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MAYO CLINIC LABORATORIES

Test Definition: L3AFP

Alpha-Fetoprotein (AFP) L3% and Total, Hepatocellular Carcinoma Tumor Marker, Serum

Overview

Useful For

Distinguishing between hepatocellular carcinoma and chronic liver disease

Monitoring individuals with hepatic cirrhosis from any etiology for progression to hepatocellular carcinoma

Surveillance for development of hepatocellular carcinoma in individuals with a positive family history of hepatic cancer

Surveillance for development of hepatocellular carcinoma in individuals within specific ethnic and sex groups who do not have hepatic cirrhosis but have a confirmed diagnosis of chronic infection by hepatitis B acquired early in life, including:
-African men above the age of 20
-Asian men above the age of 40
-Asian women above the age of 50

Method Name

Isotachophoresis with Laser-Induced Fluorescence

NY State Available

Yes

Specimen

Specimen Type

Serum

Specimen Required

Collection Container/Tube:
Preferred: Serum Gel
Acceptable: Red Top
Submission Container/Tube: Plastic vial
Specimen Volume: 0.5 mL
Collection Instructions: Centrifuge and aliquot serum into a plastic vial.

Forms

If not ordering electronically, complete, print, and send 1 of the following forms with the specimen:
-Oncology Test Request (T729)
-Gastroenterology and Hepatology Test Request (T728)

Specimen Minimum Volume

0.2 mL

Reject Due To

Gross hemolysis	Reject
Gross lipemia	OK
Gross icterus	OK

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Serum	Frozen (preferred)	180 days	
	Refrigerated	5 days	

Clinical & Interpretive

Clinical Information

Hepatocellular carcinoma is the third leading cause of death from cancer worldwide.(1) While hepatocellular carcinoma can be treated effectively in its early stages, most patients are not diagnosed until they are symptomatic and at higher grades and stages, which are less responsive to therapies. Alpha-fetoprotein (AFP) is the standard serum tumor marker utilized in the evaluation of suspected hepatocellular carcinoma. However, increased serum concentrations of AFP may be found in chronic hepatitis and liver cirrhosis as well as in other tumor types (eg, germ cell tumors),(2) decreasing the specificity of AFP testing for hepatocellular carcinoma. Furthermore, AFP is not expressed at high levels in all hepatocellular carcinoma patients, resulting in decreased sensitivity, especially in potentially curable small tumors.

Alpha-fetoprotein is differentially glycosylated in several hepatic diseases. For example, uridine diphosphate-alpha-(1->6)-fucosyltransferase is differentially expressed in hepatocytes following malignant transformation.(3) This enzyme incorporates fucose residues on the carbohydrate chains of AFP. Different glycosylated forms of AFP can be recognized following electrophoresis by reaction with different carbohydrate-binding plant lectins. The fucosylated form of serum AFP, which is most closely associated with hepatocellular carcinoma, is recognized by a lectin from the common lentil (*Lens culinaris*). This is designated as AFP-L3 (third electrophoretic form of lentil lectin-reactive AFP). AFP-L3 is most useful in the differential diagnosis of individuals with total serum AFP of 200 ng/mL or below, which may result from a variety of benign pathologies, such as chronic liver diseases.

Alpha-fetoprotein-L3 should be utilized as an adjunct to high-resolution ultrasound for surveillance of individuals at significant risk for developing hepatic lesions.

Reference Values

Total alpha-fetoprotein (AFP):
<4.7 ng/mL

AFP %L3:
<10%

Interpretation

Alpha-fetoprotein (AFP)-L3 results of 10% or above are associated with a 7-fold increased risk of developing hepatocellular carcinoma. Patients with AFP-L3 at this level should be monitored more intensely for evidence of hepatocellular carcinoma according to current practice guidelines.

A total serum AFP above 200 ng/mL is highly suggestive of a diagnosis of hepatocellular carcinoma. In patients with liver disease, a total serum AFP at this level is near 100% predictive of hepatocellular carcinoma. With lower total AFP levels, there is an increased likelihood that chronic liver disease, rather than hepatocellular carcinoma, is responsible for the AFP elevation.

Alpha-fetoprotein concentrations over 100,000 ng/mL have been reported in normal newborns, and the values rapidly decline in the first 6 years of life.

Cautions

Tumor marker tests are not specific for diagnosis of malignancy. Some hepatocellular tumors do not synthesize alpha-fetoprotein (AFP). AFP or AFP-L3 should, therefore, not be relied upon alone. Concomitant clinical assessment or imaging is recommended in hepatocellular carcinoma surveillance of high-risk patients and for hepatocellular carcinoma diagnosis.

Test results for AFP are not interpretable if the individual is pregnant.

Alpha-Fetoprotein and L3% values are not interpretable during pregnancy for the investigation of malignant disease.

Higher AFP values are found in newborns and pregnant women.

Values obtained with different assay methods or kits cannot be used interchangeably. The total AFP test value must be obtained using this method (uTASWako i30 AFP-L3 kit) in order to determine the percent AFP-L3. Mayo Clinic Laboratories other AFP tumor marker test, AFP / Alpha-Fetoprotein (AFP) Tumor Marker, Serum; is not suitable for use with AFP-L3 values.

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. Kawai K, Kojima T, Miyanaga N, et al. Lectin-reactive alpha-fetoprotein as a marker for testicular tumor activity. Int J Urol. 2005;12(3):284-289
2. Noda K, Miyoshi E, Kitada T, et al. The enzymatic basis for the conversion of nonfucosylated to fucosylated

alpha-fetoprotein by acyclic retinoid treatment in human hepatoma cells: Activation of alpha 1-6 fucosyltransferase. Tumour Biol. 2002;23(4):202-211
3. Leerapun A, Suravarapu S, Bida JP, et al. The utility of serum AFP-L3 in the diagnosis of hepatocellular carcinoma: Evaluation in a U.S. referral population. Clin Gastroenterol Hepatol. 2007;5(3):394-402
4. Chaiteerakij R, Addissie BD, Roberts LR. Update on biomarkers of hepatocellular carcinoma. Clin Gastroenterol Hepatol. 2015;13(2):237-245. doi:10.1016/j.cgh.2013.10.038
5. Johnson PJ, Pirrie SJ, Cox TF, et al. The detection of hepatocellular carcinoma using a prospectively developed and validated model based on serological biomarkers. Cancer Epidemiol Biomarkers Prev. 2014;23(1):144-153. doi:10.1158/1055-9965.EPI-13-0870
6. Yang JD, Addissie BD, Mara KC, et al. GALAD score for hepatocellular carcinoma detection in comparison with liver ultrasound and proposal of GALADUS score. Cancer Epidemiol Biomarkers Prev. 2019;28(3):531-538. doi:10.1158/1055-9965.EPI-18-0281
7. Zhou JM, Wang T, Zhang KH. AFP-L3 for the diagnosis of early hepatocellular carcinoma: A meta-analysis. Medicine (Baltimore). 2021;100(43):e27673. doi:10.1097/MD.0000000000027673

Performance

Method Description
Total alpha-fetoprotein (AFP) is measured by laser-induced fluorescence, with separation of the lentil lectin-reactive AFP-L3 and lectin nonreactive forms of AFP by isotachophoresis of their immune-complexes. Results are expressed as the percent ratio of AFP-L3 to total AFP.(Package insert: uTASWako i30 AFP-L3 18.07.18K13. Wako Diagnostics; 07/2018)

PDF Report
No

Day(s) Performed
Monday through Friday

Report Available
1 to 4 days

Specimen Retention Time
14 days

Performing Laboratory Location
Mayo Clinic Laboratories - Rochester Superior Drive

Fees & Codes

Fees

Test Definition: L3AFP

Alpha-Fetoprotein (AFP) L3% and Total, Hepatocellular Carcinoma Tumor Marker, Serum

- 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

82107

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
L3AFP	AFP-L3% and Total AFP, S	96451-0

Result ID	Test Result Name	Result LOINC® Value
TAFP	Total AFP, S	1834-1
L3	%L3	42332-7
INT67	Interpretation	69048-7