AFP Rapid Quantitative Test

Catalog No.BT2402

INTENDED USE

The Biotime AFP Rapid Quantitative Test is intended to quantify the concentration of AFP in human serum, plasma on Biotime FIA Analyzer by fluorescent immunoassay. The test is used as an aid detection of liver cancer.
-Fluorescence immunoassay
- Liver cancer
For in vitro diagnostic use only. For professional use only.

INTRODUCTION

AFP Rapid Quantitative Test is used to detect the concentration of AFP) (alpha fetoprotein) in human serum and plasma. Alpha fetoprotein is a kind of glycoprotein with relative molecular mass of about 68kDa, which consists of 590 amino acid residues. The half-life period of AFP is 5 days. In normal physiological conditions, the level of AFP is rarely low in human (<20ug/L). The concentration of AFP is high under embryonic period and it can be released into pregnant woman blood through umbilical cord. Thus, APF can be used as a marker for embryonic development. AFP is associated with primary liver cancer, stomach neoplasm, lung cancer and so on. This study suggests that AFP is regarded as a valuable marker for liver cancer [1-2].

PRINCIPLE

This test kit is based on fluorescent lateral flow immunoassay. While the sample and the buffer are mixed and applied into the test cartridge, the AFP in the sample and the mouse anti-AFP monoclonal antibody labeled with fluorescent microsphere form a reaction intermediate complex. During lateral flow, the intermediate complex moves along with the nitrocellulose membrane to a detection line (T-line: coated with AFP specific monoclonal antibodies). The intermediate complex will be captured by T-line to form final reaction compound sandwich. Thus the fluorescent signal on detection line is positively correlated with the concentration of AFP in human serum or plasma.
The fluorescent signal from microspheres of compound sandwich will be detected and calculated according to the calibration curve (in SD card provided with the reagents) to represent the concentration of AFP in human serum or plasma.

PRECAUTIONS

1. This reagent is used for in vitro diagnosis only, please do not use expired products.
2. All blood samples (including the remaining samples after testing), used reagents and waste should be treated as infectious materials.
3. The reagent is for one-time use. Once the pouch is opened, it should be used within 30 minutes to avoid failure caused by the moisture absorption.
4. While using the test cartridge and instruments, vibration and electromagnetic environment should be avoided.
5. Lot number of buffers and test cartridges must be matched.
6. Do not insert the cartridges that are contaminated with blood or other liquids on the surface. It may cause damages to the instrument.

MATERIAL

Material Provided

1. Test cartridge 25 tests/kit
2. Detection buffer 25 tubes/kit
3. SD Card 1 piece/kit
4. Instructions for use 1 copy/kit

Material Required But Not Provided

1. Biotime FIA Analyzer
2. Transfer Pipette Set (range 5~50μL and 10~100μL size)
3. Specimen collection containers
4. Timer

STORAGE AND STABILITY

1. Store the detection buffer at 2-8℃, the shelf life is 24 months.
2. Store the test cartridge at 2-30℃, the shelf life is 24 months.
3. Test Cartridge should be used within 30 minutes after opening the pouch.

SPECIMEN COLLECTION AND PREPARATION

1. The test can be performed with human plasma or serum specimen.
2. The specimen collection container shall be EDTA-K_2 tube for plasma and immune tube or pro-coagulant tube for serum.
3. The collection of the sample: the venipuncture for blood collection method referring to the National Clinical Laboratory Procedures, if the sample can't be detected in time, it can be stored in refrigerator at 2-8℃ for 7 days, or at -20℃ for 6months. Samples must be recovered to the room temperature before test.
4. Separate the serum or plasma from blood as soon as possible to avoid hemolysis.

TEST PROCEDURE

Please refer to the operational manual of Biotime FIA analyzers for details. The test should be operated at room temperature (~25℃).

Step 1: Preparation

Check/insert SD card into the equipment.
Take out one tube of buffer from refrigerator and balance it to room temperature.

Step 2: Sampling

Take 20μL of serum or plasma with a transfer pipette and add it to the buffer tube.

Step 3: Mixing

Mix well the specimen with buffer by tapping or inverting the tube.

Step 4: Loading

Take 80μL of sample mixture and load it into the well of the test cartridge.
Note: Step 2 to step 4 should be completed within 1 minute to ensure the accuracy of the test results.

Step 5: Testing

Standard test: Click "Test", and then choose "Standard Test". Immediately insert test cartridge into test cartridge inlet and click "Start Test", the cartridge will be in the process of chromatography for 150s. After chromatography, the analyzer will count down time automatically. When the test is finished, the test result will be showed on screen and printed automatically.
Quick test: Click "Test" and then choose "Quick Test". When the mixture is dropped into the well of test cartridge, immediately count down reaction time (10 min) with a timer. When time is up, insert the test cartridge into test cartridge inlet immediately and then click "Start Test", the test result will be showed on screen and printed automatically.

REFERENCE INTERVAL

Normal Reference Value: <10.0ng/mL.
Note: Individual reference range is suggested to be established for each laboratory.

LIMITATIONS OF PROCEDURE

1. The test sample should be plasma or serum.
2. Human anti-mouse antibody (HAMA) may be present in patients who have received immunotherapy with a murine monoclonal antibody. This kit has been specially designed to minimize the effect of these antibodies on the test results. However, the test result must be carefully evaluated when patients are known to have these antibodies [3-4].
3. Other factors also can induce the false results, include the technology, operational error and other sample factors.

PERFORMANCE CHARACTERISTICS

Accuracy

AFP control materials with two different concentrations were tested by every lot of test cartridges, and the deviations were within ±15%.

Assay Range: 3.0~2000.0ng/mL

The Lowest Detection Limit: 3.0ng/mL

Linearity

A serial concentration of AFP controls at 3.0~2000.0ng/mL were tested, the Correlation Coefficient (R) is≥0.9900.

Precision

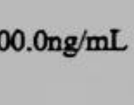
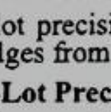
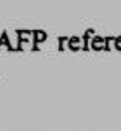
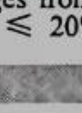
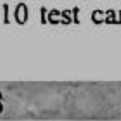
Intra-Lot Precision

Intra-lot precision was determined by testing of AFP reference materials using 10 test cartridges from the same lot. The C.V. is ⩽ 15%.

Inter-Lot Precision

Inter-lot precision was determined by testing of AFP reference materials using 30 test cartridges from 3 consecutive batches randomly (10 test cartridges from each lot). The C.V. is ⩽ 20%.

SYMBOLS

Symbol	Description	Symbol	Description
REF	Catalogue number	IVD	In vitro diagnostic medical device
LOT	Lot number		Consult instructions for use
	Date of manufacture		Keep dry
	Expiry date		Keep away from sunlight