Overview

Useful For
As an adjunct in the assessment of pancreatic cysts, when used in conjunction with carcinoembryonic antigen, amylase, imaging studies and cytology

Method Name
Immunoenzymatic Assay

NY State Available
Yes

Specimen

Specimen Type
Pancreatic Cyst Fluid

Specimen Required

Patient Preparation: For 12 hours before this test do not take multivitamins or dietary supplements containing biotin (vitamin B7), which is commonly found in hair, skin, and nail supplements and multivitamins.

Container/Tube: Plain, plastic, screw-top tube

Specimen Volume: 1mL

Forms
If not ordering electronically, complete, print, and send an Oncology Test Request (T729) with the specimen.

Specimen Minimum Volume
0.5 mL (Samples <0.5 mL may be rejected)

Reject Due To

| Gross hemolysis | Reject |

Specimen Stability Information

<table>
<thead>
<tr>
<th>Specimen Type</th>
<th>Temperature</th>
<th>Time</th>
<th>Special Container</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pancreatic Cyst Fluid</td>
<td>Frozen (preferred)</td>
<td>30 days</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Refrigerated</td>
<td>7 days</td>
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Clinical and Interpretive

Clinical Information
Carbohydrate antigen 19-9 (CA 19-9) is a modified Lewis(a) blood group antigen, and has been used as a tumor
marker. Serum CA 19-9 concentrations may be elevated in patients with gastrointestinal malignancies such as cholangiocarcinoma, colon cancer, or pancreatic cancer. While serum CA 19-9 is neither sensitive nor specific for pancreatic cancer, concentrations of CA 19-9 in pancreatic cyst fluid may help determine whether a pancreatic cyst is benign.

Cystic lesions of the pancreas are of various types:

- Benign cysts:
  - Inflammatory cysts (pseudocysts)
  - Serous cysts (serous cystadenoma)
- Mucinous cysts:
  - Premalignant (mucinous cystadenoma)
  - Malignant (cystadenocarcinoma, intrapapillary mucinous neoplasia)

Pancreatic cyst fluid CA 19-9 results should be used in conjunction with imaging studies, cytology, and other cyst-fluid tumor markers, such as carcinoembryonic antigen and amylase.

**Reference Values**
An interpretive report will be provided.

**Interpretation**
Cyst fluid carbohydrate antigen 19-9 (CA19-9) concentrations < or =37 U/mL indicate a low risk for a mucinous cyst, and are more consistent with serous cystadenoma or pseudocyst. The sensitivity and specificity are approximately 19% and 98%, respectively, at this concentration.

Correlation of these test results with cytology and imaging is recommended.

**Cautions**

**Twelve hours before this blood test, do not** take multivitamins or dietary supplements containing biotin or vitamin B7 that are commonly found in hair, skin and nail supplements and multivitamins.

Carbohydrate antigen 19-9 (CA 19-9) and other tumor markers are not specific for malignancy and CA 19-9 testing has limited utility when used as the sole tumor marker test. Other tests (eg, carcinoembryonic antigen, amylase, cytology) should be performed in conjunction with CA 19-9 for assessing pancreatic cyst aspirates.

A low or negative result (<5 U/mL) may be uninformative or misleading since some individuals (Lewis nonsecretors) do not produce the CA 19-9 antigen. In such cases, a serum CA 19-9 measurement is necessary to verify that the patient is (or is not) a CA 19-9 secretor.

This test should not be ordered for pancreatic fluid of noncyst origin (eg, pancreatic duct fluid, peripancreatic fluid) since reference values have not been established for this specimen type. Call 800-533-1710 for ordering assistance.

**Clinical Reference**
2. van der Waaij LA, van Dullemen HM, Porte RJ: Cyst fluid analysis in the differential diagnosis of pancreatic cystic


Performance

Method Description
The instrument used is a Beckman Coulter DXI 800. The Access GI Monitor assay is a 2-site immunoenzymatic sandwich assay. A sample is added to a reaction vessel along with paramagnetic particles coated with polyclonal goat antibiotin antibody, mouse monoclonal biotin conjugate, and buffered protein solution. After incubation in a reaction vessel, separation in a magnetic field, and washing to remove materials not bound to the solid phase, a monoclonal-alkaline phosphatase conjugate is added. After incubation in a reaction vessel, materials bound to the solid phase are held in a magnetic field, while unbound materials are washed away. The chemiluminescent substrate Lumi-Phos 530 is added to the vessel and light generated by the reaction is measured with a luminometer. The light production is directly proportional to the concentration of CA 19-9 antigen in the sample. The amount of analyte in the sample is determined from a stored, multipoint calibration curve. (Package insert: Beckman Coulter, Inc., Fullerton, CA, 2010)

PDF Report
No

Day(s) and Time(s) Test Performed
Monday through Friday; Varies

Analytic Time
Same day/1 day

Maximum Laboratory Time
3 days

Specimen Retention Time
12 months

Performing Laboratory Location
Rochester

Fees and Codes

Fees
- Authorized users can sign in to Test Prices for detailed fee information.
- Clients without access to Test Prices can contact Customer Service 24 hours a day, seven days a week.
- Prospective clients should contact their Regional Manager. For assistance, contact Customer Service.

Test Classification
This test has been modified from the manufacturer’s instructions. Its performance characteristics were determined by Mayo Clinic in a manner consistent with CLIA requirements. This test has not been cleared or approved by the U.S. Food and Drug Administration.

CPT Code Information
LOINC® Information

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<th>Test ID</th>
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<th>Order LOINC Value</th>
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<td>199PC</td>
<td>CA19-9, Pancreatic Cyst</td>
<td>26924-1</td>
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<table>
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<tr>
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<td>199P</td>
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