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 gender groups who do not have hepatic cirrhosis, but have a confirmed diagnosis of chronic infection by hepatitis B acquired early in life including:
- African males above the age of 20
- Asian males above the age of 40
- Asian females 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: Red top

Acceptable: Serum gel

Submission Container/Tube: Plastic vial

Specimen Volume: 0.5 mL

Forms
If not ordering electronically, complete, print, and send 1 of the following forms with the specimen:

-Oncology Test Request (T729)

-Gastroenterology and Hepatology Client Test Request (T728)
Test Definition: L3AFP
AFP-L3% and Total AFP, S

Specimen Minimum Volume
0.2 mL

Reject Due To

<table>
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<tr>
<th>Condition</th>
<th>Acceptance</th>
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<tbody>
<tr>
<td>Hemolysis</td>
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<tr>
<td>Lipemia</td>
<td>Mild OK; Gross OK</td>
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<tr>
<td>Icterus</td>
<td>NA</td>
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<td>Other</td>
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Specimen Stability Information

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<tr>
<th>Specimen Type</th>
<th>Temperature</th>
<th>Time</th>
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<tbody>
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<td>Serum</td>
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<tr>
<td></td>
<td>Refrigerated</td>
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Clinical and Interpretive

Clinical Information
Worldwide, hepatocellular carcinoma is the third leading cause of death from cancer.(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 might 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.

AFP is differentially glycosylated in several hepatic diseases. For example, UDP-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 that 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 < or =200 ng/mL, which may result from a variety of benign pathologies, such as chronic liver diseases.

AFP-L3 should be utilized as an adjunct to high-resolution ultrasound for surveillance of individuals at significant risk for developing hepatic lesions, as described below.

Reference Values
TOTAL AFP
<4.7 ng/mL

%L3
<10%

**Interpretation**

Alpha-fetoprotein (AFP-L3) > or =10% is associated with a 7-fold increased risk of developing hepatocellular carcinoma. Patients with AFP-L3 > or =10% should be monitored more intensely for evidence of hepatocellular carcinoma according to current practice guidelines.

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

Based on a retrospective study at the Mayo Clinic, for patients with total AFP levels < or =200 ng/mL, AFP-L3 specificity approaches 100% for hepatocellular carcinoma when its percentage exceeds 35% of the total AFP.(4)

AFP 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 patient is pregnant.

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.

Heterophilic antibodies may be present in the serum of some individuals, which may falsely lower or increase the apparent concentration of AFP or AFP-L3.

**Clinical Reference**


5. Package insert: LBA AFP-L3, Wako Diagnostics, Richmond, VA. 06.1.24K02

**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: uTAS Wako i30 AFP-L3, Wako Diagnostics, Richmond, VA)

**PDF Report**
No

**Day(s) and Time(s) Test Performed**
Monday, Wednesday, Friday; 10 a.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 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**
82107

**LOINC® Information**

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