

Overview

Useful For

An adjunct in the diagnosis of central nervous system (CNS) germinomas and meningeal carcinomatosis

Evaluating the presence of germ-cell tumors in the CNS, in conjunction with cerebrospinal fluid (CSF) beta-human chorionic gonadotropin measurement

A supplement to CSF cytologic analysis

Method Name

Immunoenzymatic Assay

NY State Available

Yes

Specimen

Specimen Type

CSF

Specimen Required

Container/Tube: Sterile vial

Preferred: Vial number 1

Acceptable: Any vial

Specimen Volume: 1 mL

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
Gross icterus	OK

Specimen Stability Information

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

Clinical & Interpretive

Clinical Information

Alpha-fetoprotein (AFP) is an oncofetal glycoprotein, homologous with albumin, that is produced 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 concentrations 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 and testicular teratocarcinomas.

Based on histologic components and differentiation, CNS germ cell tumors (GCT) are classified as either germinomatous or nongerminomatous germ cell tumors (NGGCT). NGGCT include embryonal carcinomas, yolk sac tumors, choriocarcinomas, and mixed tumors. Teratomas (including teratomas of testicular origin) are sometimes considered to be NGGCT. Germinomas comprise two-thirds of the CNS GCT, whereas NGGCT account for the other third. However, CNS GCT are rare, comprising only 1% to 2% of all primary CNS neoplasms. The presence of germinomas in the CNS, CNS involvement in metastatic cancer, and meningeal carcinomatosis may result in increased concentrations of AFP (and/or beta-human chorionic gonadotropin [hCG]) in cerebrospinal fluid (CSF). In some patients with primary or metastatic intracranial or intraspinal tumors containing trophoblasts, AFP secreted by trophoblasts can diffuse into the CSF. Following treatment, AFP elevation in CSF is a potential marker of tumor recurrence.

Increased concentrations of AFP in CSF are more indicative of sac tumors/yolk sac components in mixed GCT. High concentrations of hCG in CSF support the presence of choriocarcinomas/choriocarcinomatous components in mixed GCT. If a germ cell tumor is suspected, the measurement of CSF and serum AFP and hCG may be considered. The secretion of these tumor markers in the CSF is pathognomonic for NGGCT.

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 (CNS) germinoma. The presence of germinomas in the CNS, CNS involvement in metastatic cancer, and meningeal carcinomatosis may result in increased cerebrospinal fluid AFP concentrations in approximately 20% of germinomas.

Cautions

Malignancy may occur without an elevation of alpha-fetoprotein in cerebrospinal fluid .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.

In rare cases, some individuals can develop antibodies to mouse or other animal antibodies (often referred to as human anti-mouse antibodies [HAMA] or heterophile antibodies), which may cause interference in some immunoassays. Caution should be used in interpretation of results and the laboratory should be alerted if the result does not correlate with the clinical presentation.

Clinical Reference

1. Jubran RF, Finlay J: Central nervous system germ cell tumors: controversies in diagnosis and treatment. *Oncology*. 2005 May;19(6):705-711
2. Seregini E, Massimino M, Nerini Molteni S, et al: Serum and cerebrospinal fluid human chorionic gonadotropin (hCG) and alpha-fetoprotein (AFP) in intracranial germ cell tumors. *Int J Biol Markers*. 2002 Apr-Jun;17(2):112-118
3. Hu M, Guan H, Lau CC, et al: An update on the clinical diagnostic value of beta-hCG and alpha FP for intracranial germ cell tumors. *Eur J Med Res*. 2016 Mar 12;21:10. doi: 10.1186/s40001-016-0204-2
4. Shi Q, Tian C, Pu C, Yu S, Huang X: CSF and serum AFP in patients without gestational or neoplastic AFP-secretion. *Scand J Clin Lab Invest*. 2012 Dec;72(8):619-22. doi: 10.3109/00365513.2012.725865
5. Coakley J, Kellie SJ: Interpretation of alpha-fetoprotein concentrations in cerebrospinal fluid of infants. *Ann Clin Biochem*. 2005 Jan;42:24-29
6. Shajani-Yi Z, Martin IW, Brunelle AA, Cervinski MA: Method validation of human chorionic gonadotropin and alpha-fetoprotein in cerebrospinal fluid: Aiding the diagnosis of intracranial germ cell tumors. *J Appl Lab Med*. 2017 Jul 1;2(1):65-75. doi: 10.1373/jalm.2016.022822

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. The 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 the monoclonal anti-AFP-alkaline phosphatase conjugate reacts with different antigenic sites on the sample AFP. After incubation, materials bound to the solid phase are held in a magnetic field, while unbound materials are washed away. A chemiluminescence substrate is then 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. Prior to reporting, a correction is made for the dilution effect. (Package insert: Access AFP. Beckman Coulter; 04/2020)

PDF Report

No

Day(s) Performed

Monday through Saturday

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 account representative. 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 US Food and Drug Administration.

CPT Code Information

86316

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
AFPSF	Alpha-Fetoprotein, CSF	1833-3

Result ID	Test Result Name	Result LOINC® Value
AFSF	Alpha-Fetoprotein, CSF	1833-3