Overview

Useful For
An adjunct in the diagnosis of central nervous system (CNS) germinomas and meningeal carcinomatosis
Evaluating germ-cell tumors, including testicular cancer metastatic to the CNS in conjunction with beta-human chorionic gonadotropin measurement(1)
An adjunct in distinguishing between suprasellar dysgerminomas and craniopharyngiomas
A supplement to cerebrospinal fluid cytologic analysis

Method Name
Immunoenzymatic Assay

NY State Available
Yes

Specimen

Specimen Type
CSF

Specimen Required
Container/Tube: Sterile vial
Specimen Volume: 1mL

Forms
If not ordering electronically, complete, print, and send an Oncology Test Request (T729) with the specimen.

Specimen Minimum Volume
0.5 mL

Reject Due To

| Gross hemolysis | Reject |

Specimen Stability Information

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<tr>
<th>Specimen Type</th>
<th>Temperature</th>
<th>Time</th>
<th>Special Container</th>
</tr>
</thead>
<tbody>
<tr>
<td>CSF</td>
<td>Frozen (preferred)</td>
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<td></td>
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<tr>
<td></td>
<td>Refrigerated</td>
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Clinical and Interpretive
Clinical Information

Alpha-fetoprotein (AFP) is an oncofetal glycoprotein, homologous with albumin that is produced both in early fetal life and in tumors arising from midline embryonic structures. AFP is synthesized in the yolk sac, liver, and gastrointestinal track of the fetus. In adults, the liver synthesizes AFP. AFP is not normally expressed in the central nervous system (CNS). AFP levels in liver are increased in hepatomas and hepatocellular and colon carcinomas, as well as in germ-cell tumors arising from the ovaries and nonseminomatous germ-cell tumors of the testes, testicular teratocarcinomas, and primary germ-cell tumors arising within the CNS. The presence of germinomas in the CNS and CNS involvement in metastatic cancer and meningeal carcinomatosis results in increased levels of AFP in cerebrospinal fluid.

Reference Values

<1.5 ng/mL

Values for alpha-fetoprotein in cerebrospinal fluid have not been formally established for newborns and infants. The available literature indicates that by 2 months of age, levels comparable to adults should be reached. (Ann Clin Biochem 2005;42:24-29)

Interpretation

Alpha-fetoprotein (AFP) concentrations that exceed the upper end of normal are consistent with the presence of central nervous system germinoma, meningeal carcinomatosis, or metastatic nonseminomatous testicular cancer. AFP is not elevated in the presence of a craniopharyngioma.

Cautions

Malignancy may occur without elevation of alpha-fetoprotein (AFP) concentration. AFP elevation occurs in approximately 70% of central nervous system germinomas. Measurement of beta-human chorionic gonadotropin is recommended to improve sensitivity of detection.

Values obtained with different assay methods or kits may be different and cannot be used interchangeably.

Test results cannot be interpreted as absolute evidence for the presence or absence of malignant disease.

Clinical Reference


Performance

Method Description

The instrument used is a Beckman Coulter UniCel Dxl 800. The Access alpha-fetoprotein (AFP) immunoassay is a 2-site immunoenzymatic sandwich assay. A sample 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 sample 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 sample AFP. After incubation in a reaction vessel, materials bound to the solid phase are held in a magnetic field.
while unbound materials are washed away. Then a chemiluminescence 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 sample. The amount of analyte in the sample is determined by means of a stored multipoint calibration curve. Because the protein matrix is less concentrated in cerebrospinal fluid, a "protein spike" is added to each specimen prior to analysis. A correction is made for the dilution effect prior to reporting. (Beckman Coulter package insert, Beckman Coulter, Brea, CA, 2015)

**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**

Same day/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 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 U.S. Food and Drug Administration.

**CPT Code Information**

86316

**LOINC® Information**

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<th>Order LOINC Value</th>
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<td>Alpha-Fetoprotein, CSF</td>
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