Overview

Useful For
Aiding in distinguishing between pseudocysts and other types of pancreatic cysts, when used in conjunction with imaging studies, cytology, and other pancreatic cyst fluid tumor markers

Method Name
Substrate Kinetic

NY State Available
Yes

Specimen

Specimen Type
Pancreatic Cyst Fluid

Advisory Information
For other body fluid specimens (eg, peritoneal, pleural), order AMBF / Amylase, Body Fluid. Testing will be changed to AMBF if this test is ordered on any fluid other than pancreatic fluid.

Specimen Required
Supplies: Aliquot Tube, 5 mL (T465)

Container/Tube: Plain, plastic, screw top tube

Specimen Volume: 1mL

Additional Information: A minimum of 0.5 mL is required for testing; specimens <0.5 mL may be rejected.

Forms
If not ordering electronically, complete, print, and send 1 of the following forms with the specimen:

-Oncology Test Request (T729)

-Gastroenterology and Hepatology Client Test Request (T728)

Specimen Minimum Volume
0.5 mL

Reject Due To

| Gross hemolysis | Reject |

Specimen Stability Information

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<th>Temperature</th>
<th>Time</th>
<th>Special Container</th>
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<td>Pancreatic Cyst Fluid</td>
<td>Frozen (preferred)</td>
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Test Definition: AMLPC
Amylase, Pancreatic Cyst

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Clinical and Interpretive

Clinical Information
Amylases are a group of hydrolases that degrade complex carbohydrates into fragments. Amylase is produced by the exocrine pancreas and the salivary glands to aid in the digestion of starch. It is also produced by the small intestine mucosa, ovaries, placenta, liver, and fallopian tubes.

Measurement of amylase in pancreatic cyst fluid is often used in conjunction with tumor markers, carcinoembryonic antigen and CA19-9, as an aid in the differential diagnosis of pancreatic cysts lesions. Amylase seems to be particularly helpful in excluding pancreatic pseudocysts. A number of studies have demonstrated that amylase levels are typically very high, usually in the thousands in pseudocysts, therefore, low amylase values virtually excludes pseudocysts. Based on the evidence available, the American College of Gastroenterology (ACG) practice guidelines for the Diagnosis and Management of Neoplastic Pancreatic Cysts suggest that an amylase cutoff value of 250 U/L is useful to exclude pseudocysts.

Reference Values
An interpretive report will be provided.

Interpretation
A pancreatic cyst fluid amylase concentration of less than 250 U/L indicates a low risk of a pseudocyst and is more consistent with cystic neoplasms such as mucinous cystic neoplasms (MCN), intraductal papillary mucinous neoplasm (IPMN), serous cystadenomas, cystic neuroendocrine tumor, and mucinous cystadenocarcinoma. High pancreatic cyst fluid amylase values are nonspecific and occur both in pseudocysts and some mucin-producing cystic neoplasms including MCN, IPMN, and mucinous cystadenocarcinoma.

In-house studies to verify this cutoff value showed that 94% (66/70) of pseudocysts had a value of greater or equal to 250 U/L. Cysts with amylase levels of less than 250 U/L included 69% of adenocarcinomas, 31% of intraductal papillary mucinous neoplasia, 55% of mucinous cystadenomas, 64% serous cystadenomas, and 6% of pseudocysts. Therefore, using a cutoff of less than 250 U/L to exclude a pseudocyst has 94% sensitivity and 42% specificity.

Cautions
This test result should not be the sole basis for diagnosis. Test results should always be correlated with imaging and cytology.

Supportive Data
In-house studies to verify the cutoff value of 250 U/L showed that 94% (66/70) of pseudocysts had a value of greater or equal to 250 U/L. Cysts with amylase levels of less than 250 U/L included 69% of adenocarcinomas, 31% of intraductal papillary mucinous neoplasia, 55% of mucinous cystadenomas, 64% serous cystadenomas, and 6% of pseudocysts. Therefore, using a cutoff of less than 250 U/L to exclude a pseudocyst has 94% sensitivity and 42% specificity.

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 the Roche cobas. The Roche amylase (AMYL) method is an enzymatic colorimetric test using 4,6-ethyliden (G7)-p-nitrophenol (G1)-alpha, D-maltoheptaoside (ethyldene-G7PNP) as a substrate. Human salivary and pancreatic amylases (alpha-amylase) convert the substrate at approximately the same rate. The alpha-amylase cleaves the substrate into G2, G3, G4 PNP fragments. The G2, G3, and G4 PNP fragments are further hydrolyzed by an alpha-glucosidase to yield p-nitrophenol and glucose. The rate of increase in absorbance at 415 nm (measuring the increase in p-nitrophenol) is directly proportional to amylase activity.(Package insert: Roche AMYL2 reagent, Roche Diagnostic Corp, Indianapolis, IN, 12/2018, V10)

**PDF Report**

No

**Day(s) and Time(s) Test Performed**

Monday through Friday; 6 a.m.-9 p.m.; Saturday 6:30 a.m.-1 p.m.

**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**
**Test Definition: AMLPC**

Amylase, Pancreatic Cyst

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**LOINC® Information**

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