Test Definition: AFP

Alpha-Fetoprotein, Tumor Marker, S

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

Advisory Information

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

Container/Tube:

Preferred: Serum gel

Acceptable: Red top

Specimen Volume:0.6 mL

Forms

If not ordering electronically, complete, print, and send 1 of the following forms with the specimen:

-General Request (T239)

-Oncology Test Request (T729)

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 and 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

<8.4 ng/mL

Reference values are for nonpregnant subjects only; fetal production of AFP 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) in Special Instructions.

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 1 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.

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 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, Beckman Coulter Inc., Fullerton, CA, 2010)

PDF Report

No

Day(s) and Time(s) Test Performed

Monday through Friday; 5 a.m.-12 a.m.

Saturday; 6 a.m.-6 p.m.

Analytic Time

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 cleared or approved by the U.S. 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