INTRODUCTION

Alpha-Fetoprotein (AFP) is normally produced during foetal 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. Elevated AFP levels occur in several malignant diseases including hepatocellular carcinoma, testicular non-seminomatous origin, and occasionally of other entodermal origin. AFP has also been used to detect early tumours 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 tumours at an earlier stage. Detection of elevated AFP levels can also be used in the detection of foetal open neural tube defects.

INTENDED USE

The ulti med AFP Test is a highly sensitive immunoassay for rapid qualitative determination of human AFP in plasma, serum or whole blood. It is intended as an aid in monitoring patients for disease progress or response to therapy or for the detection of recurrent or residual disease. The sensitivity of the test is 25 ng/ml.

MATERIALS PROVIDED

25 AFP test cassettes
25 disposable sample droppers
Buffer (1 per kit box)
Instructions (1 per kit box)

MATERIALS REQUIRED, BUT NOT PROVIDED

Stop watch
Lancets
Alcohol pads

PRECAUTIONS

The ulti med AFP test kit must be stored at 4-30°C. The test device is sensitive to humidity as well as to heat. Perform the test immediately after removing the test device from the foil pouch. Do not use it beyond the expiration date.

PROCEDURE OF THE TEST

1. Remove the test cassette from the foil pouch, and place it on a flat, dry and clean surface. 
Note: Once the test cassette is removed from the pouch, it should be used as soon as possible.
2. Clean the second or third finger by rubbing it with an alcohol pad.
3. Collect blood from the patient's finger. Massage near the puncture site to obtain blood flow.
4. Add 150 μl of blood (6 drops) into the Sample Well (S). Before adding the next drop, the previous one should be fully absorbed. Then, add one drops of buffer into the Sample Well (S).
5. As the test begins to work, you will see a purple coloured front move across the Result Window in the centre of the test cassette.
6. Interpret test results at 10 minutes. Do not interpret test results after more than 15 minutes.

Caution: The above interpretation time is based on reading the test results at room temperature of 15 to 30°C. If your room temperature is significantly lower than 15°C, the interpretation time should be properly increased.

INTERPRETATION OF THE TEST

- A coloured line will appear in the section of the Result Window marked with “C” to show that the test is working properly. This is the Control Line.
- The section of the Result Window marked with “T” indicates the test results. If another coloured line appears in this section, it is the Test Line.
Positive Result: The presence of two coloured lines ("T" and "C") in the result window regardless of which line appears first indicates a positive result (Figure 1).

Note: Generally, the higher the AFP level in the specimen, the darker the "T" line colour will be. When the AFP level is close to but still within the sensitivity limit of the test, the colour of the "T" line will be very faint.

Negative Result: The presence of only one purple coloured line ("C"), in the Result Window, indicates a negative result (Figure 2).

Invalid Result: If after performing the test, no coloured line or only a "T"-line is visible in the Result Window, the result is considered invalid. Some causes of invalid results are not following the directions correctly or usage of an expired test (Figure 3 and 4).

Note: A positive result will not change once it has been established at 15 minutes. However, in order to prevent any incorrect results, the test result should not be interpreted after more than 15 minutes. When interpreting test results after more than 15 minutes, the sensitivity of the test will be higher than 25 ng/ml. Some specimens with a high rheumatoid factor concentration may yield a non-specific positive result.

LIMITATIONS OF THE TEST
Although the ulti med AFP Test is very accurate in detecting AFP, a low incidence of false results can occur. Other clinically available tests are required if questionable results are obtained. 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.

WARNINGS
- The same lancet needle should be used for one person only and must not be shared with another person, because used needles are a biohazard.
- Do not use test if pouch is torn or damaged.
- Do not use the kit after the expiration date.
- Do not use in vitro diagnostic use only.

REFERENCES