Finecare™ AFP (Alpha Fetal Protein) Rapid Quantitative Test

Catalog No. W208

INTENDED USE

The Finecare™ AFP (Alpha Fetal Protein) Rapid Quantitative Test along with Finecare™ FIA Meter is intended for vitro quantitative determination of AFP in human blood.
-Fluorescence immunoassay
-Early auxiliary diagnosisandevaluation of therapeutic efficiency for primary hepatic carcinoma

For in vitro diagnostic use only. For professional use only.

SUMMARY

AFP (Alpha - Fetal Protein) is glycoproteins of albumin family; AFP is synthesized by the yolk sac of fetus in the 4th ~ 8th weeks of pregnancy, when yolk sac degenerate in 11.5th weeks, AFP is mainly release byliverand gastrointestinal.
AFP was found by Bergstrand and Czar in fetal serum in 1956; Abelev found that the main sources of AFP is the yolk sac and the placenta; Tatarinov found that the high concentrations of AFP from patients with primary liver cancer in 1964.
AFP is a serological marker of primary hepatic carcinoma (PHC), which always be used in the auxiliary diagnosis and curative effect evaluation; researches also confirmed that the fetus congenital spina bifida, neural tube defects and Down's syndrome, etc. The AFP levels will change because by these diseases, AFP monitoring can be used for the screening and diagnosis of the disease during pregnancy.

Reference range: <20ng/mL
Notice: Individual reference range is suggested to be established for each laboratory.

PRINCIPLE

The Finecare™ AFP Rapid Quantitative Test is based on 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 this 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. Their lot numbers must match each other.
4. The Finecare™ AFP Rapid Quantitative Test kit is only operational in the Finecare™ FIA Meter.
5. Do not use the test Cartridge if the pouch is punctured or not well sealed.
6. Test cartridge contaminated by blood or other liquid must not be inserted into FIA meter, or the meter might be contaminated or damage. Please appropriate dispose used test cartridge.
7. High working temperature should be avoided, buffer stored in low temperature should be recovered to room temperature for a couple of minutes
8. The Test Cartridge and Meter should be used away from vibration and magnetic field. During normal usage, the Meter itself may cause vibration, which should be regarded as normal. Please do not pull out ID chip during testing.
9. Use of fresh blood specimen is recommended, please do not use sample with obvious appearance of hemolysis or blood clot , which might interfere test causing wrong result.
10. The results should be interpreted by the physician along with clinical findings and other laboratory test results.
11. If there is any problem or suggestion please contact manufacture.

MATERIAL

Material Provided

Test Cartridge	25
Test Cartridge ID Chip	1
Detector buffer	25

Leaflet with instructions for use

Material Required But Not Provided

1. Finecare™ FIA Meter
2. Transfer Pipette Set (10μL , 100μL size)
3. Specimen Collection Containers
4. Alcohol Pads
5. Centrifuge
6. Timer

STORAGE AND STABILITY

1. Store the detector buffer at 4～30℃. The buffer is stable up to 24 months.
2. Store Finecare™ AFP Rapid Quantitative Test Cartridge at 4～30℃, 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.
Test should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. Specimens may be stored at 2℃～8℃ for up to 3 days. For long-term storage, specimens should be kept below -20℃.

TEST PROCEDURE

Refer to Finecare™ FIA Meter Operation Manual for the complete instructions on use of the Test. The test should be operatedin room temperature.
Step1: Preparation
Check/insert ID Chip into the equipment.
Take out one tube of Buffer from refrigerator and balance it at room temperature for a couple of minutes
Step2: Sampling
Draw 75μL of serum with a transfer pipette and add it to the buffer tube.
Step3: Mixing
Mix well the specimen with buffer for 1minute by tapping or inverting the tube.
Step4: Loading
Take 75μL of sample mixture and load it onto the sample well of the Test Cartridge.
Step5: Testing
1. Finecare™ FIA meter:
Standard test: Insert the Test Cartridge onto the Test Cartridge Holder and click “Test”. 15 minutes later, the result will show in the display and print out when click “Print”.
Quick test: Put the Test Cartridge on the operation platform. 15 minutes later, 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”.
2. Finecare™ multi-channel FIA meter:
Insert the Test Cartridge onto the Test Cartridge Holder. 15 minutes later, the result will show in the display and print out when click “Print”.

Please refer to the **Operationin** user manual of Finecare™ FIA Meter for details.

QUALITY CONTROL

Each Finecare™ AFP Rapid Quantitative Test Cartridge contains internal control that satisfies routing quality control requirements. This internal control is performed each time a patient sample is tested. This control indicates that the 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 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.

PERFORMANCE CHARACTERISTICS

Accuracy

Test cartridges from same batch were tested with AFP control of 20ng/ml, 50ng/ml and 200ng/ml, mean and Bias% were calculated, Bias% was within 15%.

Linearity

A serial concentration of AFP controls at 10ng/ml, 20ng/ml, 50ng/ml, 100ng/ml, 200ng/ml, 300ng/ml, 400ng/ml were tested, the Correlation Coefficient (R) is ≥ 0.99

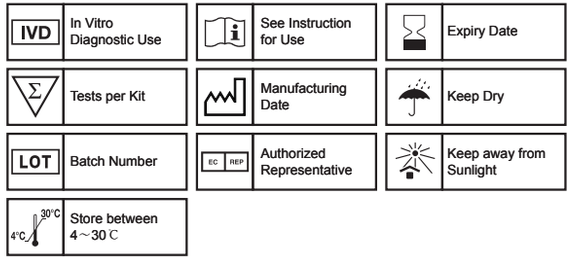
Precision

Intra-Run
Within-run precision has been determined by using 10 replicates from same batch to test with 20ng/ml AFP control. C.V. is ≤ 15%.

Inter-Run
Between-run precision has been determined by using 3 replicates from random 3 continuous batches to test with 20ng/ml AFP control. C.V. is ≤ 15%.

BIBLIOGRAPHY OF SUGGESTED READING

1. Tartarinov, Y.S. Detection of embryo specific alpha-globulin in the blood sera of patients with primary liver tumor. Vopr. Med. Khim. 10:90-91(1964).
2. Mcintire, K.R., Waidmann, T.A., Moertel, C.G and Go, V.L.W. Serum alpha-fetoprotein(AFP) in patients with neoplasms of the gastrointestinal tract. Cancer Res. 35:991-996(1975).
3. Javadpouf, N.,Mcintire, K.R. and Waidmann, T.A. Human choronic gonadotropin (HCG) and alpha-fetoprotein(AFP) in sera and tumor cells of patients with testicular seminoma. Cancer 42:2768-2772.(1978).
4. Chen, D.S. and Sung, J.L. Relationship of Hepatitis B Surface Antigen to serum alpha-fetoprotein in nonmalignant diseases of the lever. Cancer 44:984-992 (1979).
5. Rhoslati, E and Seppala, M. studies of carcinofetal proteins: Physical and Chemical Properties of Human alpha-fetoprotein. Int. J. Cancer 7:218-225(1971).
6. Abelev, GI. Alpha-fetoprotein in oncogenesis and its association with malignant tumor. Adv. Cancer Res. 7:295-358(1971).
7. Wespic, H.C. Alpha-fetoprotein: its quantification and relationship to neoplastic disease, ppp 115-129 In Alpha-fetoprotein, Laboratory Procedures and Clinical Applications, Kirkpatirck, A. and Nakamuram R (eds.), Masson Publishing, New York(1981) After Radical Prostatectomy. J. Urol. 142:1082-90(1989).



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