MAYO CLINIC LABORATORIES

# Test Definition: AFP

Alpha-Fetoprotein (AFP) Tumor Marker, Serum

## 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
**Collection Instructions:** Centrifuge and aliquot serum into a plastic vial.

### 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)

Alpha-fetoprotein 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 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.(Wu JT, Book L, Sudar K. Serum alpha fetoprotein (AFP) levels

in normal infants. Pediatr Res. 1981;15(1):50-52) For additional 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 may 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;54(12):e11-e79
2. Blohm ME, Vesterling-Hörner D, Calaminus G, Göbel U. Alpha 1-fetoprotein (AFP) reference values in infants up to 2 years of age. Pediatr Hematol Oncol. 1998;15(2):135-142
3. Milose JC, Filson CP, Weizer AZ, Hafez KS, Montgomery JS. Role of biochemical markers in testicular cancer: diagnosis, staging, and surveillance. Open Access J Urol. 2011;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;9(6):667-672
5. Adigun OO, Yarrarapu SNS, Zubair M, Khetarpal S. Alpha-Fetoprotein Analysis. In: StatPearls. Treasure Island (FL): StatPearls Publishing; May 1, 2024.6. Glowska-Ciemny J, Szymanski M, Kuszerska A, Rzepka R, von Kaisenberg CS, Kocylowski R. Role of Alpha-Fetoprotein (AFP) in Diagnosing Childhood Cancers and Genetic-Related Chronic Diseases. Cancers (Basel). 2023;15(17):4302

## Performance

### Method Description

The test is performed on 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
14 days

### 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 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 |

# Test Definition: AFP

Alpha-Fetoprotein (AFP) Tumor Marker, Serum

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