AFP Rapid test cassette

Catalog No.: BGW1102C

INTRODUCTION

Rapid AFP Test is an immunochromatography based one step in vitro test. It is designed for the rapid qualitative determination of AFP in serum or plasma specimens to aid in the diagnosis of Hepatocellular Carcinoma or fetal open neural tube defects.

SUMMARY

AFP (Alpha-Fetoprotein) is normally produced during fetal and neonatal development by the liver, yolk sac and in small concentrations by the gastrointestinal tract. [4] By the second year of life, AFP concentrations decrease rapidly and thereafter only trace amounts are normally detected in serum. [5] Normal adults have serum AFP concentrations of less than 10ng/ml. [6] Elevated AFP levels occur in several malignant diseases including hepatocellular carcinoma, testicular nonseminomatous origin, and occasionally of other entodermal origin. [7] 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. [8] In areas where liver cancer is common, the use of AFP test for screening has resulted in the detection of many tumors at an earlier stage. [9] Detection of elevated AFP levels can also be used in the detection of fetal open neural tube defects. [10] This test utilizes a combination of colloidal gold conjugate and monoclonal antibodies to selectively detect elevated levels of AFP in serum or plasma. The test has a cut-off value of 20ng/ml.

PRINCIPLE OF THE ASSAY

Rapid AFP test is a sandwich immunoassay. When serum sample is added to sample pad, it moves through the conjugate pad and mobilizes gold-mice monoclonal anti-AFP antibody conjugate. that is coated on the conjugate pad. The mixture moves along the membrane by capillary action and reacts with mice monoclonal anti-AFP antibody that is coated on the test region. If AFP is present, the result is the formation of a colored band in the test region. The gold conjugate will continue to migrate until is captured in the control region by immobilized goat anti-mouse IgG antibody and aggregating in a red line, which indicates the validity of the test .

Test Procedure

1. Bring all materials and specimens to room temperature.
2. Remove test from the sealed foil pouch.
3. Place the test kit on a flat dry sripurface.
4. Using the provided plastic dropper, dispense 30µl of serum sample (1 drops)and 1 drop of solution to the sample well of the test card. Start timing.
5. Read result at 10 minutes after adding the sample.

Note: Results after 20 minutes may not be accurate.

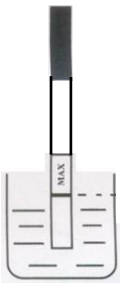
INTERPRETATION OF RESULTS

Positive:If two colored bands are visible within 10 minutes, the test result is positive and valid.

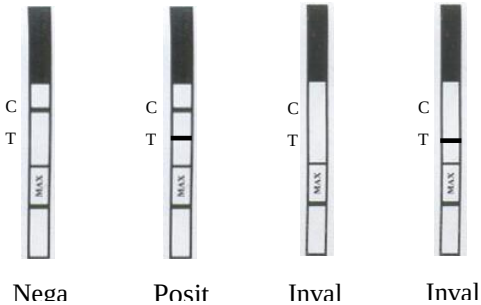
Negative:If test area has no color band and the control area displays a colored band, the result is negative and valid.

Invalid result:The test result is invalid if a colored band does not form in the control region. The sample must be re-tested, using a new test device.

Strip：



Marker



Nega Posit Inval Inval

Cassette:

Negative Positive Invalid

STORAGE AND STABILITY

The test kit can be stored at room temperature (4 to 30℃) in the sealed pouch to the date of expiration. The test kit should be kept away from direct sunlight, moisture and heat.