The Finecare™ AFP Rapid Quantitative Test along with Finecare™ FIA Meter uses a fluorescence immunoassay technology. The Finecare™ AFP Rapid Quantitative Test uses a sandwich immunodetection method, when sample is added to the sample well of the test cartridge, the fluorescence-labeled detector AFP antibody binds to AFP antigen in blood specimen. As the sample mixture migrates on the nitrocellulose matrix of test strip by capillary action, the complexes of detector antibody and AFP are captured to AFP antibody that has been immobilized on test strip. Thus the more AFP antigen is in blood specimen, the more complexes are accumulated on test strip. Signal intensity of fluorescence of detector antibody reflects amount of AFP captured and Finecare™ FIA Meter shows AFP concentrations in blood specimen. The default results unit of Finecare™ AFP Rapid Quantitative Test is displayed as XXXng/mL, from Finecare™ FIA Meter. The working range and the detection limit of the AFP Test system are 5 – 400ng/mL and 5ng/mL.

**PRECAUTIONS**

1. Serum is only applicable for the test kit. Do not repeat using test kit, do not use test kit beyond the expiration date.
2. Appropriate protective measures should be applied during the process of collection, disposal, storage and sample mixing.
3. Do not mix components (buffer, ID chip and test cartridge) from different kit lots.
4. The test can be performed with serum only.
5. Do not use the test cartridge if the pouch is punctured or not well sealed.
6. Test Cartridge should be used within 1 hour after opening the pack.

**STORAGE AND STABILITY**

1. Store the detector buffer at 4 ~ 8°C. The buffer is stable up to 24 months.
2. Store Finecare™ AFP Rapid Quantitative Test Cartridge at 4 ~ 30°C, shelf life is up to 24 months.
3. Test Cartridge should be used within 1 hour after opening the pack.

**SPECIMEN COLLECTION AND PREPARATION**

The test can be performed with serum only. For serum:

Separate the serum from blood as soon as possible to avoid hemolysis. The test should be performed immediately after the specimen has been collected. Do not leave the specimens at room temperature for prolonged periods. Specimens may be stored at 2 ~ 8°C for up to 3 days. For long-term storage, specimens should be kept below -20°C.

**TEST PROCEDURE**

Refer to Finecare™ FIA Meter Operation Manual for the complete instructions on use of the Test. The test should be operated in room temperature.

1. Prepare:
2. Finecare™ multi-channel FIA meter: Insert the Test Cartridge onto the Test Cartridge Holder and click "Test". The result will show in the display and print out when click "Print". Quick test: Check/insert ID Chip into the equipment. Take one tube of Buffer from refrigerator and balance it at room temperature for a couple of minutes.
3. Sampling:
   - Draw 75μL of serum with a transfer pipette and add it to the buffer tube.
   - Mix well the specimen with buffer 1 minute by tapping or inverting the tube.
4. Loading: Take 75μL of sample mixture and load it onto the sample well of the Test Cartridge.
5. Timing: Please refer to the Operation manual user of Finecare™ FIA Meter for details.

**QUALITY CONTROL**

Each Finecare™ AFP Rapid Quantitative Test Cartridge contains internal control that satisfies ruling quality control requirements. This internal control is performed each time a patient sample is tested. This control indicates that the Finecare™ AFP Rapid Quantitative Test Cartridge was inserted and read properly by Finecare™ FIA Meter. An invalid result from the internal control causes an error message on Finecare™ FIA Meter.
indicating that the test should be repeated.

LIMITATIONS OF PROCEDURE

1. This test has been developed for testing human serum only. The results of Finecare™ AFP Rapid Quantitative Test should be evaluated with all clinical and laboratory data available. If AFP test results do not agree with the clinical evaluation, additional tests should be performed.

2. The false positive results may come from cross-reactions with some similar antibodies in blood, and similar epitopes from non-specific components in blood capturing fluorescent labeled antibodies.

3. The false negative results may come from some unknown substance blocking epitope, adhering antibodies, unstable or degenerated AFP that cannot be identified due to prolonged time and temperature and storage condition of sample and reagent.

4. Other factors may interfere with Finecare™ AFP Rapid Quantitative Test and may cause erroneous results. These include technical or procedural errors, as well as additional substances in blood specimens.

BIBLIOGRAPHY OF SUGGESTED READING


