MAYO CLINIC LABORATORIES

Test Definition: AFPPT

Alpha-Fetoprotein (AFP), 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
Sources: Peritoneal, abdominal, ascites, paracentesis (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.

Alpha-fetoprotein (AFP) measurement in serum is used in the management of patients with hepatocellular carcinoma (HCC). Measurement of AFP in ascites fluid might be useful when used in conjunction with cytology in patients with a history of HCC in whom a cause of peritoneal fluid accumulation is uncertain.

Reference Values

An interpretive report will be provided.

Interpretation

A peritoneal fluid alpha-fetoprotein (AFP) concentration greater than 6.0 ng/mLis suspicious but not diagnostic of ascites related to hepatocellular carcinoma (HCC). This clinical decision limit cutoff yielded a sensitivity of 58%, specificity of 96% in a study of 137 patients presenting with ascites. AFP concentrations were significantly higher in ascites caused by HCC. Ascites caused by malignancies other than HCC routinely had AFP concentrations less than 6.0 ng/mL. Therefore, negative results should be interpreted with caution.

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 alpha-fetoprotein (AFP) concentration as absolute evidence of the presence or the absence of malignant disease. The AFP result should be interpreted in conjunction with information from the clinical evaluation of the patient and other diagnostic procedures.

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.

Alpha-fetoprotein 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 and 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 12 cases of hepatocellular carcinoma (HCC). Using a clinical decision limit cutoff of greater than 6 ng/mL, the specificity was 96% for the benign ascites group. The sensitivity for the HCC was 58%.

Clinical Reference

1. 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

2. Owen WE, Hunsaker JJH, Genzen JR. Alpha-fetoprotein in pericardial, peritoneal, and pleural fluids: A body fluid matrix evaluation. Clin Biochem. 2018;56:109-112. doi:10.1016/j.clinbiochem.2018.04.019

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

Performance

Method Description

The instrument used is the Beckman Coulter UniCel DxI 800. The Beckman Coulter Access alpha-fetoprotein (AFP) immunoassay is a 2-site immunoenzymatic sandwich assay. A specimen is added to a reaction vessel with mouse monoclonal anti-AFP alkaline phosphatase conjugate, and paramagnetic particles coated with a second mouse monoclonal anti-AFP antibody. The AFP in the specimen binds to the immobilized monoclonal anti-AFP on the solid phase while, at the same time, the monoclonal anti-AFP-alkaline phosphatase conjugate reacts with different antigenic sites on the specimen AFP. After incubation in a reaction vessel, materials bound by the solid phase are held in a magnetic field while unbound materials are washed away. A chemiluminescent substrate is added to the reaction vessel, and light generated by the reaction is measured with a luminometer. The light production is directly proportional to the amount of AFP in the specimen. The amount of analyte in the specimen is determined by means of a stored multipoint calibration curve.(Package insert: Access AFP 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

86316

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
AFPPT	AFP, Peritoneal Fluid	49761-0

Result ID	Test Result Name	Result LOINC® Value
AFPPN	AFP, Peritoneal Fluid	49761-0
SITEF	Site	39111-0