

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.

Reject Due To

Gross hemolysis Reject

Specimen Minimum Volume

0.5 mL

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 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

1. Jubran RF, Finlay J: Central nervous system germ cell tumors: controversies in diagnosis and treatment. *Oncology* 2005;19:705-711
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;17(2):112-118
3. Coakley J, Kellie SJ: Interpretation of alpha-fetoprotein concentrations in cerebrospinal fluid of infants. *Ann Clin Biochem* 2005;42:24-29

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

Specimen Retention Time

12 months

Performing Laboratory Location

Rochester

Fees & Codes**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