GP

CE IVD

AFP

Fast Test Kit

(Immunofluorescence Assay)

IF1050 for Getein 1100
IF5050 for Getein 1160
IF3050 for Getein 1180
REF IF2050 for Getein 1600
IF4050 for Getein 1200

Instructions for Use

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 monitoring of primary liver cancer. For professional and laboratory use only.
This test can NOT be used to guide the diagnosis of pair trisomy 21.

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

AFP Fast Test Kit (Immunofluorescence Assay) is a lateral flow immunoassay in a sandwich design. After sample has been applied to the test strip, the fluorescence-labelled AFP monoclonal antibody binds with the AFP in sample and forms marked antibody-antigen complex. The complex moves to the detection zone by capillary action. Then marked antigen-antibody complex is captured on the test line by another AFP monoclonal antibody. The fluorescence intensity of the test line increases in proportion to the amount of AFP in the sample. Fluorescent signals intensity can be analyzed by applicable device thus the AFP in sample be detected quantitatively.

APPLICABLE DEVICE

Getein 1100 Immunofluorescence Quantitative Analyzer
Getein 1160 Immunofluorescence Quantitative Analyzer
Getein 1180 Immunofluorescence Quantitative Analyzer
Getein 1600 Immunofluorescence Quantitative Analyzer
Getein 1200 Immunofluorescence Quantitative Analyzer

CONTENTS

Materials provided	Getein 1100/Getein 1160/ Getein 1180		Getein 1200/ Getein 1600	
	10 T/kit	25 T/kit	2*24 T/kit	2*48 T/kit
AFP test card*	10 pcs	25 pcs	24 test cards in 1 cartridge, and 2 cartridges in 1 box	48 test cards in 1 cartridge, and 2 cartridges in 1 box
Disposable pipet	10 pcs	25 pcs	/	/
Sample diluent**	10 tube	25 tube	1 box	1 box
Instructions for use	1 pc	1 pc	1 pc	1 pc
SD card	1 pc	1 pc	1 pc in each cartridge	1 pc in each cartridge

*AFP test card
A test card consists of: Fluorescence-labelled AFP monoclonal antibody, AFP monoclonal antibody.
** Sample diluent
(1) Sample diluent for Getein 1100/Getein 1160/Getein 1180 is 0.2 mL contained in each tube consists of:
- Sample diluent mainly contains phosphate buffer (20 mmol/L), NaN_3 (<0.1%).
(2) Sample diluent for Getein 1200/Getein 1600 is an independent packing box mainly consists of:
- Phosphate buffer (20 mmol/L), NaN_3 (<0.1%) (25 mL/bottle for Getein 1200, 40 mL/bottle for Getein 1600),
- Box with pipette tips (96 tips/box),
- Mixing plate (1 piece/box).

Note:
1. The standard curve data can be written to RFID card in the kit. According to the function of RFID card, we define it as "Standard Curve Data Card", short for "SD Card".
2. Do not mix or interchange different batches of kits.

STORAGE AND STABILITY

Realtime stability:
Store the kit at 4~30°C with a valid period of 24 months. The test kits are stable until the expiry date printed on the labels.
In-use stability:
- For the test card of Getein 1100/Getein 1160/Getein 1180: Use the test card within 1 hour once the foil pouch is opened.
- For test card of Getein 1200/Getein 1600: if the cartridge is opened, it could be stable within 24 hours once exposed to air. If the test cards can't be used up at a time, 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 follow by local regulations.
8. Carefully read and follow the instructions for use to ensure an appropriate test performance.

SPECIMEN COLLECTION AND PREPARATION

1. This test can be used for serum and plasma samples. Heparin, sodium citrate and EDTA can be used as the anticoagulant for plasma.
2. The test should be performed within 4 hours after blood collection.
3. If testing is delayed, serum and plasma samples may be stored up to 7 days at 2~8°C or stored at -20°C for 6 months before testing.
4. Refrigerated or frozen sample should be reached to room temperature and be homogeneous before testing. Avoid multiple freeze-thaw cycles.
5. Do not use heat-inactivated or hemolysis samples.
6. SAMPLE VOLUME (for Getein 1100/Getein 1160/Getein 1180): 100 µL.

TEST PROCEDURE

1. User must carefully read and operate in strict accordance with the instructions for use before testing, otherwise reliable results cannot be guaranteed.
2. Test kit and sample should be brought to room temperature before testing.

For Getein 1100:
1. Confirm SD card lot No. in accordance with test kit lot No. Perform calibration using the SD card when necessary.
2. Select the corresponding sample type on the analyzer (refer to the user manual of analyzer for details)
3. Remove the test card from the sealed pouch before use. Horizontally place the test card.
4. Deliver 100 µL of sample into one tube of sample diluent using disposable pipet or pipette, mix gently and thoroughly. Then drop 100 µL of sample mixture into the sample port “S” on the test card.
5. Reaction time: 15 minutes. After reaction time is elapsed, insert the test card into Getein 1100 and press “ENT” button (click on “Start” icon for Android Getein 1100). The result will be shown on the

For Getein 1160/Getein 1180:
1. Confirm SD card lot No. in accordance with test kit lot No. Perform “SD card” calibration when necessary.
2. Select the corresponding sample type on the analyzer (refer to the user manual of analyzer for details)
3. Remove the test card from the sealed pouch before use. Horizontally place the test card.
4. Deliver 100 µL of sample into one tube of sample diluent using disposable pipet or pipette, mix gently and thoroughly. Then drop 100 µL of sample mixture into the sample port “S” on the test card.
5. Insert the test card into Getein 1160/Getein 1180 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 Getein 1200/Getein 1600:
1. Each cartridge for Getein 1200/Getein 1600 contains a specific RFID card which can calibrate automatically.
2. Put the sample diluent at the correct position in Getein

1200/Getein 1600.

3. Place samples in the designed area of the sample holder, insert the holder, set parameters (more operational details refer to the user manual of analyzer) and run the instrument, Getein 1200/Getein 1600 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 Getein 1100/Getein 1160/Getein 1180.
3. Make sure the test card and the sample insertion are correct and complete.

RESULTS

Getein 1100/Getein 1160/Getein 1180/Getein 1200/Getein 1600 can scan the test card automatically and display the result on the screen. For additional information, please refer to the user manual of Getein 1100/Getein 1160/Getein 1180/Getein 1200/Getein 1600.

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 sample diluent, and the recommended dilution ratio is less than 5 times.

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

EXPECTED VALUE

The expected normal value for AFP was determined by testing samples from 1000 apparently healthy individuals. The 95th percentile of AFP is 7.0 ng/mL

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%

REFERENCES

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2. Joanna G ,Marcin S ,Jakub P , et al. Influence of selected factors on serum AFP levels in pregnant women in terms of prenatal screening accuracy - literature review. [J]. Ginekologia polska, 2023, 94 (2).
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4. Yong L, Da-Jiang L, Jian C, et al. Application of Joint Detection of AFP, CA19-9, CA125 and CEA in Identification and Diagnosis of Cholangiocarcinoma. [J]. Asian Pacific journal of cancer prevention : APJCP, 2015, 16 (8): 3451-5.
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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		Caution

Thank you for using AFP Fast Test Kit (Immunofluorescence Assay). Please read the instructions for use carefully before operating to ensure proper use.

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