

AFP Rapid Test Cassette (Whole Blood/Serum/Plasma) Package Insert

A rapid test for the qualitative detection of Alpha-Fetoprotein (AFP) in whole blood, serum or plasma.

For professional in vitro diagnostic use only.

【INTENDED USE】

The AFP Rapid Test Cassette (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.

【SUMMARY】

Alpha-Fetoprotein (AFP) is normally produced during fetal and neonatal development by the liver, yolk sac and in small concentrations by the gastrointestinal tract.¹ By the second year of life, AFP concentrations decrease rapidly, and thereafter only trace amounts are normally detected in serum.² In general, normal adults have serum AFP concentrations of less than 10ng/ml.³ Elevated AFP levels occur in several malignant diseases including hepatocellular carcinoma, testicular nonseminomatous origin, and occasionally of other endodermal origin.⁴ 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.⁵ 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.⁶ Detection of elevated AFP levels can also be used in the detection of fetal open neural tube defects.⁷

The AFP Rapid Test Cassette (Whole Blood/Serum/Plasma) utilizes a combination of anti-AFP antibody coated particles and anti-AFP antibodies to detect elevated levels of AFP in whole blood, serum or plasma. The minimum detection level is 10ng/ml.

【PRINCIPLE】

The AFP Rapid Test Cassette (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】

The test cassette contains anti-AFP antibody coated particles and anti-AFP antibody coated on the membrane.

【PRECAUTIONS】

Please read all the information in this package insert before performing the test.

- For professional in vitro diagnostic use only. Do not use after the expiration date.
- The test cassette should remain in the sealed pouch until use.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The used test should be discarded according to local regulations.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Humidity and temperature can adversely affect results.

【STORAGE AND STABILITY】

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

【SPECIMEN COLLECTION AND PREPARATION】

- The AFP Rapid Test Cassette (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 by using **a capillary tube**:
 - Touch the end of the capillary tube to the blood until filled to approximately 50 μ L. 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 area of the test cassette.
- Add the Fingerstick Whole Blood specimen to the test by using **hanging drops**:
 - Position the patient's finger so that the drop of blood is just above the specimen area of the test cassette.
 - Allow 2 hanging drops of fingerstick whole blood to fall into the center of the specimen area on the test cassette, or move the patient's finger so that the hanging drop touches the center of the specimen area. Avoid touching the finger directly to the specimen area.
- 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 the specimens have been collected. 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.

【MATERIALS】

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| | Materials provided | |
| ● Test Cassettes | ● Droppers ● Buffer | ● Package Insert |
| | Materials required but not provided | |
| ● Specimen collection containers | | ● Centrifuge |
| ● Lancets (for fingerstick whole blood only) | | ● Timer |
| ● Heparinized capillary tubes and dispensing bulb (for fingerstick whole blood only) | | |

【DIRECTIONS FOR USE】

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

1. Bring the pouch to room temperature before opening it. Remove the test cassette from the sealed pouch and use it as soon as possible.
2. Place the cassette on a clean and level surface.

For **Serum or Plasma** specimen:

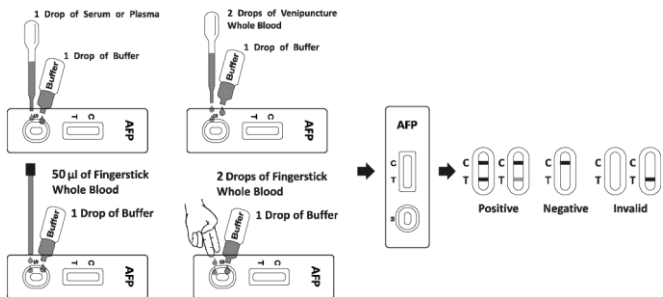
- Hold the dropper vertically and transfer **1 drop of serum or plasma** (approximately 25 μ L) to the specimen well of test Cassette, then add **1 drop of buffer** (approximately 40 μ L) and start the timer. See illustration below.

For **Venipuncture Whole Blood** specimen:

- Hold the dropper vertically and transfer **2 drops of whole blood** (approximately 50 μ L) to the specimen area, then add **1 drop of buffer** (approximately 40 μ L), and start the timer. See illustration below.

For **Fingerstick Whole Blood** specimen:

- To use a capillary tube: Fill the capillary tube and transfer **approximately 50 μ L of fingerstick whole blood specimen** to the specimen area of test cassette, then add **1 drop of buffer (approximately 40 μ L)** and start the timer. See illustration below.
 - To use hanging drops: Allow **2 hanging drops of fingerstick whole blood specimen** (approximately 50 μ L) to fall into the specimen area of test cassette, then add **1 drop of buffer** (approximately 40 μ L) and start the timer. See illustration below.
3. Wait for the colored line(s) to appear. **Read results at 10 minutes.** Do not interpret the result after 20 minutes.



【INTERPRETATION OF RESULTS】

(Please refer to the illustration above)

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

NEGATIVE: **One colored line appears in the control region (C).** No apparent colored line appears in the test 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 cassette. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

【QUALITY CONTROL】

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

【LIMITATIONS】

1. The AFP Rapid Test Cassette (Whole Blood/Serum/Plasma) is for in vitro diagnostic use only. 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.
2. The AFP Rapid Test Cassette (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.
3. The AFP Rapid Test Cassette (Whole Blood/Serum/Plasma) cannot detect less than 10ng/ml of AFP in specimens. A negative result at any time does not preclude the possibility of Hepatocellular Carcinoma or fetal open neural tube defects.
4. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
5. 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.

【EXPECTED VALUES】

The AFP Rapid Test Cassette (Whole Blood/Serum/Plasma) has been compared with a leading commercial AFP EIA test. The correlation between these two systems is over 99.2%.

【PERFORMANCE CHARACTERISTICS】

Sensitivity and Specificity

The AFP Rapid Test Cassette (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 Rapid Test Cassette (Whole Blood/Serum/Plasma) is 99.4%, and the relative specificity is 99.0%.

Method		EIA		Total Results
AFP Rapid Test Cassette	Results	Positive	Negative	
	Positive	317	5	322
	Negative	2	503	505
Total Results		319	508	827

Relative Sensitivity: 99.4% (95%CI*: 97.8%-99.9%)

* Confidence Interval

Relative Specificity: 99.0% (95%CI*: 97.7%-99.7%)

Accuracy: 99.2% (95%CI*: 98.3%-99.7%)

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 Rapid Test Cassette (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 Rapid Test Cassette (Whole Blood/Serum/Plasma) has a high degree of specificity for Alpha-Fetoprotein.

Interfering Substances

The AFP Rapid Test Cassette (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 2,000mg/dl Hemoglobin, 1,000mg/dl Bilirubin, and 2,000mg/dl human serum Albumin.

【BIBLIOGRAPHY】

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