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**

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: _____/_____/____

INTERPACE USE ONLY: Rec'd by: _____ Date/Time Rec'd: _____

PANCRAGEN®

PANCREATIC CANCER RISK CLASSIFIER

Interpace Diagnostics®

Resolving Diagnostic Uncertainty

Incomplete or incorrect information will lead to testing delays

Questions?

Contact Interpace Diagnostics Customer Service at:
Phone: 800-495-9885 or 412-224-6900
Fax: 888-674-6894 or 412-224-6425
Email: clientservices@interpace.com / labsupport@interpace.com
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.

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 acronym. 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.

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 non-hospital/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.

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.

** 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 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.

Section 5. Test Menu and Authorization (continued)

Details of each test and requested specimen type can be found within our Directory of Laboratory Services located on our website (pancragen.

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

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). Testing is used to assess malignancy potential by looking at the quality and quantity of DNA, provides a "molecular only" reporting option for clinician integration.

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

1. 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

Criteria for Coverage

The specific requirements for medical necessity involve:

1. 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.
2. 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:

1. 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
2. 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 > 1cm 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

Point2™

PANCRAGEN® PANCREATIC CANCER RISK CLASSIFIER

PANDNA® PANCREATIC CYST MOLECULAR CLASSIFIER