**Overview**

**Useful For**
The 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)

**Testing Algorithm**
See Alpha-Fetoprotein (AFP) in Special Instructions.

**Special Instructions**
- Alpha-Fetoprotein (AFP)

**Method Name**
Immunoenzymatic Assay

**NY State Available**
Yes

**Specimen**

**Specimen Type**
Serum

**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**

<table>
<thead>
<tr>
<th>Condition</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gross hemolysis</td>
<td>Reject</td>
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<tr>
<td>Gross lipemia</td>
<td>OK</td>
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</table>
Specimen Stability Information

<table>
<thead>
<tr>
<th>Specimen Type</th>
<th>Temperature</th>
<th>Time</th>
<th>Special Container</th>
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<tbody>
<tr>
<td>Serum</td>
<td>Refrigerated (preferred)</td>
<td>7 days</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Frozen</td>
<td>90 days</td>
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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 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

<6.0 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.

AFP is not recommended as a screening procedure for cancer detection in the general population.

Amniotic fluid should not be sent, because this test is only used as a tumor marker. This test is not the correct AFP test for pregnant patients.

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

Higher values are found in newborns and pregnant women.

Not useful in patients with pure seminoma or dysgerminoma.

**Clinical Reference**


**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.
Test Definition: AFP
Alpha-Fetoprotein, Tumor Marker, S

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

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<tr>
<th>Test ID</th>
<th>Test Order Name</th>
<th>Order LOINC Value</th>
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<tbody>
<tr>
<td>AFP</td>
<td>Alpha-Fetoprotein, Tumor Marker, S</td>
<td>53962-7</td>
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<table>
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<th>Result LOINC Value</th>
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