

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

Package Insert

A RAPID TEST FOR THE QUALITATIVE DETECTION OF ALPHA-FETOPROTEIN IN HUMAN SERUM/PLASMA/WHOLE BLOOD.

For Professional In Vitro Diagnostic Use Only.

INTENDED USE

The AFP Rapid Test Cassette is a lateral flow chromatographic immunoassay for qualitative detection of Alpha-Fetoprotein in human serum or plasma. This kit is intended to be used as a screening test and as an aid in the diagnosis of infection with AFP.

Any reactive specimen with the AFP Rapid Test Cassette must be confirmed with alternative testing method(s) and clinical findings.

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. 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 endodermal 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 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 lateral flow chromatographic immunoassay based on the principle of the double antibody-sandwich technique. The test Cassette consists of: 1) a red colored conjugate containing AFP antibodies conjugated with colloid gold (AFP antibody conjugates) and rabbit IgG-gold conjugates, 2) a nitrocellulose membrane strip containing a test band (T band) and a control band (C band). The T band is pre-coated with non-conjugated AFP antibodies, and the C band is pre-coated with goat anti-rabbit IgG.

When an adequate volume of test specimen is dispensed into the sample well of the Cassette, the specimen migrates by capillary action across the Cassette. The antibodies to AFP if present in the specimen will bind to the AFP conjugates. The immune complex is then captured on the membrane by the pre-coated AFP antibodies, forming a burgundy colored T band, indicating a positive test result.

Absence of the T band suggests a negative result. The test contains an internal control (C band) which should exhibit a burgundy colored band of the immune complex of goat anti-rabbit IgG/rabbit IgG-gold conjugate regardless of the presence of any antibodies to AFP. Otherwise, the test result is invalid and the specimen must be retested with another Cassette.

REAGENTS

The test contains AFP antibodies pre-coated on the surface of the membrane. And AFP antibody conjugated colloid gold.

PRECAUTIONS

- For professional in vitro diagnostic use only. Do not use after expiration date.
- The test must 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 if pouch is damaged.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow the 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.
- The used test should be discarded according to local regulations.

STORAGE AND STABILITY

Store as packaged in the sealed pouch either at room temperature or refrigerated (2-30°C). The test is stable through the expiration date printed on the sealed pouch. 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 (Serum/Plasma/Whole Blood) can be performed using whole blood (from venipuncture or fingerstick), serum or plasma.
- To collect **Finger stick 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.
 - Touch the end of the dropper to the blood until filled to approximately 75µL. Avoid air bubbles.
 - Place the bulb onto the top end of the dropper, then squeeze the bulb to dispense the whole blood to the specimen area of the test Cassette.
- 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.

MATERIALS

Materials provided			
• Test Cassette	• Dropper	• Buffer	• Package Insert
Materials required but not provided			
• Specimen collection containers	• Timer		
• Lancets (for fingerstick whole blood only)	• Centrifuge		

DIRECTIONS FOR USE

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

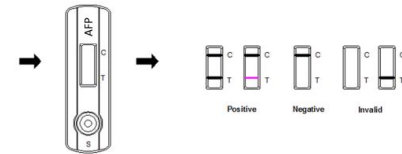
- Bring the pouch to room temperature before opening it. Remove the test cassette from the sealed pouch and use it as soon as possible. Best results will be obtained if the test is performed immediately after opening the foil pouch.
- Place the test cassette on a clean and level surface.

For **Serum or Plasma** specimens: Hold the dropper vertically and transfer 2 drops of serum or plasma (approximately 50µL) to the specimen well (S) of the test cassette, then add 1 drop of buffer (approximately 40µL), and start the timer. See illustration below.

For **Venipuncture Whole Blood** specimens: Hold the dropper vertically and transfer 3 drops of venipuncture whole blood (approximately 75µL) to the specimen well (S) of the test cassette, then add 1 drop of buffer (approximately 40µL), and start the timer. See illustration below.

For **Finger stick Whole Blood** specimens: To use a dropper: Hold the dropper vertically and transfer 3 drops of Finger stick Whole Blood (approximately 75µL)

- to the specimen well (S) of the test cassette, then add 1 drop of buffer (approximately 40µL), and start the timer. See illustration below.
- Wait for the colored line(s) to appear. **Read results at 15 minutes.** Do not interpret results after 20 minutes.



INTERPRETATION OF RESULTS

(Please refer to the illustration above)

POSITIVE: **Two lines appear.** One colored line should always appear in the control line region (C) and another one apparent colored 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 regions should be considered positive.

NEGATIVE: **One colored line appears in the control line region (C).** No apparent colored lines appear in any of the test line region (T). This indicates that the concentration of AFP are below the minimum detection levels.

INVALID: **Control line (C) 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. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

QUALITY CONTROL

An internal procedural control is included in the test. A colored line appearing in the control line region (C) is an internal 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.

LIMITATIONS

- The Assay Procedure and the Test Result Interpretation must be followed closely when testing the presence of antibodies to AFP in serum/plasma/whole blood from individual subjects. Failure to follow the procedure may give inaccurate results.
- The AFP Rapid Test Cassette is limited to the qualitative detection of the antibodies to AFP in human serum/plasma/whole blood. The intensity of the test band does not linearly correlate with the antibody titer in the specimen.
- A negative result for an individual subject indicates absence of detectable AFP. However, a negative test result does not preclude the possibility of exposure to or infection with AFP.
- A negative result can occur if the quantity of the AFP antigens present in the specimen is below the detection limits of the assay, or the antigens that are detected are not present during the stage of disease in which a sample is collected.
- Some specimens containing unusually high titer of heterophile antibodies or rheumatoid factor may affect expected results.
- The results obtained with this test should only be interpreted in conjunction with other diagnostic procedures and clinical findings.

PERFORMANCE CHARACTERISTICS

Clinical Sensitivity, Specificity

The AFP Rapid Test Cassette (Serum/Plasma/Whole Blood) has been evaluated with a leading commercial AFP EIA test using clinical specimens. The results show that relative to leading EIA tests, the AFP Rapid Test Cassette (Serum/Plasma/Whole Blood) exhibits 99.5% sensitivity and 99.97% specificity .

AFP Test vs. EIA				
Method		EIA		Total
AFP Test	Results	Positive	Negative	Results
	Positive	199	1	200
	Negative	1	399	400
Total Results		200	400	600

Relative Sensitivity: 99.5% (95%CI*: 96.94%~99.99%)*
Relative Specificity: 99.97% (95%CI*: 98.45%~99.99%)*
Accuracy: 99.67% (95%CI*: 98.71%~99.99%)*
*Confidence Interval

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(Serum/Plasma/Whole blood) have been tested over a 3-day period using negative,low positive,and high positive specimens.The specimens were correctly identified >99% of the time.

Cross-reactivity

The AFP Rapid Test Cassette(Serum/Plasma/Whole blood) has been tested with specimens positive for HAMA, Carcinectomy and Rheumatoid factor (RF). No cross-reactivity was observed, indicating that the performance of the AFP Rapid Test (Whole Blood/Serum/Plasma) is stable in presence of these factors.

Interfering Substances

The AFP Rapid Test Cassette(Serum/Plasma/Whole blood) has been tested for possible interference from visibly hemolyzed and lipemic specimens, as well as serum specimens containing high bilirubin levels. Results indicate that no interference was observed in specimens containing 2,000mg/dl Hemoglobin, 1,000mg/dl Bilirubin, and 2,000mg/dl human serum Albumin.

BIBLIOGRAPHY

1. Gitlin D, Pericelli A, Gitlin GM. Synthesis of a-Fetoprotein by Liver, Yolk Sac, and Gastrointestinal Tact of the Human Conceptus. Cancer Res. 32: 979, 1972.
2. Gitlin D. Normal biology of a-fetoprotein. Ann N Y Acad Sci. 259:7-16, 1975.
3. Davids, Jacobs, et al. Laboratory test handbook, Lexi-Comp Inc, 1996, 4th Edition: 73.
4. Abelev GI. Alpha-fetoprotein in ontogenesis and its association with malignant tumors. Adv. Cancer Res. 14: 295-358,1971.
5. Ding-Shinn C, Juei-Low S. Serum Alphafetoprotein in Hepatocellular Carcinoma. Cancer. 40(2):779-783, 1977.
6. Nasser J. The Role of Biologic Tumor Markers in Testicular Cancer. Cancer. 45(7):1755-1761,1980.
7. Bock J. Current Issues in Maternal Serum Alpha-Fetoprotein Screening. Clinical Chemistry. 97(4)541-554, 1992.

SYMBOLS

Symbol	Meaning	Symbol	Meaning
	In vitro diagnostic medical device		Storage temperature limit
	Manufacturer		Authorized representative in the European Community
	Date of Manufacture		Use by date

	Do not reuse		Consult instruction for use
	Batch code		Meet the requirements of EC Directive 98/79/EC

Number: AFP-W611
Version: 1.0
Effective Date: 2025-10-17