

## Overview

### Useful For

Follow-up management of patients undergoing cancer therapy, especially for testicular and ovarian tumors and for hepatocellular carcinoma

Often used in conjunction with human chorionic gonadotropin.(2)

This test is **not recommended** as a screening procedure for cancer detection in the general population.

This test is **not intended for** the detection of neural tube defects.

This test is **not useful for** patients with pure seminoma or dysgerminoma.

### Special Instructions

- [Alpha-Fetoprotein \(AFP\)](#)

### Method Name

Immunoenzymatic Assay

### NY State Available

Yes

## Specimen

### Specimen Type

Serum

### Ordering Guidance

This test is used as a tumor marker and is **not intended for** the detection of neural tube defects. For testing amniotic fluid specimens, order AFPA / Alpha-Fetoprotein, Amniotic Fluid.

### Specimen Required

#### Collection Container/Tube:

**Preferred:** Serum gel

**Acceptable:** Red top

**Submission Container/Tube:** Plastic vial

**Specimen Volume:** 0.6 mL

### Forms

If not ordering electronically, complete, print, and send [Oncology Test Request](#) (T729) with the specimen.

**Specimen Minimum Volume**

0.5 mL

**Reject Due To**

Gross hemolysis	Reject
Gross lipemia	OK

**Specimen Stability Information**

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

**Clinical & Interpretive****Clinical Information**

Alpha-fetoprotein (AFP) is a glycoprotein that is produced in early fetal life by the liver and by a variety of tumors including hepatocellular carcinoma, hepatoblastoma, and nonseminomatous germ cell tumors of the ovary and testis (eg, yolk sac and embryonal carcinoma). Most studies report elevated AFP concentrations in approximately 70% of patients with hepatocellular carcinoma. Elevated AFP concentrations are found in 50% to 70% of patients with nonseminomatous testicular tumors.(1)

AFP is elevated during pregnancy. Persistence of AFP in the mother following birth is a rare hereditary condition.(2) Neonates have markedly elevated AFP levels (>100,000 ng/mL) that rapidly fall to below 100 ng/mL by 150 days and gradually return to normal over their first year.(2)

Concentrations of AFP above the reference range also have been found in the serum of patients with benign liver disease (eg, viral hepatitis, cirrhosis), gastrointestinal tract tumors, and along with carcinoembryonic antigen, in ataxia telangiectasia.

The biological half-life of AFP is approximately 5 days.

**Reference Values**

&lt;8.4 ng/mL

Reference values are for nonpregnant subjects only; fetal production of alpha-fetoprotein elevates values in pregnant women.

Range for newborns is not available, but concentrations over 100,000 ng/mL have been reported in normal newborns, and the values rapidly decline in the first 6 months of life.(See literature reference: Ped Res 1981;15:50-52) For further interpretive information, see [Alpha-Fetoprotein \(AFP\)](#)

Serum markers are not specific for malignancy, and values may vary by method.

**Interpretation**

Alpha-fetoprotein (AFP) levels may be elevated in association with a variety of malignancies or benign diseases.

Failure of the AFP value to return to normal by approximately one month after surgery suggests the presence of residual tumor.

Elevation of AFP after remission suggests tumor recurrence; however, tumors originally producing AFP may recur without an increase in AFP.

**Cautions**

This assay is intended only as an adjunct in the diagnosis and monitoring of alpha-fetoprotein (AFP)-producing tumors. The diagnosis should be confirmed by other tests or procedures.

Higher values are found in newborns and pregnant women.

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. For diagnostic purposes, these immunoassay results should always be assessed in conjunction with the patient's medical history, clinical examination, and other findings. For the Beckman Access AFP assay a hook effect is not expected up to 500,000 ng/mL. Concentrations greater than 500,000 ng/mL might result in a falsely low result.

**Clinical Reference**

1. Sturgeon CM, Duffy MJ, Stenman UH, et al: National Academy of Clinical Biochemistry laboratory medicine practice guidelines for use of tumor markers in testicular, prostate, colorectal, breast, and ovarian cancers. *Clin Chem*. 2008 Dec; 54(12):e11-79
2. Blohm ME, Vesterling-Horner D, Calaminus G, et al: Alpha-1-fetoprotein (AFP) reference values in infants up to 2 years of age. *Pediatr Hematol Onco*. 1998 Mar-April;15(2):135-142
3. Milose JC, Filson CP, Weizer AZ, et al: Role of biochemical markers in testicular cancer: diagnosis, staging, and surveillance. *Open Access J Urol*. 2011 Dec 30;4:1-8
4. Schefer H, Mattmann S, Joss RA: Hereditary persistence of alpha-fetoprotein. Case report and review of the literature. *Ann Oncol*. 1998 June;9(6):667-672

**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. Beckman Coulter Inc.; 04/2020)

**PDF Report**

No

**Day(s) Performed**

Monday through Friday

**Report Available**

1 to 3 days

**Specimen Retention Time**

12 months

**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 Regional Manager. For assistance, contact [Customer Service](#).

**Test Classification**

This test has been cleared, approved, or is exempt by the US Food and Drug Administration and is used per manufacturer's instructions. Performance characteristics were verified by Mayo Clinic in a manner consistent with CLIA requirements.

**CPT Code Information**

82105

**LOINC® Information**

Test ID	Test Order Name	Order LOINC® Value
AFP	Alpha-Fetoprotein, Tumor Marker, S	53962-7

Result ID	Test Result Name	Result LOINC® Value
AFP	Alpha-Fetoprotein, Tumor Marker, S	53962-7