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CE IVD

AFP

Fast Test Kit

(Immunofluorescence Assay)

IF1050 for Getein1100
IF5050 for Getein1160
IF3050 for Getein1180
REF IF2050 for Getein1600
IF4050 for Getein1200

User Manual

INTENDED USE

AFP Fast Test Kit (Immunofluorescence Assay) is intended for *in vitro* quantitative determination of AFP in human serum or plasma samples. This test can be used as an aid in the diagnosis and management of patients with liver cancer or cancer of the ovaries or testicles, and also help to monitor the health of people with cirrhosis or hepatitis.

SUMMARY

Alpha-Fetoprotein (AFP) is a glycoprotein that in human is encoded by the AFP gene with a molecular weight of approximately 70 KD. AFP is made in the liver of a developing baby, which is a major plasma protein produced by the yolk sac and the fetal liver during fetal development. AFP levels are usually high when a baby is born, but fall to very low levels by the age of 1. Healthy adults should have very low levels of AFP. AFP is produced by fetal liver and passes into the amniotic fluid (AF) via fetal urine. A small amount crosses the membranes into the maternal circulation. Excluding fetal blood contamination, elevated AF/AFP levels indicate fetal demise or one of several abnormalities. The AFP elevations in maternal serum and amniotic fluid are valuable diagnostically in the detection of fetal abnormalities, particularly neural-tube defects.

Most studies report elevated AFP concentrations in approximately 70% of patients with hepatocellular carcinoma. Elevated AFP concentrations are found in 50% to 70% of patients with nonseminomatous testicular tumors. It is widely recognized as a liver cancer marker as AFP levels can be elevated in the presence of a liver cancer (hepatocellular carcinoma). High levels of AFP can be a sign of liver cancer or cancer of the ovaries or testicles, as well as noncancerous liver diseases such as cirrhosis and hepatitis.

PRINCIPLE

The test uses an anti-human AFP monoclonal antibody Ⅰ conjugated with fluorescence latex coated on the fluorescent pad and another anti-human AFP monoclonal antibody Ⅱ coated on the test line. After the sample has been applied to the test strip, the fluorescence latex-labeled anti-human AFP antibody Ⅰ binds with the AFP in sample and forms marked antigen-antibody complex. This complex moves to the test card detection zone by capillary action. Then the marked antigen-antibody complex is captured on the test line by anti-human AFP antibody Ⅱ. The fluorescence intensity of the test line increases in proportion to the amount of AFP in the sample.

Then insert test card into Getein1100/Getein1160/Getein1180 Immunofluorescence Quantitative Analyzer/automatically inserted by Getein1200/Getein1600 Immunofluorescence Quantitative Analyzer (hereafter referred to as Getein1100, Getein1160, Getein1180, Getein1200 and Getein1600), the concentration of AFP in the sample will be measured and displayed on the screen. The value will be stored in Getein1100/Getein1160/Getein1180/Getein1200/Getein1600 and available for downloading. The result can be easily transmitted to the laboratory or hospital information system.

CONTENTS

1. A kit for Getein1100/Getein1160/Getein1180 contains:
Package specifications: 25 tests/kit, 10 tests/kit
1) Getein AFP test card in a sealed pouch with desiccant
2) Disposable pipet
3) Sample diluent
4) User manual: 1 piece/kit
5) SD card: 1 piece/kit

2. A kit for Getein1200/Getein1600 contains:
Package specifications: 2×24 tests/kit, 2×48 tests/kit
Sealed cartridge with 24/48 Getein AFP test cards
User manual: 1 piece/kit
Materials required for Getein1200/Getein1600:
1) Sample diluent: 1 bottle/kit
2) Box with pipette tips: 96 tips/kit
3) Mixing plate: 1 piece/kit

3. Sample diluent composition:
Phosphate buffered saline, protein stabilizer and surfactant.

4. A test card consists of:
A plastic shell and a reagent strip which is composed of a sample pad, nitrocellulose membrane (the end of the membrane is coated with fluorescence latex-labeled anti-human AFP monoclonal antibody Ⅰ, the test line is coated with another AFP monoclonal antibody Ⅱ, and the control line C is coated with rabbit anti-mouse IgG antibody), absorbent paper and liner.

Note: Do not mix or interchange different batches of kits.

APPLICABLE DEVICE

Getein1100 Immunofluorescence Quantitative Analyzer
Getein1160 Immunofluorescence Quantitative Analyzer
Getein1200 Immunofluorescence Quantitative Analyzer
Getein1180 Immunofluorescence Quantitative Analyzer
Getein1600 Immunofluorescence Quantitative Analyzer

STORAGE AND STABILITY

Store the test kit at 4~30°C with a valid period of 24 months.
Use the test card for Getein1100/Getein1160/Getein1180 within 1 hour once the foil pouch is opened.
For test card of Getein1200/Getein1600: If the cartridge is opened, it could be stable within 24 hours once exposure to air. Please put the cartridge back to the foil pouch and reseal along the entire edge of zip-seal. The remaining test cards should be used up within 7 days.

PRECAUTIONS

1. For *in vitro* diagnostic use only.
2. Do not use the kit beyond the expiration date.
3. Do not use the test card if the foil pouch is damaged.
4. Do not open pouches until ready to perform the test.
5. Do not reuse the test card.
6. Do not reuse the pipet.
7. Handle all specimens as potentially infectious. Proper handling and disposal methods should be followed in accordance with local regulations.
8. Carefully read and follow user manual to ensure proper test performance.

SPECIMEN COLLECTION AND PREPARATION

1. This test can be used for ***serum and plasma samples. Heparin, EDTA and sodium citrate*** can be used as the anticoagulant for plasma. Samples should be free of hemolysis.
2. The test should be performed within 4 hours after blood collection.
3. If testing is delayed, serum samples may be stored up to 7 days at 2~8°C or stored at -20°C for 3 months before testing.
4. Refrigerated or frozen sample should be reached room temperature and be homogeneous before testing. Avoid multiple freezethaw cycles.
5. Do not use heat-inactivated samples or hemolysis samples.
6. SAMPLE VOLUME***(Getein1100/Getein1160/Getein1180) : 100 μL***

TEST PROCEDURE

1. Collect specimens according to user manual.
2. Test card, sample and reagent should reach to room temperature before testing.

For Getein1100:
1. Confirm SD card lot No. in accordance with test kit lot No. Perform “SD card” calibration when necessary.
2. Enter testing interface of Getein1100.
3. Remove the test card from the sealed pouch immediately before use. Label the test card with patient or control identification.
4. Put the test card on a clean table, horizontally placed.
5. Using sample transfer pipette, deliver ***100 μL*** of sample into one tube of sample diluent, mix gently and thoroughly. Then drop ***100 μL*** of sample mixture into the sample well on the test card.
6. ***Reaction time: 15 minutes***. Insert the test card into Getein1100 and click on “Start” icon after reaction time is elapsed. The result will be shown on the screen and printed automatically.

For Getein1160/Getein1180:
1. Confirm SD card lot No. in accordance with test kit lot No. Perform “SD card” calibration when necessary.
2. Enter testing interface of Getein1160/Getein1180.
3. Remove the test card from the sealed pouch immediately before use. Label the test card with patient or control identification.
4. Put the test card on a clean table, horizontally placed.
5. Using sample transfer pipette, deliver ***100 μL*** of sample into one tube of sample diluent, mix gently and thoroughly. Then drop ***100 μL*** of sample mixture into the sample well on the test card.
6. Insert the test card into Getein1160/Getein1180 immediately after sample loading. The analyzer will count down the reaction time (15 minutes) and automatically test the card after reaction time is elapsed. The result will be shown on the screen and printed automatically.

For Getein1200/Getein1600:
1. Each cartridge for Getein1200/Getein1600 contains a specific RFID card which can calibrate automatically.
2. Put the sample diluent at the correct position in Getein1200/Getein1600.

3.Place samples in the designed area of the sample holder, insert the holder and select the right test item, Getein1200/Getein1600 will do the testing and print the result automatically.

Notes:

1. It is required to perform “SD card” calibration when using a new batch of kits.
2. It is suggested to calibrate once for one batch of kits for Getein1100/Getein1160/Getein1180.
3. Make sure the test card and the sample insertion is correct and complete.

TEST RESULTS

Getein1100/Getein1160/Getein1180/Getein1200/Getein1600 can scan the test card automatically and display the result on the screen. For additional information, please refer to the user manual of Getein1100/Getein1160/Getein1180/Getein1200/Getein1600.

Others:

Measuring range of the AFP test kit is 2.0 ng/mL~500.0 ng/mL. Dilute the sample which concentration is higher than the upper limit with negative diluent, and the recommended dilution ratio is less than 5 times.

EXPECTED VALUE

The expected normal value for AFP was determined by testing samples from 1000 apparently healthy individuals. The reference value of AFP is 7.0 ng/mL calculated by using normal distribution methods giving a level of confidence of approximately 95%.

It is recommended that each laboratory establish its own expected values for the population it serves.

PERFORMANCE CHARACTERISTICS

Measuring Range	2.0~500.0 ng/mL
Lower Detection Limit	≤2.0 ng/mL
Within-Run Precision	≤10%
Between-Run Precision	≤15%

LIMITATIONS

1. As with all diagnostic tests, a definitive clinical diagnosis should not be made based on the result of a single test. The test results should be interpreted considering all other test results and clinical information such as clinical signs and symptoms.
2. Interferents in samples may influence the results.The table below listed the maximum allowance of these potential interferents.

Interferent	Triglyceride	Bilirubin
Concentration(Max)	10 g/L	0.2g/L

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DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on AFP Fast Test Kit (Immunofluorescence Assay) are the most common ones appearing on medical devices and their packaging. They are explained in more details in the European Standard EN ISO 15223-1:2021.

Key to symbols used			
	Manufacturer		Use-by date
	Do not re-use		Date of manufacture
	Consult *instructions for use* or consult electronic *instructions for use*	LOT	Batch code
	Temperature limit	IVD	*In vitro* diagnostic medical device
	Contains sufficient for <n> tests	EC REP	Authorized representative in the European Community/European Union
CE	CE mark		Do not use if package is damaged and consult *instructions for use*
REF	Catalogue number		

Thank you for purchasing AFP Fast Test Kit (Immunofluorescence Assay).

Please read this user manual carefully before operating to ensure proper use.

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Getein Biotech, Inc.
Add.: No.9 Bofu Road, Luhe District, Nanjing, 211505, China
Tel: +86-25-68568508
Fax: +86-25-68568500
E-mail: tech@getein.com.cn
overseas@getein.com.cn
Website: www.getein.com

EC REP CMC Medical Devices & Drugs S.L.
Add.: C/ Horacio Lengo Nº 18, CP 29006, Málaga, Spain
Tel: +34951214054