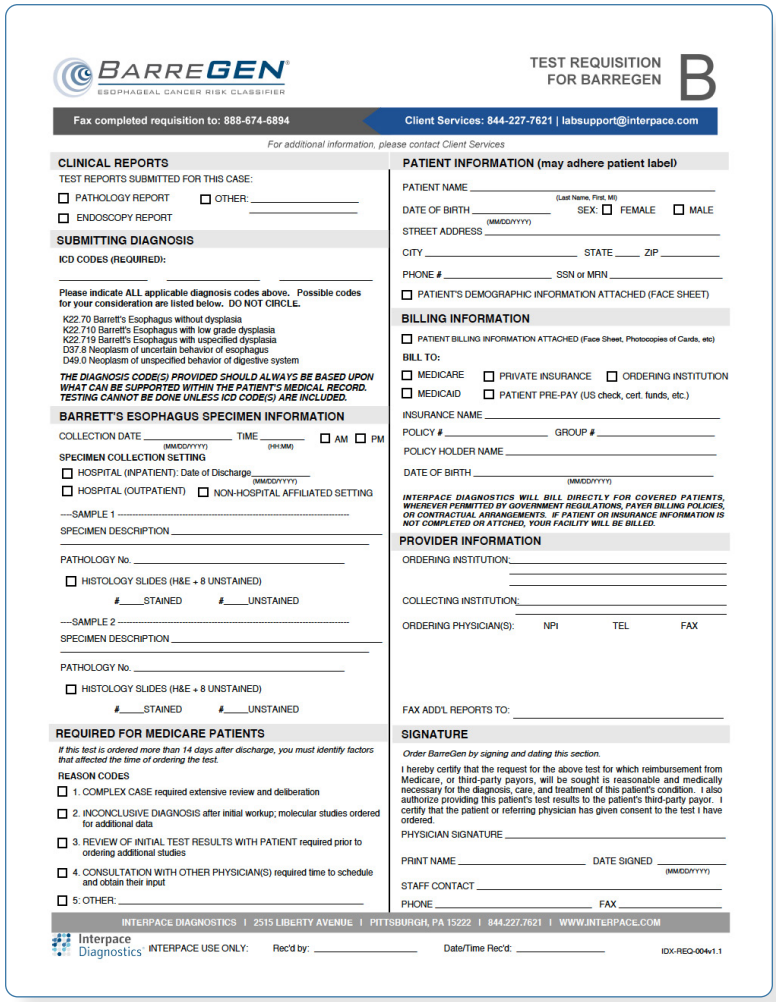
Testing requisitions can vary. The following are general guidelines to assist in completing the Interpace Diagnostics Testing Requisitions to ensure timely and correct handling of submitted specimens to our laboratory. Please refer to examples below to help answer questions that you may have for completion 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.

Directions for Requisition Completion

All fields are required.

Please ensure the following:

- 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
- 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**
- *Specimen Collection Date* should be the date the 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**
- Select box to indicate where procedure was performed (inpatient with discharge date (required), outpatient, or non-hospital/freestanding clinic)
- For patients with Medicare, a reason code is required 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**
- Include patient first and last name, date of birth, SSN/MRN, and sex



BARREGEN
ESOPHAGEAL CANCER RISK CLASSIFIER

TEST REQUISITION FOR BARREGEN B

Fax completed requisition to: 888-674-6894 | Client Services: 844-227-7621 | labsupport@interpace.com

For additional information, please contact Client Services

CLINICAL REPORTS
TEST REPORTS SUBMITTED FOR THIS CASE:
☐ PATHOLOGY REPORT ☐ OTHER: _____
☐ ENDOSCOPY REPORT

SUBMITTING DIAGNOSIS
ICD CODES (REQUIRED):
_____ _____ _____
Please indicate ALL applicable diagnosis codes above. Possible codes for your consideration are listed below. DO NOT CIRCLE.
K22.70 Barrett's Esophagus without dysplasia
K22.710 Barrett's Esophagus with low grade dysplasia
K22.719 Barrett's Esophagus with unspecified dysplasia
D37.8 Neoplasm of uncertain behavior of esophagus
D49.0 Neoplasm of unspecified behavior of digestive system
THE DIAGNOSIS CODE(S) PROVIDED SHOULD ALWAYS BE BASED UPON WHAT CAN BE SUPPORTED WITHIN THE PATIENT'S MEDICAL RECORD. TESTING CANNOT BE DONE UNLESS ICD CODE(S) ARE INCLUDED.

BARRETT'S ESOPHAGUS SPECIMEN INFORMATION
COLLECTION DATE _____ (MM/DD/YYYY) TIME _____ (HH:MM) ☐ AM ☐ PM
SPECIMEN COLLECTION SETTING
☐ HOSPITAL (INPATIENT): Date of Discharge_____ (MM/DD/YYYY)
☐ HOSPITAL (OUTPATIENT) ☐ NON-HOSPITAL AFFILIATED SETTING
----SAMPLE 1----
SPECIMEN DESCRIPTION _____
PATHOLOGY No. _____
☐ HISTOLOGY SLIDES (H&E + 8 UNSTAINED)
#____STAINED #____UNSTAINED
----SAMPLE 2----
SPECIMEN DESCRIPTION _____
PATHOLOGY No. _____
☐ HISTOLOGY SLIDES (H&E + 8 UNSTAINED)
#____STAINED #____UNSTAINED

REQUIRED FOR MEDICARE PATIENTS
If this test is ordered more than 14 days after discharge, you must identify factors that affected the time of ordering the test.
REASON CODES
☐ 1. COMPLEX CASE required extensive review and deliberation
☐ 2. INCONCLUSIVE DIAGNOSIS after initial workup; molecular studies ordered for additional data
☐ 3. REVIEW OF INITIAL TEST RESULTS WITH PATIENT required prior to ordering additional studies
☐ 4. CONSULTATION WITH OTHER PHYSICIAN(S) required time to schedule and obtain their input
☐ 5: OTHER: _____

PATIENT INFORMATION (may adhere patient label)
PATIENT NAME _____ (Last Name, First, MI)
DATE OF BIRTH _____ (MM/DD/YYYY) SEX: ☐ FEMALE ☐ MALE
STREET ADDRESS _____
CITY _____ STATE ____ ZIP _____
PHONE # _____ SSN or MRN _____
☐ PATIENT'S DEMOGRAPHIC INFORMATION ATTACHED (FACE SHEET)

BILLING INFORMATION
☐ PATIENT BILLING INFORMATION ATTACHED (Face Sheet, Photocopies of Cards, etc)
BILL TO:
☐ MEDICARE ☐ PRIVATE INSURANCE ☐ ORDERING INSTITUTION
☐ MEDICAID ☐ PATIENT PRE-PAY (US check, cert. funds, etc.)
INSURANCE NAME _____
POLICY # _____ GROUP # _____
POLICY HOLDER NAME _____
DATE OF BIRTH _____ (MM/DD/YYYY)
INTERPACE DIAGNOSTICS WILL BILL DIRECTLY FOR COVERED PATIENTS, WHEREVER PERMITTED BY GOVERNMENT REGULATIONS, PAYER BILLING POLICIES, OR CONTRACTUAL ARRANGEMENTS. IF PATIENT OR INSURANCE INFORMATION IS NOT COMPLETED OR ATTCHED, YOUR FACILITY WILL BE BILLED.

PROVIDER INFORMATION
ORDERING INSTITUTION: _____
COLLECTING INSTITUTION: _____
ORDERING PHYSICIAN(S): NPI TEL FAX
FAX ADD'L REPORTS TO: _____

SIGNATURE
Order BarreGen by signing and dating this section.
I hereby certify that the request for the above test for which reimbursement from Medicare, or third-party payors, will be sought is reasonable and medically necessary for the diagnosis, care, and treatment of this patient's condition. I also authorize providing this patient's test results to the patient's third-party payor. I certify that the patient or referring physician has given consent to the test I have ordered.
PHYSICIAN SIGNATURE _____
PRINT NAME _____ DATE SIGNED _____ (MM/DD/YYYY)
STAFF CONTACT _____
PHONE _____ FAX _____

INTERPACE DIAGNOSTICS | 2515 LIBERTY AVENUE | PITTSBURGH, PA 15222 | 844.227.7621 | WWW.INTERPACE.COM

Interpace Diagnostics INTERPACE USE ONLY: Rec'd by: _____ Date/Time Rec'd: _____ IDX-REQ-004v1.1

Please ensure the following (continued):

- 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**
- Provider information may be pre-filled if an account has been set up with Interpace Diagnostics. If blank, complete each field. 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**
- Check appropriate box to indicate type of insurance/payor for patient. **A copy of the patient's billing information MUST be submitted with specimen**
- 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 (DiffQuik 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) from 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

Slide Recuts from an FFPE Tissue Block (continued)

- 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:

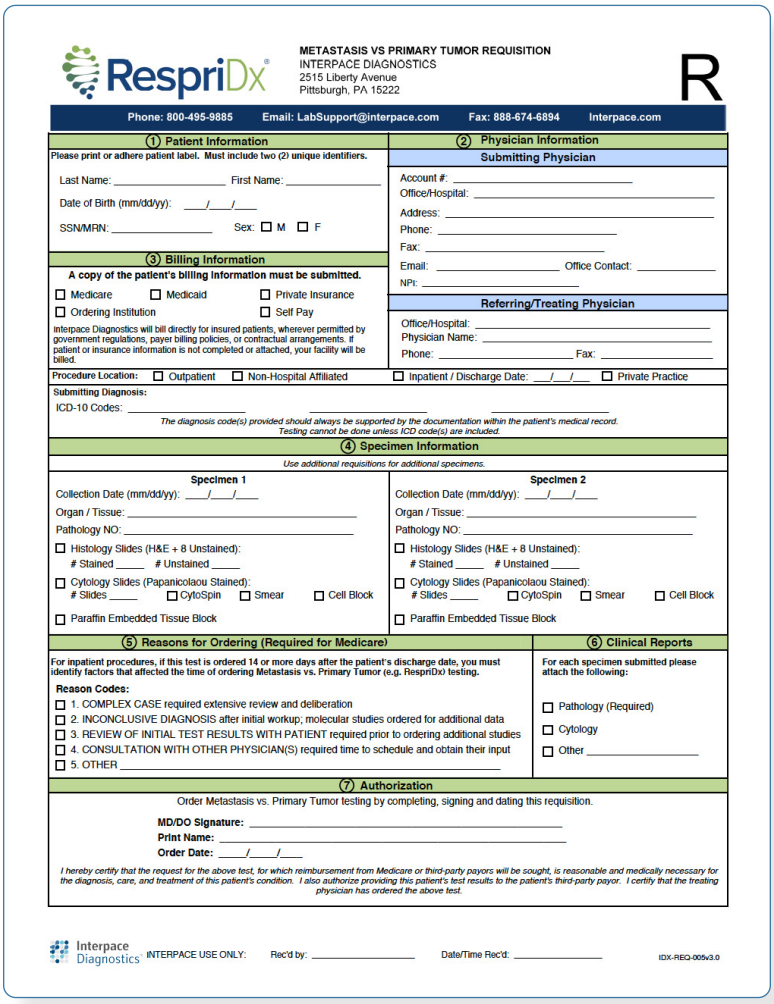
- None

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.



RespriDx®

METASTASIS VS PRIMARY TUMOR REQUISITION
INTERPACE DIAGNOSTICS
2515 Liberty Avenue
Pittsburgh, PA 15222

R

Phone: 800-495-9885 Email: LabSupport@interpace.com Fax: 888-674-6894 Interpace.com

(1) Patient Information

Please print or adhere patient label. Must include two (2) unique identifiers.

Last Name: First Name:

Date of Birth (mm/dd/yy): ___/___/___

SSN/MRN: Sex: ☐ M ☐ F

(2) Physician Information

Submitting Physician

Account #:
Office/Hospital:
Address:
Phone:
Fax:
Email: Office Contact:
NPI:

(3) Billing Information

A copy of the patient's billing information must be submitted.

☐ Medicare ☐ Medicaid ☐ Private Insurance
☐ Ordering Institution ☐ Self Pay

Interpace Diagnostics will bill directly for insured patients, wherever permitted by government regulations, payer billing policies, or contractual arrangements. If patient or insurance information is not completed or attached, your facility will be billed.

Referring/Treating Physician

Office/Hospital:
Physician Name:
Phone: Fax:

Procedure Location: ☐ Outpatient ☐ Non-Hospital Affiliated ☐ Inpatient / Discharge Date: ___/___/___ ☐ Private Practice

Submitting Diagnosis:
ICD-10 Codes:

The diagnosis code(s) provided should always be supported by the documentation within the patient's medical record. Testing cannot be done unless ICD code(s) are included.

(4) Specimen Information

Use additional requisitions for additional specimens.

Specimen 1	Specimen 2
Collection Date (mm/dd/yy): ___/___/___	Collection Date (mm/dd/yy): ___/___/___
Organ / Tissue:	Organ / Tissue:
Pathology NO:	Pathology NO:
☐ Histology Slides (H&E + 8 Unstained): # Stained ____ # Unstained ____	☐ Histology Slides (H&E + 8 Unstained): # Stained ____ # Unstained ____
☐ Cytology Slides (Papanicolaou Stained): # Slides ____ ☐ CytoSpin ☐ Smear ☐ Cell Block	☐ Cytology Slides (Papanicolaou Stained): # Slides ____ ☐ CytoSpin ☐ Smear ☐ Cell Block
☐ Paraffin Embedded Tissue Block	☐ Paraffin Embedded Tissue Block

(5) Reasons for Ordering (Required for Medicare)

For inpatient procedures, if this test is ordered 14 or more days after the patient's discharge date, you must identify factors that affected the time of ordering Metastasis vs. Primary Tumor (e.g. RespnDx) testing.

Reason Codes:

☐ 1. COMPLEX CASE required extensive review and deliberation
☐ 2. INCONCLUSIVE DIAGNOSIS after initial workup; molecular studies ordered for additional data
☐ 3. REVIEW OF INITIAL TEST RESULTS WITH PATIENT required prior to ordering additional studies
☐ 4. CONSULTATION WITH OTHER PHYSICIAN(S) required time to schedule and obtain their input
☐ 5. OTHER

(6) Clinical Reports

For each specimen submitted please attach the following:

☐ Pathology (Required)
☐ Cytology
☐ Other

(7) Authorization

Order Metastasis vs. Primary Tumor testing by completing, signing and dating this requisition.

MD/DO Signature:
Print Name:
Order Date: ___/___/___

I hereby certify that the request for the above test, for which reimbursement from Medicare or third-party payors will be sought, is reasonable and medically necessary for the diagnosis, care, and treatment of this patient's condition. I also authorize providing this patient's test results to the patient's third-party payor. I certify that the treating physician has ordered the above test.

Interpace Diagnostics INTERPACE USE ONLY: Rec'd by: Date/Time Rec'd:

IDX-REQ-005v3.0

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, 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 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. 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.

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.

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) from 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.

Specimen Viability Service

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

Interpace Diagnostics®, LLC is a subsidiary of Interpace Biosciences, Inc.
www.interpace.com | 800.495.9885
IDX-0007-07-0723-v15

Interpace Diagnostics®