

## 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:** 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
Peritoneal	Ambient	7 days	
	Refrigerated	7 days	
	Frozen (preferred)	90 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 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 greater than 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 less than 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.

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.

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 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 Nov-Dec;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 Jun;56:109-112. doi: 10.1016/j.clinbiochem.2018.04.019
3. Block DR, Algeciras-Schimmich 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 Jul-Oct;50(4-5):107-124. doi: 10.3109/10408363.2013.844679

**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 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; 2020)

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

**PDF Report**

No

**Day(s) Performed**

Monday through Saturday

**Report Available**

1 to 3 days

**Specimen Retention Time**

12 months

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**Performing Laboratory Location**

Rochester

**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