MAYO CLINIC LABORATORIES

Test Definition: 199PC

Carbohydrate Antigen 19-9 (CA 19-9), Pancreatic Cyst Fluid

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

Ordering Guidance

This test should not be ordered for pancreatic fluid of noncystic origin (eg, pancreatic duct fluid, peripancreatic fluid) since reference values have not been established for those specimen types. For ordering assistance call 800-533-1710.

Additional Testing Requirements

This test has limited utility when used as the sole tumor marker test. Additional tests should be performed (CEAPC / Carcinoembryonic Antigen (CEA), Pancreatic Cyst Fluid; AMLPC / Amylase, Pancreatic Cyst Fluid, and cytology testing) in conjunction with this test for assessing pancreatic cyst aspirates.

Specimen Required

Patient Preparation: For 12 hours before specimen collection, patient **should not** take multivitamins or dietary supplements (eg, hair, skin, and nail supplements) containing biotin (vitamin B7).
Source: Pancreatic cyst or pancreatic pseudocyst
Container/Tube: Plain, plastic, screw-top tube
Specimen Volume: 1 mL

Forms

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

Specimen Minimum Volume

0.5 mL

Reject Due To

Gross hemolysis	Reject
Gross icterus	OK

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Pancreatic Cyst Fluid	Frozen (preferred)	90 days	
	Ambient	72 hours	
	Refrigerated	7 days	

Clinical & Interpretive

Clinical Information

Carbohydrate antigen 19-9 (CA 19-9) is a modified Lewis(a) blood group antigen that 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 less than 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

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 a CA 19-9 secretor.

In rare cases, some individuals can develop antibodies to mouse or other animal antibodies (often referred to as human anti-mouse antibodies [HAMA] or heterophile antibodies), which may cause interference in some immunoassays. Caution should be used in interpretation of results, and the laboratory should be alerted if the result does not correlate with the clinical presentation.

Clinical Reference

1. Snozek CL, Jenkins SM, Bryant SC, et al. Analysis of CEA, CA19-9 and amylase in pancreatic cyst fluid for diagnosis of pancreatic lesions. Clin Chem. 2008;54(6 Suppl S):A126-127
2. van der Waaij LA, van Dullemen HM, Porte RJ. Cyst fluid analysis in the differential diagnosis of pancreatic cystic lesions: a polled analysis. Gastrointest Endosc. 2005;62(3):383-389
3. Khalid A, Brugge W. ACG practice guidelines for the diagnosis and management of neoplastic pancreatic cysts. Am J Gastroenterol. 2007;102(10):2339-2349
4. Elta GH, Enestvedt BK, Sauer BG, Lennon AM. ACG clinical guideline: diagnosis and management of pancreatic cysts. Am J Gastroenterol. 2018;113(4):464-479. doi:10.1038/ajg.2018.14

Performance

Method Description

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: Access GI Monitor. Beckman Coulter, Inc.; 04/2019)

PDF Report

No

Day(s) Performed

Monday through Friday

Report Available

1 to 3 days

Specimen Retention Time

12 months

Performing Laboratory Location

Mayo Clinic Laboratories - Rochester Superior Drive

Fees & 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 account representative. 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 US Food and Drug Administration.

CPT Code Information

86301

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
199PC	CA19-9, Pancreatic Cyst	97750-4

Result ID	Test Result Name	Result LOINC® Value
199P	CA19-9, Pancreatic Cyst	97750-4
SITE6	Site	39111-0