Alpha-Fetoprotein Rapid Test

Cat. No.: DTS557
Pkg. Size:

Intended use

The AFP Rapid Test Device (Whole Blood/Serum/Plasma) is a rapid chromatographic immunoassay for the qualitative detection of AFP in whole blood, serum or plasma to aid in the diagnosis of Hepatocellular Carcinoma or fetal open neural tube defects.

General Description

Alpha-Fetoprotein (AFP) is normally produced during fetal and neonatal development by the liver, yolk sac and in small concentrations by the gastrointestinal tract. By the second year of life, AFP concentrations decrease rapidly, and thereafter only trace amounts are normally detected in serum. In general, normal adults have serum AFP concentrations of less than 10ng/mL. Elevated AFP levels occur in several malignant diseases including hepatocellular carcinoma, testicular nonseminomatous origin, and occasionally of other entodermal origin. AFP has also been used to detect early tumors in people at high risk for liver cancer. Studies of patients with large hepatic metastases or viral hepatitis also indicate slightly elevated or persistent AFP values. In areas where liver cancer is common, the use of AFP tests for screening has resulted in the detection of many tumors at an earlier stage. Detection of elevated AFP levels can also be used in the detection of fetal open neural tube defects. The AFP Alpha-Fetoprotein Rapid Test Device (Whole Blood/Serum/Plasma) utilizes a combination of colloidal gold conjugate and monoclonal antibodies to selectively detect elevated levels of AFP in whole blood, serum or plasma. The test has a cut-off value of 10ng/mL.

Principle Of The Test

The AFP Alpha-Fetoprotein Rapid Test Device (Whole Blood/Serum/Plasma) is a qualitative membrane based immunoassay for the detection of AFP in whole blood, serum or plasma. The membrane is pre-coated with anti-AFP antibodies on the test line region. During testing, the specimen reacts with the particle coated with anti-AFP antibodies. The mixture migrates upward on the membrane chromatographically by capillary action to react with anti-AFP antibodies on the membrane and generate a colored line. The presence of this colored line in the test line region indicates a positive result, while its absence indicates a negative result. To serve as a procedural control, a colored line will always appear in the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

Reagents And Materials Provided

The test device contains AFP monoclonal antibody particles and AFP monoclonal antibody coated on the membrane. Test devices; Droppers; Buffer; Package inser

Materials Required But Not Supplied

Specimen collection containers Lancets (for fingerstick whole blood only)
Centrifuge (for plasma only)
Timer
Disposable capillary tubes and dispensing bulb (for fingerstick whole blood only)

Storage
Store as packaged in the sealed pouch either at room temperature or refrigerated (2-30°C). The test device is stable through the expiration date printed on the sealed pouch. The test device must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

### Specimen Collection And Preparation

The AFP Alpha-Fetoprotein Rapid Test Device (Whole Blood/Serum/Plasma) can be performed using whole blood (from venipuncture or fingerstick), serum or plasma.

To collect Fingerstick Whole Blood specimens: Wash the patient’s hand with soap and warm water or clean with an alcohol swab. Allow to dry. Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger.

Puncture the skin with a sterile lancet. Wipe away the first sign of blood. Gently rub the hand from wrist to palm to finger to form a rounded drop of blood over the puncture site.

Add the Fingerstick Whole Blood specimen to the test device by using a capillary tube: Touch the end of the capillary tube to the blood until filled to approximately 50L. Avoid air bubbles. Place the bulb onto the top end of the capillary tube, then squeeze the bulb to dispense the whole blood to the specimen well (S) of the test device.

Add the Fingerstick Whole Blood specimen to the test device by using hanging drops: Position the patient’s finger so that the drop of blood is just above the specimen well (S) of the test device. Allow 2 hanging drops of fingerstick whole blood to fall into the specimen well (S) of the test device, or move the patient’s finger so that the hanging drop touches the specimen well (S). Avoid touching the finger directly to the specimen well (S).

Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed specimens. Testing should be performed immediately after specimen collection. Do not leave the specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8°C for up to 3 days. For long-term storage, specimens should be kept below -20°C. Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be run within 2 days of collection. Do not freeze whole blood specimens. Whole blood collected by fingerstick should be tested immediately.

Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly. If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiologic agents.

### Assay Procedure

Allow the test device, specimen, buffer, and/or controls to reach room temperature (15-30°C) prior to testing.

Remove the test device from the foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.

Place the test device on a clean and level surface.

For Serum or Plasma specimens: Hold the dropper vertically and transfer 1 drop of serum or plasma (approximately 25uL) to the specimen well (S) of the test device, then add 1 drop of buffer (approximately 40uL) and start the timer. See illustration of Assay Procedure.
For Venipuncture Whole Blood specimens: Hold the dropper vertically and transfer 2 drops of whole blood (approximately 50μL) to the specimen well (S) of the test device, then add 1 drop of buffer (approximately 40μL) and start the timer. See illustration of Assay Procedure.

For Fingerstick Whole Blood specimens: To use a capillary tube: Fill the capillary tube and transfer approximately 50μL of fingerstick whole blood specimen to the specimen well (S) of the test device, then add 1 drop of buffer (approximately 40μL) and start the timer. See illustration of Assay Procedure.

To use hanging drops: Allow 2 hanging drops of fingerstick whole blood specimen (approximately 50μL) to fall into the center of the specimen well (S) on the test device, then add 1 drop of buffer (approximately 40μL) and start the timer. See illustration of Assay Procedure. Wait for the colored line(s) to appear. Read results at 10 minutes. Do not read results after 20 minutes.

**Quality Control**

An internal procedural control is included in the test. A colored line appearing in the control line region (C) is an internal positive procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.
Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

**Interpretation of Results**

(Please refer to the illustration of Assay Procedure image)

**POSITIVE:** Two distinct colored lines appear. One line should be in the control line region (C) and another line should be in the test line region (T).

*NOTE:* The intensity of the color in the test line region (T) will vary depending on the concentration of AFP present in the specimen. Therefore, any shade of color in the test line region (T) should be considered positive.

**NEGATIVE:** One colored line appears in the control line region (C). No apparent colored line appears in the test line region (T).

**INVALID:** Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test device. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

**Sensitivity**

The AFP Alpha-Fetoprotein Rapid Test Device (Whole Blood/Serum/Plasma) has correctly identified a panel of specimens and has been compared to a leading commercial AFP EIA test using clinical specimens. The results show that the relative sensitivity of the AFP Alpha-Fetoprotein Rapid Test Device (Whole Blood/Serum/Plasma) is 99.0%.

**Specificity**

The AFP Rapid Test Device (Whole Blood/Serum/Plasma) has correctly identified a panel of specimens and has been compared to a leading commercial AFP EIA test using clinical specimens. The results show that the relative specificity of the AFP Rapid Test Device (Whole Blood/Serum/Plasma) is 98.7%.

**Accuracy**

Relative Accuracy: 98.8% (97.8%-99.5%)

**Precision**

*Intra-Assay*

Within-run precision has been determined by using 10 replicates of three specimens: a negative, a low positive and a high positive. The negative, low positive and high positive values were correctly identified >99% of the time.

*Inter-Assay*

Between-run precision has been determined by 10 independent assays on the same three specimens: a negative, a low positive and a high positive. Three different lots of the AFP Alpha-Fetoprotein Rapid Test Device (Whole Blood/Serum/Plasma) have been tested using negative, low positive and high positive specimens. The specimens were correctly identified >99% of the time.

**Cross-Reactivity**

Specimens positive for HAMA, Carcinectomy and rheumatoid factor (RF) have been tested. No cross-reactivity was observed, indicating that the AFP Alpha-Fetoprotein Rapid Test Device (Whole Blood/Serum/Plasma) has a high degree of specificity for Alpha-Fetoprotein.

*Interfering Substances*

The AFP Alpha-Fetoprotein Rapid Test Device (Whole Blood/Serum/Plasma) has been tested for possible interference from visibly hemolyzed and lipemic specimens. No interference was observed. In addition, no interference was observed in specimens containing up to 2,000 mg/dL Hemoglobin; up to 1,000 mg/dL Bilirubin; and up to 2,000 mg/dL human serum Albumin.
Precautions

Do not use after expiration date. The test device should remain in the sealed pouch until use. Do not eat, drink or smoke in the area where the specimens or kits are handled. Do not use test if pouch is damaged. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing and follow standard procedures for proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested. Humidity and temperature can adversely affect results.

Limitations

The test should be used for the detection of AFP in whole blood, serum or plasma specimens only. Neither the quantitative value nor the rate of increase in AFP concentration can be determined by this qualitative test. The AFP Rapid Test Device (Whole Blood/Serum/Plasma) will only indicate the presence of AFP in the specimen and should not be used as the sole criteria for the diagnosis of Hepatocellular Carcinoma or fetal open neural tube defects. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician. If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. A negative result does not at any time preclude the possibility of Hepatocellular Carcinoma or fetal open neural tube defects.

Analyte Gene Information

<table>
<thead>
<tr>
<th>Gene Name</th>
<th>AFP alpha-fetoprotein</th>
</tr>
</thead>
<tbody>
<tr>
<td>Official Symbol</td>
<td>AFP</td>
</tr>
<tr>
<td>Synonyms</td>
<td>AFP; alpha-fetoprotein ; alpha-fetoglobulin; alpha-1-fetoprotein; alpha 1 fetoprotein; alpha fetoglobulin; alpha Fetoprotein; Alpha fetoprotein precursor; FETA; HPAFP</td>
</tr>
<tr>
<td>GeneID</td>
<td>174</td>
</tr>
<tr>
<td>mRNA Refseq</td>
<td>NM_001134</td>
</tr>
<tr>
<td>Protein Refseq</td>
<td>NP_001125</td>
</tr>
<tr>
<td>MIM</td>
<td>104150</td>
</tr>
<tr>
<td>UniProt ID</td>
<td>P02771</td>
</tr>
<tr>
<td>Chromosome Location</td>
<td>4q13.3</td>
</tr>
<tr>
<td>Pathway</td>
<td>Direct p53 effectors; FOXA2 and FOXA3 transcription factor networks; Glucocorticoid receptor regulatory network</td>
</tr>
<tr>
<td>Function</td>
<td>metal ion binding</td>
</tr>
</tbody>
</table>

REFERENCES