

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

Container/Tube: Plain, plastic, screw-top tube

Specimen Volume: 2mL

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
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Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Peritoneal	Frozen (preferred)	90 days	
	Ambient	7 days	
	Refrigerated	7 days	

Clinical and 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 and 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 >6.0 ng/mL [is 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 <6.0 ng/mL. Therefore, negative results should be interpreted with caution.

Cautions

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.

Immunometric assays can, in rare occasions, be subject to interferences such as "hooking" at very high analyte concentrations (false-low results) and heterophilic antibody interference (false-high results). If the clinical picture does not fit the laboratory result, these possibilities should be considered.

AFP 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 >6 ng/mL, the specificity was 96% for the benign ascites group. The sensitivity for the HCC was 58%.

Clinical Reference

Sari R, Yildirim B, Sevinc A, et al: 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 Nov-Dec;48(42):1616-1621

Performance

Method Description

The instrument used is the Beckman Coulter UniCel Dxl 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 Lumi-Phos 530 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 Incorporated, Fullerton, CA, 2010)

For all samples with AFP concentrations >6 ng/mL, a dilution series is performed. A linear dilution excludes hooking and most major interferences. Samples that contain AFP concentrations < or =6 ng/mL are spiked with exogenous AFP to identify possible interferences that may cause a false-low result.

PDF Report

No

Day(s) and Time(s) Test Performed

Monday through Friday; Varies

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

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