Test Definition: PF199

Carbohydrate Antigen 19-9 (CA 19-9), Pleural Fluid

Overview

Useful For
An adjuvant to cytology and imaging studies to differentiate between nonmalignant and malignant causes of pleural effusions

Method Name
Immunoenzymatic Assay

NY State Available
Yes

Specimen

Specimen Type
Pleural Fluid

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: Pleural fluid, thoracentesis fluid
Container/Tube: Plain, plastic, screw-top tube
Specimen Volume: 2 mL

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
Gross icterus	OK

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Pleural Fluid	Frozen (preferred)	90 days	

	Ambient	7 days	
	Refrigerated	14 days	

Clinical & Interpretive

Clinical Information

Pleural effusions occur as a consequence of either nonmalignant conditions (including congestive heart failure, pneumonia, pulmonary embolism, and liver cirrhosis) or malignant conditions (including lung, breast, and lymphoma cancers). Diagnosing the cause of an effusion can be difficult, requiring cytological examination of the fluid. Analysis of various tumor markers in pleural fluid has shown that these markers can differentiate between effusions caused by nonmalignant and malignant conditions and can enhance cytology findings.

Carbohydrate antigen 19-9 (CA 19-9) is a modified Lewis(a) blood group antigen. Healthy adults typically produce low to undetectable levels of CA 19-9. Serum concentrations of CA 19-9 may be elevated in patients with certain malignancies that secrete CA 19-9 into circulation, including cholangiocarcinoma, colorectal, stomach, bile duct, lung, ovarian, and pancreatic cancers.

Pleural fluid concentrations of CA 19-9 have been reported to be elevated in patients with certain malignancies. Malignancies that can secrete CA 19-9 and elevate serum CA 19-9 concentrations, including cholangiocarcinoma, colorectal, stomach, bile duct, lung, ovarian, and pancreatic cancers, typically also elevate CA 19-9 in pleural fluid. In contrast, malignancies that do not secrete CA 19-9, including mesothelioma, lymphoma, leukemia, and melanoma, have low concentrations of CA 19-9 in pleural fluid comparable to concentrations observed in nonmalignant effusions.

Carbohydrate antigen results should be used in conjunction with cytological analysis of pleural fluid, imaging studies, and other clinical findings.

Reference Values

An interpretive report will be provided.

Interpretation

A pleural fluid carbohydrate antigen 19-9 (CA 19-9) concentration of 20.0 U/mL or higher is suspicious, but not diagnostic, of a malignant source of the effusion. This cutoff yielded a sensitivity of 35%, specificity of 95%, and positive predictive value of 88% in a study of 200 patients presenting with effusion. CA 19-9 concentrations were significantly higher in effusions caused by CA 19-9-secreting malignancies, including cholangiocarcinoma, colorectal, stomach, bile duct, lung, ovarian, and pancreatic cancers. However, effusions caused by non-CA 19-9-secreting malignancies, including lymphoma, mesothelioma, leukemia, and melanoma, routinely had CA 19-9 concentrations below 20.0 U/mL. Therefore, negative results should be interpreted with caution, especially in patients who have or are suspected of having a non-CA 19-9-secreting malignancy.

Correlation of all tumor marker results with cytology and imaging is highly recommended.

Cautions

This test result should not be the sole basis for diagnosis. Carbohydrate antigen 19-9 (CA 19-9) is not specific for

malignancy and testing has limited utility when used as the sole diagnostic test. Test results should be always correlated with cytology, imaging, and other clinical findings.

A low or negative CA 19-9 result (<20.0 U/mL) may be uninformative or misleading, as certain malignancies do not secrete CA 19-9 and will not produce elevated CA 19-9 concentrations in pleural effusions. Negative results should be interpreted with caution in patients who have or are suspected of having a non-CA 19-9-secreting malignancy or who have cancer of unknown primary origin. Alternative methodologies, including cytology, imaging, and other tumor markers, are recommended instead.

Certain individuals (Lewis nonsecretors) do not produce the CA 19-9 antigen. A low or negative CA 19-9 result may, therefore, be uninformative or misleading in these individuals. Measuring serum CA 19-9 concentrations may be helpful to determine if the patient is a Lewis nonsecretor.

Serum CA 19-9 concentrations have been reported to be elevated as a consequence of certain nonmalignant conditions, including liver cirrhosis, pancreatitis, gallstones, and cholecystitis. It is unknown whether these conditions also cause CA 19-9 elevations in pleural fluid. Results should therefore be interpreted with caution in patients with these conditions.

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. Shitrit D, Zingerman B, Shitrit ABG, Shlomi D, Kramer MR. Diagnostic value of CYFRA 21-1, CEA, CA 19-9, CA 15-3, and CA 125 assays in pleural effusions: analysis of 116 cases and review of the literature. Oncologist. 2005;10(7):501-507
2. Hackbarth JS, Murata K, Reilly WM, Algeciras-Schimnich A. Performance of CEA and CA19-9 in identifying pleural effusions caused by specific malignancies. Clin Biochem. 2010;43(13-14):1051-1055
3. Block DR, Algeciras-Schimnich A. Body fluid analysis: clinical utility and applicability of published studies to guide interpretation of today's laboratory testing in serous fluids. Crit Rev Clin Lab Sci. 2013;50(4-5):107-124. doi:10.3109/10408363.2013.844679
4. Yang Y, Liu YL, Shi HZ. Diagnostic accuracy of combinations of tumor markers for malignant pleural effusion: An updated meta-analysis. Respiration. 2017;94(1):62-69. doi:10.1159/000468545

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 carbohydrate antigen 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 assay. Beckman Coulter, Inc.; 2020)

PDF Report
No

Day(s) Performed
Monday through Saturday

Report Available
1 to 3 days

Specimen Retention Time
14 days

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
PF199	CA 19-9, Pleural Fluid	19163-5

Result ID	Test Result Name	Result LOINC® Value
P199	CA 19-9, Pleural Fluid	19163-5
SITE8	Site	39111-0