MAYO CLINIC LABORATORIES

Test Definition: 199PT

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

Overview

Useful For
An adjunct to cytology to differentiate between malignancy-related ascites and benign causes of ascites formation

Method Name
Immunoenzymatic Assay

NY State Available
Yes

Specimen

Specimen Type
Peritoneal

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).
Sources: Peritoneal, abdominal, ascites, paracentesis fluid (peritoneal washings are **not acceptable**)
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

Reject Due To

Gross hemolysis	Reject
Gross lipemia	OK
Gross icterus	OK

Specimen Stability Information

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

	Ambient	7 days	
	Refrigerated	7 days	

Clinical & Interpretive

Clinical Information

Malignancy accounts for approximately 7% of cases of ascites formation. Malignant disease can cause ascites by various mechanisms including peritoneal carcinomatosis (53%), massive liver metastasis causing portal hypertension (13%), peritoneal carcinomatosis plus massive liver metastasis (13%), hepatocellular carcinoma plus cirrhosis (7%), and chylous ascites due to lymphoma (7%). The evaluation and diagnosis of malignancy-related ascites is based on the patient clinical history, ascites fluid analysis, and imaging tests.

The overall sensitivity of cytology for the detection of malignancy-related ascites ranges from 58% to 75%. Cytology examination is most successful in patients with ascites related to peritoneal carcinomatosis, as viable malignant cells are exfoliated into the ascitic fluid. However, only approximately 53% of patients with malignancy-related ascites have peritoneal carcinomatosis. Patients with other causes of malignancy-related ascites almost always have a negative cytology.

Carbohydrate antigen 19-9 (CA 19-9) is a modified Lewis(a) blood group antigen. CA 19-9 may be elevated in the serum patients with gastrointestinal malignancies, such as cholangiocarcinoma, pancreatic cancer, or colon cancer. Measurement of CA 19-9 in ascitic fluid is sometimes used in combination with cytology for detecting malignancy-related ascites.

Reference Values

An interpretive report will be provided.

Interpretation

A peritoneal fluid carbohydrate antigen 19-9 (CA 19-9) concentration greater than 32 U/mL is suspicious, but not diagnostic, of a malignancy-related ascites. This clinical decision limit cutoff yielded 44% sensitivity and 93% specificity in a study of 137 patients presenting with ascites. However, ascites caused by malignancies not associated with increase serum CA 19-9 concentrations, including lymphoma, mesothelioma, leukemia, and melanoma, routinely had CA 19-9 concentrations less than 32 U/mL. Therefore, negative results should be interpreted with caution, especially in patients who have or are suspected of having a malignancy not associated with elevated CA 19-9 levels in serum.

Cautions

Peritoneal washings are not an approved specimen type for this assay. Therefore, the interpretive comments for peritoneal fluid do not apply when peritoneal washings are the collected specimen type.

Do not use peritoneal fluid carbohydrate antigen 19-9 (CA 19-9) concentrations as absolute evidence of the presence or the absence of malignant disease. The CA 19-9 result should be interpreted in conjunction with information from the clinical evaluation of the patient and other diagnostic procedures.

Approximately 10% of the White population does not express CA 19-9 due to the deficiency of a fucosyltransferase

enzyme. Consequently, low values in these individuals are not informative regarding malignancy-related ascites.

In some immunoassays, the presence of unusually high concentrations of analyte may result in a high-dose "hook" effect. This may result in a lower or even normal measured analyte concentration. If the reported result is inconsistent with the clinical presentation, the laboratory should be alerted for troubleshooting.

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.

Carbohydrate antigen 19-9 values are method dependent; therefore, the same method should be used to serially monitor patients.

Supportive Data

An in-house study was performed to select a clinical decision limit to differentiate between malignancy-related benign causes of ascites with high specificity. The study included 83 cases of benign ascites and 54 cases of malignancy-related ascites. Within the malignancy-related ascites, there were 9 specimens with malignancies known not to secrete carbohydrate antigen 19-9 (CA 19-9) in serum (lymphoma, leukemia, melanoma, sarcoma, and neuroendocrine tumors). Amongst the group that are known to secrete CA 19-9 in serum (n=45), there were the following malignancies: pancreatic, breast, gastric, colon, bladder, cholangiocarcinoma, gynecological cancers, peritoneal carcinomatosis, and hepatocellular carcinoma. Using a clinical decision limit cutoff of greater than 32 U/mL, the specificity was 93% for the benign ascites group. The sensitivity was 49% for those malignancies associated with elevated CA 19-9 in serum.

Clinical Reference

1. Trape J, Molina R, Sant F. Clinical evaluation of the simultaneous determination of tumor markers in fluid and serum and their ratio in the differential diagnosis of serous effusions. Tumour Biol. 2004;25(5-6):276-281
2. Sari R, Yildirim B, Sevinc A, Bahceci F, Hilmioglu F. The importance of serum and ascites fluid alpha-fetoprotein, carcinoembryonic antigen, CA 19-9, and CA 15-3 levels in differential diagnosis of ascites etiology. Hepatogastroenterology. 2001;48(42):1616-1621
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. Jain T, Ram S, Kumar H, Saroch A, Sharma V, Singh H. Ascitic and serum levels of tumor biomarkers (CA 72-4, CA 19-9, CEA AND CA 125) in discrimination of cause of ascites: A prospective study. Arq Gastroenterol. 2022;59(2):198-203. doi:10.1590/S0004-2803.202202000-37

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 (CA 19-9) 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; 2024)

PDF Report
No

Day(s) Performed
Monday through Saturday

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
199PT	CA 19-9, Peritoneal Fluid	50781-4

Test Definition: 199PT

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

Result ID	Test Result Name	Result LOINC® Value
199PN	CA 19-9, Peritoneal Fluid	50781-4
SITEE	Site	39111-0