One Step Alpha-Fetoprotein (AFP) Serum/Plasma Test Cassette

Cat. No.: AFP512

1. INTENDED USE

One-Step human alpha-fetoprotein (AFP) Test is a rapid and convenient immunochromatographic assay for the qualitative detection of human AFP in serum or plasma samples at or above the cutoff level of 25 ng/ml. It is intended for professional use as an aid in the diagnosis of primary hepatocellular carcinomas, testicular teratocarcinomas, and neural tube defects (NTD). This assay provides only a preliminary result. Clinical expertise and professional judgment should be sought to further evaluate the results of the test.

2. SUMMARY AND PRINCIPLE OF THE ASSAY

Alfa-fetoprotein (AFP) is a major protein in fetal circulation during early life. It is mainly synthesized and secreted from the liver and yolk sac. It is a glycoprotein with a molecular weight between 65,000 and 70,000 and contains 4% carbohydrate. Serum AFP has been shown to increase in various disease states, including hepatic primary and metastatic tumors, germ cell tumors, hepatitis, and cirrhosis. AFP is also found at an elevated level in amniotic fluid and maternal serum in the case of neural tube defects (25ng/ml).

One Step AFP test device is an antigen-capture immunochromatographic assay, detecting the presence of AFP in blood samples. Monoclonal antibodies specifically against AFP are 1) conjugated with colloidal gold and deposited on the conjugate pad and 2) immobilized on the Test Zone on the nitrocellulose membrane. When adequate volumes of the test sample is added the antibody conjugate is rehydrated and the AFP, if any in the samples, will interact with the colloidal gold conjugated antibodies. The antigen-antibody-colloidal gold complex will migrate towards the test window until the Test Zone (T) where they are captured by immobilized antibodies, forming a visible pink line (Test line), indicating a positive result. If AFP is absent in the sample, no pink line will appear in the Test Zone (T), indicating a negative result.

To serve as an internal process control, a control line should always appear at Control Zone (C) after the test is completed. Absence of a pink control line in the Control Zone is an indication of an invalid result.

3. PACKAGE CONTENTS

1) Pouch contents: Test Cassette, Sample dropper, Desiccant.
2) Sample buffer (3ml) per bottle for 25 tests
3) Test instruction.

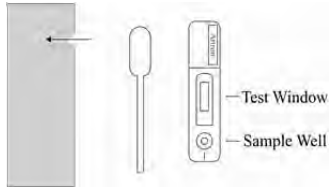
4. WARNINGS AND PRECAUTIONS

1) For professional in vitro diagnostic use only.
2) Do not reuse.
3) Do not use if the pouch seal or its packaging is compromised.
4) Do not use after the expiration date shown on the pouch.
5) Do not mix and interchange different specimens.
6) Wear protective clothing such as laboratory coats, disposable gloves and eye protection while handling potentially infectious materials and performing the assay.
7) Wash hands thoroughly after finishing the tests.
8) Do not eat, drink or smoke in the area where the specimens or kits are handled.
9) Clean up spills thoroughly with appropriate disinfectants.
10) Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing procedures.
11) Dispose of all specimens and used devices in a proper bio-hazard container. The handling and disposal of the hazardous materials should follow local, national or regional regulations.
12) Keep out of children's reach.

5. SPECIMEN PREPARATION

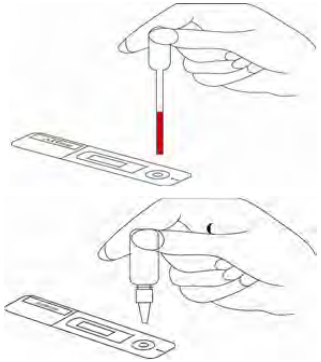
1) For serum samples, collect blood in a tube without anticoagulant and allow it to clot.
2) For plasma samples, collect blood in a tube containing anticoagulant.
3) Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed specimens.
4) Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods.
5) The blood may be stored at 2^{o}C to 8^{o}C for up to three days if the tests cannot be performed immediately. Ensure that the blood samples should be allowed to attain room temperature prior to use.

6. TEST PROCEDURE



1) Remove the testing device from the sealed pouch by tearing at the notch and place the testing device on a leveled surface.
2) Hold the sample dropper vertically. Add 1 drop (40 μl) of specimen without air bubbles into the

Sample Well that is marked with an arrow on the testing device;



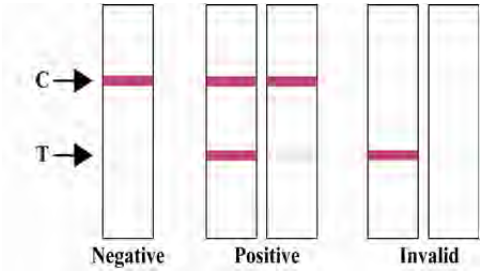
3) Immediately add 2 drops (80μl) of the assay buffer to the same Sample Well of the testing device.

4) Read the results in 10 minutes. Read results as shown under interpretation of Results.

NOTE: Specimens with high concentrations of AFP may produce positive results in as little as 1 minute. Confirm negatives in 20 minutes.

5) Do not read results after 30 minutes.

7. RESULT INTERPRETATIONS



Negative

A pink colored band appears only at the control region (C), indicating a negative result for AFP.

Positive

A clear pink control band (C) and a detectable test band (T) appear, indicating a positive result for AFP.

Invalid

No visible band at the control region (C). Repeat with a new test device. If the test still fails, please contact the distributor with the lot number

8. QUALITY CONTROL

Although the testing device contains an internal quality control (pink colored band in the control region), good laboratory practice recommends the daily use of an outside control to ensure proper testing device performance. Quality control samples should be tested according to the standard quality control requirements established by your laboratory.

9. STORAGE AND STABILITY

1) Test device in the sealed pouch can be stored at 2-30^{o}C up to the expiration date. Do not freeze the test device.

2) The bottle containing the buffer should be stored at 2-30^{o}C.

3) The test device should be kept away from direct sunlight, moisture and heat.

10. LIMITATIONS

1) This product is an in vitro diagnostic test designed for professional use only.

2) Humidity and temperature can adversely affect results.

3) The instructions for the use of the test should be followed during testing procedures.

4) There is always a possibility that false results will occur due to the presence of interfering substances in the specimen or factors beyond the control of the manufacturer, such as technical or procedural errors associated with the testing.

6) Although the test demonstrates superior accuracy in detecting AFP infections, a low incidence of false results can occur. Therefore, other clinically available tests are required in case of questionable results. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

MANUFACTURER

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Revision: 20181204BJ