GP CE IVD

AFP Fast Test Kit
(Immunofluorescence Assay)

MOLDOVA EUROPEANĂ

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

REF

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 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 hole, 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/box, 10 tests/box
1) Getein AFP test card in a sealed pouch with desiccant
2) Disposable pipet
3) Sample diluent
4) User manual: 1 piece/box
5) SD card: 1 piece/box

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/box
Materials required for Getein1200/Getein1600:
1) Sample diluent: 1 bottle/box
2) Box with pipette tips: 96 tips/box
3) Mixing plate: 1 piece/box

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 card 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:
3. Confirm SD card lot No. in accordance with test kit lot No. Perform “SD card” calibration when necessary.
4. Enter testing interface of Getein1100.
5. Remove the test card from the sealed pouch immediately before use. Label the test card with patient or control identification.
6. Put the test card on a clean table, horizontally placed.
7. 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 port on the test card.
8. ***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:
9. Confirm SD card lot No. in accordance with test kit lot No. Perform “SD card” calibration when necessary.
10. Enter testing interface of Getein1160/Getein1180.
11. Remove the test card from the sealed pouch immediately before use. Label the test card with patient or control identification.
12. Put the test card on a clean table, horizontally placed.
13. 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 port on the test card.
14. ***Reaction time: 15 minutes***. Insert the test card into Getein1160/Getein1180 immediately after sample loading. The analyzer will count down the reaction time and automatically test the card after reaction time is elapsed. The result will be shown on the screen and printed automatically.

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

17.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. Samples containing interferent 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

REFERENCES

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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.

Version: WIF54-S-07

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 Lotus NL B.V.
Add: Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.
E-mail: peter@lotusnl.com
Tel: +31644168999

GP

CE IVD

ASO

Fast Test Kit

(Immunofluorescence Assay)

REF IF1076 for Getein1100
IF5076 for Getein1160
IF3076 for Getein1180
IF4076 for Getein1200
IF2076 for Getein1600

User Manual

INTENDED USE

ASO Fast Test Kit (Immunofluorescence Assay) is intended for in vitro quantitative determination of anti streptolysin "O" antibody (ASO) in serum, plasma or whole blood samples. ASO is a very valuable marker for the diagnosis of group A streptococcal infection, its titer can reflect the severity of infection. Some diseases will lead to a significant increase in ASO titer, such as wind damp heat, acute glomerulonephritis, nodular erythema, scarlet fever, acute tonsillitis.

SUMMARY

Streptolysin "O", a protein with hemolytic activity, is one of the important metabolites of group A streptococcus. It can dissolve the red blood cells of human and some animals. Streptolysin "O" has strong antigenicity. When human is infected with group A hemolytic streptococcus, B lymphocytes will secrete corresponding antibodies under the stimulation of streptolysin "O", that is, anti streptolysin "O" (ASO). This antibody can neutralize streptolysin "O" and disable its hemolytic ability.

ASO began to rise one week after group A Streptococcus infection, peaked in 4-5 weeks and lasted for several months. As the infection subsides, ASO decreased and returned to normal value within 6 months. The disease condition can be judged by repeated measurements over time. The increase of ASO over time indicates the early stage of infection, decrease indicates the subside stage of infection. The lack of decline in ASO titer suggested the possibility of recurrent or chronic infection.

PRINCIPLE

The test kit adopts a double-antigen sandwich method to quantitatively detect the concentration of ASO in human serum, plasma and whole blood samples.

After the sample has been applied to the test card, the fluorescence latex-labelled ASO antigen Ⅰ binds with ASO in sample and forms a marked antigen-antibody complex. The complex moves to the detection area by capillary action, then it is captured by ASO antigen Ⅱ coated on the detection area of nitrocellulose membrane, forming a double-antigen complex. The complex generates a fluorescent signal and the intensity increases in proportion to the amount of ASO in sample.

Then insert test card into Getein1100/Getein1160/Getein1180 Immunofluorescence Quantitative Analyzer/ automatically inserted by Getein1200/Getein1600 Immunofluorescence Quantitative Analyzer (hereinafter referred to as Getein1100, Getein1160, Getein1180, Getein1200 and Getein1600), the concentration of ASO in 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/box, 10 tests/box
1) Getein ASO test card in a sealed pouch with desiccant
2) Capillary pipet
3) Sample diluent
4) User manual: 1 piece/box
5) SD card: 1 piece/box

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

3. A test card consists of:
A plastic shell and a reagent strip which is composed of a sample pad, nitrocellulose membrane (one end of the membrane is coated with fluorescence latex-labelled ASO antigen Ⅰ, the test line is coated with another ASO antigen Ⅱ and the control line is coated with polyclonal goat anti streptolysin "O" antibody), absorbent paper and liner.

4. Sample diluent composition:
Phosphate buffered saline, proteins, detergent, preservative, stabilizer.

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

APPLICABLE DEVICE

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

STORAGE AND STABILITY

Store the test card at 4~30℃ with a valid period of 24 months.

Use the test card for Getein1100/Getein1160/Getein1180 within one 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 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. For professional use only.
3. Do not use the kit beyond the expiration date.
4. Do not use the test card if the foil pouch or the cartridge is damaged.
5. Do not open pouches or the cartridge until ready to perform the test.
6. Do not reuse the test card.
7. Do not reuse the pipet.
8. Handle all specimens as potentially infectious. Proper handling and disposal methods should be followed in accordance with local regulations.
9. Carefully read and follow user manual to ensure proper test performance.

SPECIMEN COLLECTION AND PREPARATION

1. ***Serum, plasma or whole blood*** samples can be used for the test. Other body fluids and samples may not give accurate results. Samples should be free of hemolysis.
2. Venous blood should be collected under aseptic conditions; serum or plasma is preferred for testing.
3. Heparin, sodium citrate or EDTA can be used as the anticoagulant for plasma and whole blood samples.
4. The test should be performed at room temperature within 4 hours after sample collection.
5. If testing is delayed, serum and plasma samples may be stored up to 5 days at 2 ~ 8℃ and 6 months at -20℃ before testing. Whole blood samples should not be frozen and can be stored at 2 ~ 8℃ for 3 days. Do not heat inactivated samples or use hemolyzed blood samples.
6. Refrigerated or frozen sample should be reached to room temperature before testing. Frozen samples must be completely thawed, rewarmed and evenly mixed. Avoid multiple freeze-thaw cycles.
7. Sample volume ***(for Getein1100/Getein1160/Getein1180): 10 μL.***

TEST PROCEDURE

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

For Getein1100:

3. Confirm SD card lot No. in accordance with test kit lot No. Perform “SD card” calibration when necessary.
4. Remove the test card from the sealed pouch immediately before use. Label the test card with patient or control identification.
5. Put the test card on a clean table, horizontally placed.
6. Using sample transfer pipette, deliver ***10 μL*** of sample into one tube of sample diluent, mix gently and thoroughly. Then drop ***100μL*** of sample mixture into the sample port on the test card.
7. ***Reaction time: 10 minutes.*** Insert the test card into Getein1100 and click on “Start” icon (for Android Getein 1100) after reaction time is elapsed. The result will be shown on the screen and printed automatically.

For Getein1160/Getein1180:

8. Confirm SD card lot No. in accordance with test kit lot No..Perform “SD card” calibration when necessary.
9. Enter testing interface of Getein1160/Getein1180.
10. Remove the test card from the sealed pouch immediately before use. Label the test card with patient or control identification.
11. Put the test card on a clean table, horizontally placed.
12. Using sample transfer pipette, deliver ***10 μL*** of sample into one tube of sample diluent, mix gently and thoroughly. Then drop ***100μL*** of sample mixture into the sample port on the test card.
13. ***Reaction time: 10 minutes.*** Insert the test card into Getein 1160/Getein1180 immediately after sample loading. The analyzer will count down the reaction time and automatically test the card after reaction time is elapsed. The result will be shown on the screen and printed automatically.

For Getein1200/Getein1600:

14. Each cartridge for Getein1200/Getein1600 contains a specific RFID card which can calibrate automatically.
15. Put the sample diluent at the correct position of Getein 1200/Getein1600.
16. Place samples in the designed area of the sample holder, insert the holder and select the right test item, Getein 1200/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 are 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: Samples whose concentration exceeds the upper limit should be diluted no more than 4 times.

EXPECTED VALUE

The expected normal value for ASO is determined by testing samples from 282 apparently healthy individuals. The upper 80th percentile value is 200.0 IU/mL. The upper 95th percentile value is 400.0 IU/mL.
It is recommended that each laboratory determine the applicability of the reference value through experiments and establish its own reference ranges if necessary.

PERFORMANCE CHARACTERISTICS

Measuring Range	60.0-1370.0 IU/mL
Lower Detection Limit	≤60.0 IU/mL
Within-run Precision	≤10%
Between-run Precision	≤15%

LIMITATIONS

1. Bilirubin and triglyceride in the sample may interfere with the test results, and the maximum allowable concentrations are 0.1 mg/mL and 10 mg/mL respectively.
2. The test results of this kit are for clinical reference only, and should not be used as the sole criteria for clinical diagnosis.It is recommended to conduct a comprehensive analysis on the condition in combination with symptoms/signs, history and other laboratory tests.

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DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on the test kit 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 ASO Fast Test Kit (Immunofluorescence Assay).
Please read this user manual carefully before operating to ensure proper use.

Version: WIF83-S-03

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 Lotus NL B.V.
Add: Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.
E-mail: peter@lotusnl.com
Tel: +31644168999

GP

CE IVD

CEA

Fast Test Kit

(Immunofluorescence Assay)

IF1051 for Getein 1100
IF5051 for Getein 1160
IF3051 for Getein 1180
REF IF2051 for Getein 1600
IF4051 for Getein 1200

Instructions for Use

INTENDED USE

CEA Fast Test Kit (Immunofluorescence Assay) is intended for *in vitro* quantitative determination of carcinoembryonic antigen (CEA) in serum or plasma samples. The test is used clinically as an aid in the diagnosis and management of cancer patients. For professional and laboratory use only.
This test can NOT be used to guide the diagnosis of pair trisomy 21.

SUMMARY

CEA is a glycosylated molecule with a molecular weight of approximately 180,000 Daltons. CEA (Carcinoembryonic Antigen) is synthesized by epithelial tissues of the fetal gastrointestinal tract, pancreas, and liver cells. Typically, the levels of CEA increase during the first six months of pregnancy and become very low in the serum after birth. CEA is a non-organ-specific tumor-associated antigen, and tumors that secrete CEA are mostly located in hollow organs such as the gastrointestinal tract, respiratory tract, and urinary tract.
Normally, CEA is metabolized by the gastrointestinal tract, but in the presence of tumors, CEA enters the blood and lymphatic circulation, causing abnormally high serum CEA levels. This results in elevated serum CEA in patients with various types of tumors mentioned above.
Clinically, when CEA exceeds 60 μg/L, it can be seen in colon cancer, rectal cancer, gastric cancer, and lung cancer. Elevated CEA levels indicate the presence of residual or progressive lesions. For patients with lung cancer, breast cancer, bladder cancer, and ovarian cancer, serum CEA levels significantly increase, mostly indicating tumor infiltration, with about 70% being metastatic cancers. Generally, CEA levels return to normal 6 weeks after surgical resection; otherwise, it suggests the presence of residual tumor. If the CEA concentration continuously increases or its value exceeds the normal range by 5-6 times, it indicates a poor prognosis.

PRINCIPLE

CEA 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 CEA monoclonal antibody binds with the CEA 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 CEA monoclonal antibody. The fluorescence intensity of the test line increases in proportion to the amount of CEA antigen in the sample. Fluorescent signals intensity can be analyzed by applicable device thus the CEA 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
CEA 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

*CEA test card
A test card consists of: Fluorescence-labelled CEA monoclonal antibody, CEA monoclonal antibody.
** Sample diluent
(1) Sample diluent for Getein 1100/Getein 1160/Getein 1180 is 1.0 mL contained in each tube consists of:
- 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 screen and printed automatically.

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: Dilute the sample which concentration is higher than the upper limit with sample diluent, and the dilution ratio should be 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	1000 mg/dL
Bilirubin	20 mg/dL

EXPECTED VALUE

The expected normal value for CEA was determined by testing serum samples from 1000 apparently healthy individuals. The 95th percentile of CEA is 4.7 ng/mL.

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

PERFORMANCE CHARACTERISTICS

Measuring Range	2.0 ng/mL-500.0 ng/mL
Limit of Detection	≤ 2.0 ng/mL
Within-run Precision	≤ 10%
Between-lot Precision	≤ 15%

REFERENCES

1. Ren W, Benjie X, Mingming S , et al. Dynamic monitoring of serum CEA and CA19-9 predicts the prognosis of postoperative stage II colon cancer. [J]. European journal of surgical oncology : the journal of the European Society of Surgical Oncology and the British Association of Surgical Oncology, 2023, 49 (12): 107138-107138.
2. Huang X, Zheng X ,Li Y , et al. Performance Evaluation of Combined Detection of Serum CEA, CYFRA21-1, CA125, and NSE in Patients with Lung Cancer by Fluorescence Flow Cytometry [J]. Proceedings of Anticancer Research, 2023, 7 (3).
3. Zhi L, Liming L, Yibin D , et al. Genetic susceptibility loci of lung cancer are associated with malignant risk of pulmonary nodules and improve malignancy diagnosis based on CEA levels. [J]. Chinese journal of cancer research = Chung-kuo yen cheng yen chiu, 2023, 35 (5): 501-510.
4. Lin Z, Jia L, Feng L. Serum tumor markers for detection of hepatocellular carcinoma. [J]. World journal of gastroenterology, 2006, 12 (8): 1175-81.
5. Das S, Kaushik S. Cancer antigen 125 (CA 125) and carcinoembryonic antigen (CEA) ratio can identify different stages of ovarian cancer preoperatively [J]. Clinica Chimica Acta, 2019, 493 (Supl.1): S116-S116.

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on CEA 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 CEA Fast Test Kit (Immunofluorescence Assay). Please read the instructions for use carefully before operating to ensure proper use.

Version: WIF49-S-10

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

CE IVD

CK-MB/cTnI/Myo

Fast Test Kit

(Immunofluorescence Assay)

User Manual

Getein1100: Cat.# IF1005
Getein1600: Cat.# IF2005

INTENDED USE

CK-MB/cTnI/Myo Fast Test Kit (Immunofluorescence Assay) is intended for *in vitro* quantitative determination of CK-MB/cTnI/Myo in serum, plasma or whole blood. This test is used as an aid in the clinical diagnosis, prognosis and evaluation of myocardial injury such as Acute Myocardial Infarction (AMI), Unstable Angina, Acute Myocarditis and Acute Coronary Syndrome (ACS).

SUMMARY

Creatine kinases are dimer isozymes composed of two monomer subunits, CK-M (for skeletal muscle derived) and CK-B (for brain derived), which can form all three combinations of monomers: CK-BB, CK-MM, and CK-MB. BB is found primarily in the brain. Skeletal muscles primarily contain the MM isoform, with trace amount of MB (around 1-4% of total CK activity). Cardiac muscles also contain the MM isoform, but higher amount of MB, typically around 20% of total CK activity. CK-MB is a more sensitive marker of myocardial injury than total CK activity, because it has a lower basal level and a much narrower normal range. Medical literatures commonly state that CK-MB levels are elevated in 4 to 6 hours, peak at 10 to 24 hours, and return to normal within 3 to 4 days after an acute myocardial infarction. Classically, an increase of the myocardial-specific enzyme CK-MB is considered as the hallmark of acute myocardial infarction, and increased levels are frequently interpreted by the clinician as objective evidence of myocardial cell damage.

Troponin complex consists of three regulatory proteins: T, which connects the troponin complex and tropomyosin (another cardiac muscle regulatory protein); I, which prevents muscle contraction in the absence of calcium; and C, which binds calcium. Cardiac troponin I (MW 22.5 kDa) and the two skeletal muscle isoforms of troponin I have considerable amino acid sequence homology, but cTnI contains an additional N-terminal sequence and is highly specific for myocardia.

Clinical studies have demonstrated the release of cTnI into the blood stream within hours following acute myocardial infarctions (AMI) or ischemic damage. Elevated levels of cTnI are detectable in blood within 4 to 6 hours after the onset of chest pain, reaching peak concentrations in approximately 8 to 28 hours, and remain elevated for 3 to 10 days following AMI. Due to the high myocardial specificity and the long duration of elevation, cTnI has become an important marker in the diagnosis and evaluation of patients suspected of having an AMI.

Myoglobin is a small monomeric protein which serves as an intracellular oxygen storage site. It is found in abundance in the muscle and can get through into the blood circulation directly when myocardial cell is damaged mildly. Therefore, myoglobin has been advocated as a sensitive marker for early acute myocardial injury by American College of Cardiology Committee.

PRINCIPLE

Mixed monoclonal antibodies against human CK-MB, cTnI and Myo are conjugated with fluorescence latex and another set of anti-human CK-MB/cTnI/Myo monoclonal antibodies were coated on different test lines respectively. After the sample has been applied to the test strip, the fluorescence latex-labelled anti-human CK-MB, cTnI and Myo monoclonal antibodies will bind with the CK-MB, cTnI and Myo in sample respectively and form marked antigen-antibody complexes. These complexes move to the test card detection zone by capillary action. Then marked antigen-antibody complexes will be captured on different test lines by another set of monoclonal antibodies against human CK-MB, cTnI or Myo respectively resulting in the accumulation of fluorescence particles on the test lines. The fluorescence intensity of each test line increases in proportion to the amount of CK-MB, cTnI or Myo in sample.

Then insert test card into Getein1100 Immunofluorescence Quantitative Analyzer/Getein1600 Immunofluorescence Quantitative Analyzer (hereinafter referred to as Getein1100 and Getein1600), the concentration of CK-MB, cTnI and Myo in sample will be measured and displayed on the screen. The value will be stored in Getein1100/Getein1600 and available for downloading. The result can be easily transmitted to LIS and HIS.

CONTENTS

1. A kit for Getein1100 contains:
   Getein CK-MB/cTnI/Myo test card in a sealed pouch with desiccant ····· 25
   Disposable pipet ····· 25
   Whole blood buffer ····· 1
   SD card ····· 1
   User manual ····· 1
2. A kit for Getein1600 contains:
   Sealed cartridge with 24/48 Getein CK-MB/cTnI/Myo test cards ····· 2
   User manual ····· 1
   Package specifications:
   2×24 tests/kit, 2×48 tests/kit
   Materials required for Getein1600:
   Sample diluent ····· 1
   Box with pipette tips ····· 1
   Mixing plate ····· 1
3. Sample diluent/Whole blood buffer composition:
   Phosphate buffered saline, proteins, detergent, preservative, stabilizer.
4. A test card consists of:
   A plastic shell and a reagent strip which is composed of a sample pad, nitrocellulose membrane (one end of the membrane is coated with fluorescence latex-labelled anti-human CK-MB, cTnI and Myo monoclonal antibodies, these three lines are coated with another anti-human CK-MB, another anti-human cTnI and another anti-human Myo monoclonal antibody, respectively. 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
Getein1600 Immunofluorescence Quantitative Analyzer

STORAGE AND STABILITY

Store the test card at 4~30℃ with a valid period of 24 months. Use the test card for Getein1100 within 1 hour once the foil pouch is opened.

For test card of Getein1600: 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.

Store the sample diluent/whole blood buffer at 0~30℃ with a valid period of 24 months.

Store the sample diluent/whole blood buffer at 2~8℃ for better results.

PRECAUTIONS

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

SPECIMEN COLLECTION AND PREPARATION

1. This test can be used for ***serum, plasma and whole blood samples. Heparin and sodium citrate*** should be used as the anticoagulant for plasma and whole blood. Samples should be free of hemolysis.
2. Suggest using serum or plasma for better results.
3. Serum or plasma can be used directly. For whole blood sample, one drop of whole blood buffer must be added before testing.
4. If testing will be delayed, serum and plasma samples may

be stored up to 7 days at 2~8℃ or stored at -20℃ for 6 months before testing (whole blood sample may be stored up to 3 days at 2~8℃).

5. Refrigerated or frozen sample should reach room temperature and be homogeneous before testing. Avoid multiple freeze-thaw cycles.
6. Do not use heat-inactivated samples.
7. SAMPLE VOLUME *(for Getein1100): 100 µl*.

TEST PROCEDURE

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

For Getein1100:

3. Confirm SD card lot No. in accordance with test kit lot No.. Perform “SD Card Calib” calibration when necessary (Details refer to 8.5.2 of Getein1100 User Manual).
4. On the main interface of Getein1100, press "ENT" button to enter testing interface.
5. Remove the test card from the sealed pouch immediately before use. Label the test card with patient or control identification.
6. Put the test card on a clean table, horizontally placed.
7. Using sample transfer pipette, deliver ***100 µl*** of sample (or 3~4 drops of sample when using disposable pipet) into the sample port on the test card (for whole blood sample, one drop of whole blood buffer must be added after loading 100 µl sample on the test card).
8. *Reaction time: 15 minutes.* Insert the test card into Getein1100 and press "ENT" button after reaction time is elapsed. The result will be shown on the screen and printed automatically.

For Getein1600:

9. Each cartridge for Getein1600 contains a specific RFID card which can calibrate automatically.
10. Place samples in the designed area of the sample holder, insert the holder and select the right test item, Getein1600 will do the testing and print the result automatically.

Notes:

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

TEST RESULTS

Getein1100/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/Getein1600.

EXPECTED VALUE

The expected normal value for CK-MB was determined by testing samples from 500 apparently healthy individuals. The 99th percentile of the concentration for CK-MB is 5.0 ng/ml. (The probability that value of a normal person below 5.0 ng/ml is 99%.)

The expected normal value for cTnI was determined by testing samples from 500 apparently healthy individuals. The 99th percentile of the concentration for cTnI is 0.1 ng/ml. (The probability that value of a normal person below 0.1 ng/ml is 99%.)

The expected normal value for Myo was determined by testing samples from 500 apparently healthy individuals. The 95th percentile of the concentration for Myo is 50 ng/ml. The 97.5th percentile of the concentration for Myo is 70 ng/ml. (According to different Statistics method, the probability that value of a normal person below 50 ng/ml is 95% or below 70 ng/ml is 97.5%.)

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

PERFORMANCE CHARACTERISTICS

	CK-MB	cTnI	Myo
Measuring Range	2.5~80.0 ng/ml	0.1~50.0 ng/ml	30.0~600.0 ng/ml
Lower Detection Limit	≤ 2.5 ng/ml	≤ 0.1 ng/ml	≤ 30.0 ng/ml
Within-Run Precision	≤10%		
Between-Run Precision	≤15%		

Method Comparison:

The assay was compared with HITACHI 7600/OLYMPUS AU5400 and its matching CK-MB test kits, SIEMENS IMMULITE 1000/2000 and its matching cTnI and Myo test kits with 200 serum samples (60 positive samples and 140 negative samples). The correlation coefficient (r) for CK-MB is 0.928, the correlation coefficient (r) for cTnI is 0.952, the correlation coefficient (r) for Myo is 0.938.

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. Samples containing interferents may influence the results. The table below listed the maximum allowance of these potential interferents.

Interferent	Hemoglobin	Triglyceride	Bilirubin
Concentration (Max)	5 g/L	10 g/L	0.2 g/L

REFERENCES

1. Mauro Pantaghini; Undefined International Federation of Clinical Chemistry and Laboratory Medicine (IFCC). Scientific Division Committee on Standardization of Markers of Cardiac Damage. Clin Chem Lab Med,1998, 36:887~893.
2. Antman EM, Anbe DT, Armstrong PW, et al. ACC/AHA guidelines for the management of patients with ST-elevation myocardial infarction: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Committee to Revise the 1999 Guidelines for the Manage 2004).
3. EN ISO 18113-1:2009 *In vitro* diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements.
4. EN ISO 18113-2:2009 *In vitro* diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: *In vitro* diagnostic reagents for professional use (ISO 18113-2:2009).

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on CK-MB/cTnI/Myo 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 980:2008 and International Standard ISO 15223-1:2007.

Key to symbols used			
	Manufacturer		Expiration date
	Do not reuse		Date of manufacture
	Consult instructions for use	LOT	Batch code
	Temperature limitation	IVD	*In vitro* diagnostic medical device
	Sufficient for	EC REP	Authorized representative in the European Community
CE	CE mark		Do not use if package is damaged

Thank you for purchasing CK-MB/cTnI/Myo Fast Test Kit (Immunofluorescence Assay). Please read this user manual carefully before operating to ensure proper use.

Version: WIF09-S-02

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.bio-GP.com.cn

GP

CE IVD

CK-MB/cTnI Fast Test Kit

(Immunofluorescence Assay)

REF IF1012 for Getein1100
IF5012 for Getein1160
IF3012 for Getein1180
IF4012 for Getein1200
IF2012 for Getein1600

Instructions for Use

INTENDED USE

CK-MB/cTnI Fast Test Kit (Immunofluorescence Assay) is intended for *in vitro* quantitative determination of CK-MB/cTnI in human serum, plasma or whole blood samples. This test is used as an aid in the clinical diagnosis, prognosis and evaluation of myocardial injury such as Acute Myocardial Infarction (AMI), Unstable Angina, Acute Myocarditis and Acute Coronary Syndrome (ACS).

SUMMARY

Creatine kinases are dimer isozymes composed of two monomer subunits, CK-M (for skeletal muscle derived) and CK-B (for brain derived), which can form all three combinations of monomers: CK-BB, CK-MM, and CK-MB. BB is found primarily in the brain. Skeletal muscles primarily contain the MM isoform, with trace amount of MB (around 1-4% of total CK activity). Cardiac muscles also contain the MM isoform, but higher amount of MB, typically around 20% of total CK activity. CK-MB is a more sensitive marker of myocardial injury than total CK activity, because it has a lower basal level and a much narrower normal range. Medical literatures commonly state that CK-MB levels are elevated in 4 to 6 hours, peak at 10 to 24 hours, and return to normal within 3 to 4 days after an acute myocardial infarction. Classically, an increase of the myocardial-specific enzyme CK-MB is considered as the hallmark of acute myocardial infarction, and increased levels are frequently interpreted by the clinician as objective evidence of myocardial cell damage.

Troponin complex consists of three regulatory proteins: T, which connects the troponin complex and tropomyosin (another cardiac muscle regulatory protein); I, which prevents muscle contraction in the absence of calcium; and C, which binds calcium. Cardiac troponin I (MW 22.5 kDa) and the two skeletal muscle isoforms of troponin I have considerable amino acid sequence homology, but cTnI contains an additional N-terminal sequence and is highly specific for myocardia.

Clinical studies have demonstrated the release of cTnI into the blood stream within hours following acute myocardial infarctions (AMI) or ischemic damage. Elevated levels of cTnI are detectable in blood within 4 to 6 hours after the onset of chest pain, reaching peak concentrations in approximately 8 to 28 hours, and remain elevated for 3 to 10 days following AMI. Due to the high myocardial specificity and the long duration of elevation, cTnI has become an important marker in the diagnosis and evaluation of patients suspected of having an AMI.

PRINCIPLE

Mixed monoclonal antibodies against human CK-MB and cTnI were conjugated with fluorescence latex and another set of anti-human CK-MB/cTnI monoclonal antibodies were coated on different test lines respectively. After the sample has been applied to the test strip, the fluorescence latex-labelled anti-human CK-MB and cTnI monoclonal antibodies will bind with the CK-MB and cTnI in sample respectively and form marked antigen-antibody complexes. These complexes move to the test card detection zone by capillary action. Then marked antigen-antibody complexes will be captured on different test lines by another set of monoclonal antibodies against human CK-MB or cTnI respectively resulting in the accumulation of fluorescence particles on the test lines. The fluorescence intensity of each test line increases in proportion to the amount of CK-MB or cTnI in sample.

Then insert test card into Getein1100/Getein1160/Getein 1180 Immunofluorescence Quantitative Analyzer/automatically inserted by Getein1200/Getein1600 Immunofluorescence Quantitative Analyzer (hereafter referred to as Getein1100, Getein1160, Getein1180, Getein1200 and Getein1600), the concentration of CK-MB and cTnI in 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) CK-MB/cTnI test card in a sealed pouch with desiccant
2) Disposable pipet
3) User manual: 1 piece/kit
4) SD card: 1 piece/kit
5) Whole blood buffer: 1 bottle/kit

2. A kit for Getein1200/Getein1600 contains:
Package specifications: 2×24 tests/kit, 2×48 tests/kit
1) Sealed cartridge with 24/48 Getein CK-MB/cTnI test cards
2) 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/Whole blood buffer composition:
Phosphate buffered saline, proteins, detergent, preservative, stabilizer.

4. A test card consists of:
A plastic shell and a reagent strip which is composed of a sample pad, nitrocellulose membrane (one end of the membrane is coated with a fluorescence latex-labelled anti-human CK-MB and cTnI monoclonal antibodies, these two test lines are coated with another anti-human CK-MB monoclonal antibody and another anti-human cTnI monoclonal antibody, respectively. The control line 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
Getein1180 Immunofluorescence Quantitative Analyzer
Getein1200 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 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 or the cartridge is damaged.
4. Do not open pouches or the cartridge 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, plasma and whole blood samples***. ***Heparin and EDTA*** can be used as the anticoagulant for plasma and whole blood. Samples should be free of hemolysis.
2. Suggest using serum or plasma for better results.
3. Serum or plasma can be used directly. For whole blood sample, one drop of whole blood buffer must be added before testing.
4. 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 (whole blood sample may be stored up to 3 days at 2~8°C).
5. Refrigerated or frozen sample should reach room temperature and be homogeneous before testing. Avoid multiple freeze-thaw cycles.
6. Do not use heat-inactivated samples.
7. ***SAMPLE VOLUME (for Getein1100/Getein1160/Getein 1180): 100 µL***

TEST PROCEDURE

1. Collect specimens according to user manual.
2. Test card, sample and reagent should be brought 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. Remove the test card from the sealed pouch immediately before use. Label the test card with patient or control identification.
3. Put the test card on a clean table, horizontally placed.
4. Using sample transfer pipette, deliver ***100 µL*** of sample into the sample well on the test card (for whole blood sample, one drop of whole blood buffer must be added after loading 100 µL sample on the test card).
5. ***Reaction time: 10 minutes.*** Insert the test card into Getein1100 and press "ENT" button or click on "Start" icon (for Android Getein1100) 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 the sample well on the test card (for whole blood sample, one drop of whole blood buffer must be added after loading 100 μL sample on the test card).
6.Insert the test card into Getein1160/Getein1180 immediately after sample loading. The analyzer will count down the reaction time (10 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.Place the sample diluent at the correct position in Getein 1200/Getein1600.
3.Place samples in the designed area of the sample holder, insert the holder and select the right test item, Getein 1200/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 for Getein1100/Getein1160/Getein 1180.
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.

EXPECTED VALUE

The expected normal value for CK-MB was determined by testing samples from 500 apparently healthy individuals. The 99th percentile of the concentration for CK-MB is 5.00 ng/ml. (The probability that value of a normal person below 5.00 ng/ml is 99%.)

The expected normal value for cTnI was determined by testing samples from 500 apparently healthy individuals. The 99th percentile of the concentration for cTnI is 0.10 ng/ml. (The probability that value of a normal person below 0.10 ng/ml is 99%.)

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

PERFORMANCE CHARACTERISTICS

	Measuring Range	Lower Detection Limit	Within-Run Precision	Between-Run Precision
CK-MB	2.50~80.00ng/ml	≤ 2.50ng/ml	≤ 10%	≤ 15%
cTnI	0.10~50.00ng/ml	≤ 0.10ng/ml		

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	Hemoglobin	Triglyceride	Bilirubin
Concentration (Max)	5 g/L	10 g/L	0.2 g/L

REFERENCES

1. Mauro Pantaghini; Undefined International Federation of Clinical Chemistry and Laboratory Medicine (IFCC). Scientific Division Committee on Standardization of Markers of Cardiac Damage. Clin Chem Lab Med, 1998, 36:887~893.
2. Antman EM, Anbe DT, Armstrong PW, et al. ACC/AHA guidelines for the management of patients with ST-elevation myocardial infarction: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Committee to Revise the 1999 Guidelines for the Manage 2004).
3. EN ISO 18113-1:2011 In vitro diagnostic medical devices-Information supplied by the manufacturer (labeling)-Part 1: Terms, definitions and general requirements.
4. EN ISO 18113-2:2011 In vitro diagnostic medical devices-Information supplied by the manufacturer (labeling)-Part 2: In vitro diagnostic reagents for professional use.

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on CK-MB/cTnI 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
Σ	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 CK-MB/cTnI Fast Test Kit (Immunofluorescence Assay).

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

Version: WIF23-S-13

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

GP

CE IVD

CK-MB
Fast Test Kit
(Immunofluorescence Assay)

IF1018 for Getein1100
IF5018 for Getein1160
IF3018 for Getein1180
REF IF2018 for Getein1600
IF4018 for Getein1200

User Manual

INTENDED USE

CK-MB Fast Test Kit (Immunofluorescence Assay) is intended for *in vitro* quantitative determination of CK-MB in human serum, plasma or whole blood samples. This test is used as an aid in the clinical diagnosis, prognosis and evaluation of myocardial injury such as Acute Myocardial Infarction (AMI), Unstable Angina, Acute Myocarditis and Acute Coronary Syndrome (ACS).

SUMMARY

Creatine kinases are dimer isozymes composed of two monomer subunits, CK-M (for skeletal muscle derived) and CK-B (for brain derived), which can form all three combinations of monomers: CK-BB, CK-MM, and CK-MB. BB is found primarily in the brain. Skeletal muscles primarily contain the MM isoform, with trace amount of MB (around 1-4% of total CK activity). Cardiac muscles also contain the MM isoform, but higher amount of MB, typically around 20% of total CK activity. CK-MB is a more sensitive marker of myocardial injury than total CK activity, because it has a lower basal level and a much narrower normal range. Medical literatures commonly state that CK-MB levels are elevated in 4 to 6 hours, peak at 10 to 24 hours, and return to normal within 3 to 4 days after an acute myocardial infarction. Classically, an increase of the myocardial-specific enzyme CK-MB is considered as the hallmark of acute myocardial infarction, and increased levels are frequently interpreted by the clinician as objective evidence of myocardial cell damage.

PRINCIPLE

Monoclonal antibody against human CK-MB were conjugated with fluorescence latex and another set of anti-human CK-MB monoclonal antibodies were coated on test line. After the sample has been applied to the test strip, the latex-labeled anti-human CK-MB monoclonal antibody will bind with the CK-MB in sample and form marked antigen-antibody complex. This complex move to the test card detection zone by capillary action. Then marked antigen-antibody complex will be captured on test line by another set of monoclonal antibody against human CK-MB resulting in purplish red streaks appear on the test line. The color intensity of test line increases in proportion to the amount of CK-MB in sample.

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 concentrations of CK-MB in sample will be determined 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 LIS and HIS.

CONTENTS

1. A kit for Getein1100/Getein1160/Getein1180 contains:
Package specifications: 25 tests/kit, 10 tests/kit
1) CK-MB test card in a sealed pouch with desiccant
2) Disposable pipet
3) User manual: 1 piece/kit
4) SD card: 1 piece/kit
5) Whole blood buffer: 1 bottle/kit

2. A kit for Getein1200/Getein1600 contains:
Package specifications: 2×24 tests/kit, 2×48 tests/kit
1) Sealed cartridge with 24/48 Getein CK-MB test cards
2) 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/Whole blood buffer composition:
Phosphate buffered saline, proteins, detergent, preservative, stabilizer.

4. A test card consists of:
A plastic shell and a reagent strip which is composed of a sample pad, nitrocellulose membrane (one end of the membrane is coated with a fluorescence latex-labelled anti-human CK-MB monoclonal antibody, the test line is coated with another anti-human CK-MB monoclonal antibody and the control line 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 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 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, plasma and whole blood samples.Heparin and sodium citrate*** can beused as the anticoagulant for plasma and whole blood. Samples should be free of hemolysis.
2. Suggest using serum or plasma for better results.
3. Serum or plasma can be used directly. For whole blood sample, one drop of whole blood buffer must be added before testing.
4. 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 (whole blood sample may be stored up to 3 days at 2~8°C).
5. Refrigerated or frozen sample should reach room temperature and be homogeneous before testing. Avoid multiple freeze-thaw cycles.
6. Do not use heat-inactivated samples.
7. SAMPLE VOLUME ***(for Getein1100/Getein1160/Getein1180): 100 µL.***

TEST PROCEDURE

1. Collect specimens according to user manual.
2. Test card, sample should be brought 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. Remove the test card from the sealed pouch immediately before use. Label the test card with patient or control identification.
3. Put the test card on a clean table, horizontally placed.
4. Using sample transfer pipette, deliver ***100 µL*** of sample into the sample well on the test card (for whole blood sample, one drop of whole blood buffer must be added after loading ***100 µL*** sample on the test card).
5. ***Reaction time: 10 minutes.*** Insert the test card into Getein1100 and press "ENT" button or click on “Start” icon (for Android Getein 1100) 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 the sample well on the test card (for whole blood sample, one drop of whole blood buffer must be added after loading ***100 μL*** sample on the test card).
6. Insert the test card into Getein1160/Getein1180 immediately after sample loading. The analyzer will count down the reaction time (10 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. Place 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 for Getein1100/Getein1160/ Getein1180.
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.

EXPECTED VALUE

The expected normal value for CK-MB was determined by testing samples from 500 apparently healthy individuals. The 99th percentile of the concentration for CK-MB is 5.00 ng/ml. CK-MB concentration less than 5.00 ng/ml can be estimated as normal.

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

PERFORMANCE CHARACTERISTICS

Measuring Range	2.50~80.00 ng/ml
Lower Detection Limit	≤ 2.50 ng/ml
Within-Run Precision (n=10)	≤ 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	Hemoglobin	Triglyceride	Bilirubin
Concentration (Max)	5 g/L	10 g/L	0.2 g/L

REFERENCES

1. Mauro Pantaghini; Undefined International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) Scientific Division Committee on Standardization of Markers of Cardiac Damage. Clin Chem Lab Med, 1998, 36:887~893.
2. Antman EM, Anbe DT, Armstrong PW, et al. ACC/AHA guidelines for the management of patients with ST-elevation myocardial infarction: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Committee to Revise the 1999 Guidelines for the Manage 2004).
3. EN ISO 18113-1:2011 In vitro diagnostic medical devices - Information supplied by the manufacturer (labeling) - Part 1: Terms, definitions and general requirements.
4. EN ISO 18113-2:2011 In vitro diagnostic medical devices - Information supplied by the manufacturer (labeling) - Part 2: In vitro diagnostic reagents for professional use.

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on CK-MB Fast Test Kit (Immunofluorescence Assay) are the most common ones appearing on medical devices and their packaging. They are explained in more detail 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 CK-MB Fast Test Kit (Immunofluorescence Assay).

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

Version: WIF28-S-11

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

CE IVD

Cardiac Troponin I

Fast Test Kit

(Immunofluorescence Assay)

User Manual

Getein1100: Cat.# IF1001
Getein1600: Cat.# IF2001

INTENDED USE

Cardiac Troponin I Fast Test Kit (Immunofluorescence Assay) is intended for *in vitro* quantitative determination of Cardiac Troponin I (cTnI) in serum, plasma or whole blood. This test is used as an aid in the diagnosis of myocardial injury such as Acute Myocardial Infarction (AMI), Unstable Angina, Acute Myocarditis and Acute Coronary Syndrome (ACS).

SUMMARY

Troponin, a molecular complex that is bound to the thin filament (actin) of striated muscle fibers, acts with intracellular calcium to control the interaction of the thin filament with the thick filament (myosin), thus regulating muscle contraction. Troponin consists of three regulatory proteins: T, which connects the troponin complex and tropomyosin (another cardiac muscle regulatory protein); I, which prevents muscle contraction in the absence of calcium; C, which binds calcium. Cardiac Troponin I (MW 22.5 kDa) and the two skeletal muscle isoforms of Troponin I have considerable amino acid sequence homology, but cTnI contains an additional N-terminal sequence and is highly specific for myocardium.

Clinical studies have demonstrated the release of cTnI into the blood stream within hours following acute myocardial infarction (AMI) or ischemic damage. Elevated levels of cTnI are detectable in blood within 4 to 6 hours after the onset of chest pain, reaching peak concentrations in approximately 8 to 28 hours, and remain elevated for 3 to 10 days following AMI. Due to the high myocardial specificity and the long duration of elevation, cTnI has become an important marker in the diagnosis and evaluation of patients suspected of having an AMI.

The current guideline of The Joint European Society of Cardiology/ American College of Cardiology Committee support the use of cTnI as a preferred marker of myocardial injury. Several major studies have shown that cTnI is also a predictor of cardiac risk in patients with unstable angina. The American College of Cardiology and the American Heart Association's current guidelines recommend using troponin results when making treatment decisions regarding unstable angina and non-ST segment elevation MI (NSTEMI).

PRINCIPLE

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

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

CONTENTS

1. A kit for Getein1100 contains:
   Getein cTnI test card in a sealed pouch with desiccant 25
   Disposable pipet 25
   Whole blood buffer 1
   SD card 1
   User manual 1
2. A kit for Getein1600 contains:
   Sealed cartridge with 24/48 Getein cTnI test cards 2
   User manual 1
   Package specifications:
   2×24 tests/kit, 2×48 tests/kit
   Materials required for Getein1600:
   Sample diluent 1
   Box with pipette tips 1
   Mixing plate 1
3. Sample diluent/Whole blood buffer composition:
   Phosphate buffered saline, proteins, detergent, preservative, stabilizer.
4. A test card consists of:
   A plastic shell and a reagent strip which is composed of a sample pad, nitrocellulose membrane (one end of the membrane is coated with a fluorescence latex-labelled anti-human cTnI monoclonal antibody, the test line is coated with another anti-human cTnI monoclonal antibody, and the control line 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
Getein1600 Immunofluorescence Quantitative Analyzer

STORAGE AND STABILITY

Store the test card at 4~30℃ with a valid period of 24 months. Use the test card for Getein1100 within 1 hour once the foil pouch is opened.

For test card of Getein1600: 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.

Store the sample diluent/whole blood buffer at 0~30℃ with a valid period of 24 months.

Store the sample diluent/whole blood buffer at 2~8℃ for better results.

PRECAUTIONS

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

SPECIMEN COLLECTION AND PREPARATION

1. This test can be used for ***serum, plasma and whole blood samples. Heparin and sodium citrate*** should be used as the anticoagulant for plasma and whole blood. Samples should be free of hemolysis.

2. Suggest using serum or plasma for better results.
3. Serum or plasma can be used directly. For whole blood sample, one drop of whole blood buffer must be added before testing.
4. If testing will be delayed, serum and plasma samples may be stored up to 7 days at 2~8℃ or stored at -20℃ for 6 months before testing (whole blood sample may be stored up to 3 days at 2~8℃).
5. Refrigerated or frozen sample should reach room temperature and be homogeneous before testing. Avoid multiple freeze-thaw cycles.
6. Do not use heat-inactivated samples.
7. SAMPLE VOLUME *(for Getein1100): 100 µl*.

TEST PROCEDURE

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

For Getein1100:

3. Confirm SD card lot No. in accordance with test kit lot No.. Perform “SD Card Calib” calibration when necessary (Details refer to 8.5.2 of Getein1100 User Manual).
4. On the main interface of Getein1100, press "ENT" button to enter testing interface.
5. Remove the test card from the sealed pouch immediately before use. Label the test card with patient or control identification.
6. Put the test card on a clean table, horizontally placed.
7. Using sample transfer pipette, deliver *100 µl* of sample (or 3~4 drops of sample when using disposable pipet) into the sample port on the test card (for whole blood sample, one drop of whole blood buffer must be added after loading 100 µl sample on the test card).
8. *Reaction time: 10 minutes.* Insert the test card into Getein1100 and press "ENT" button after reaction time is elapsed. The result will be shown on the screen and printed automatically.

For Getein1600:

9. Each cartridge for Getein1600 contains a specific RFID card which can calibrate automatically.
10. Place samples in the designed area of the sample holder, insert the holder and select the right test item, Getein1600 will do the testing and print the result automatically.

Notes:

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

TEST RESULTS

Getein1100/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/Getein1600.

EXPECTED VALUE

The expected normal value for Troponin I was determined by testing samples from 500 apparently healthy individuals. The 99th percentile of the concentration for cTnI is 0.1 ng/ml. (The probability that value of a normal person below 0.1 ng/ml is 99%.)
It is recommended that each laboratory establish its own expected values for the population it serves.

PERFORMANCE CHARACTERISTICS

Measuring Range	0.1~50 ng/ml
Lower Detection Limit	≤ 0.1 ng/ml
Within-Run Precision	≤10%
Between-Run Precision	≤15%

Method Comparison:

The assay was compared with SIEMENS IMMULITE 2000 and its matching cTnI test kits with 200 serum samples (60 positive samples and 140 negative samples). The correlation coefficient (r) for cTnI is 0.952.

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. Samples containing interferents may influence the results. The table below listed the maximum allowance of these potential interferents.

Interferent	Hemoglobin	Triglyceride	Bilirubin
Concentration (Max)	5 g/L	10 g/L	0.2 g/L

REFERENCES

1. Mauro Pantaghini. Undefined International Federation of Clinical Chemistry and Laboratory Medicine (IFCC). Scientific Division Committee on Standardization of Markers of Cardiac Damage. Clin Chem Lab Med, 1998, 36:887~893.
2. Antman EM, Anbe DT, Armstrong PW, et al. ACC/AHA guidelines for the management of patients with ST-elevation myocardial infarction: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Committee to Revise the 1999 Guidelines for the Manage 2004).
3. EN ISO 18113-1:2009 *In vitro* diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements.
4. EN ISO 18113-2:2009 *In vitro* diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: *In vitro* diagnostic reagents for professional use (ISO 18113-2:2009).

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on Cardiac Troponin I 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 980:2008 and International Standard ISO 15223-1:2007.

Key to symbols used			
	Manufacturer		Expiration date
	Do not reuse		Date of manufacture
	Consult instructions for use	LOT	Batch code
	Temperature limitation	IVD	*In vitro* diagnostic medical device
Σ	Sufficient for	EC REP	Authorized representative in the European Community
CE	CE mark		Do not use if package is damaged

Thank you for purchasing Cardiac Troponin I Fast Test Kit (Immunofluorescence Assay). Please read this user manual carefully before operating to ensure proper use.

Version: WIF02-S-02

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.bio-GP.com.cn

CE IVD

D-Dimer

Fast Test Kit

(Immunofluorescence Assay)

User Manual

Getein1100: Cat.# IF1006
Getein1600: Cat.# IF2006

INTENDED USE

D-Dimer Fast Test Kit (Immunofluorescence Assay) is intended for *in vitro* quantitative determination of D-Dimer in plasma or whole blood. The test is used as an aid in the assessment and evaluation of patients suspected of deep-vein thrombosis or pulmonary embolism.

SUMMARY

Deep-vein thrombosis is a common condition, with a lifetime cumulative incidence of 2 to 5 percent. Untreated deep-vein thrombosis can result in pulmonary embolism, a potentially fatal outcome. Anticoagulant therapy reduces both morbidity and mortality from venous thromboembolism, and early diagnosis is therefore important. Accurate diagnosis of deep-vein thrombosis minimizes the risk of thromboembolic complications and averts the exposure of patients without thrombosis to the risks of anticoagulant therapy.

D-Dimer is a marker of endogenous fibrinolysis and should therefore be detectable in patients with deep-vein thrombosis. In recent years, an increasing number of studies have shown the D-Dimer assay has a high negative predictive value and D-Dimer is a sensitive but nonspecific marker of deep-vein thrombosis. Negative D-Dimer can exclude deep-vein thrombosis and pulmonary embolism.

PRINCIPLE

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

Then insert test card into Getein1100 Immunofluorescence Quantitative Analyzer/Getein1600 Immunofluorescence Quantitative Analyzer (hereinafter referred to as Getein1100 and Getein1600), the concentration of D-Dimer in sample will be measured and displayed on the screen. The value will be stored in Getein1100/Getein1600 and available for downloading. The result can be easily transmitted to the laboratory or hospital information system.

CONTENTS

1. A kit for Getein1100 contains:
   Getein D-Dimer test card in a sealed pouch with desiccant 25
   Disposable pipet 25
   Sample diluent 25
   SD card 1
   User manual 1
2. A kit for Getein1600 contains:
   Sealed cartridge with 24/48 Getein D-Dimer test cards 2
   User manual 1
   Package specifications:
   2×24 tests/kit, 2×48 tests/kit
   Materials required for Getein1600:
   Sample diluent 1
   Box with pipette tips 1
   Mixing plate 1
3. Sample diluent composition:
   Phosphate buffered saline, proteins, detergent, preservative, stabilizer.
4. A test card consists of:
   A plastic shell and a reagent strip which is composed of a sample pad, nitrocellulose membrane (one end of the membrane is coated with a fluorescence latex-labelled anti-human D-Dimer monoclonal antibody, the test line is coated with another anti-human D-Dimer monoclonal antibody and the control line 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
Getein1600 Immunofluorescence Quantitative Analyzer

STORAGE AND STABILITY

Store the test card at 4~30℃ with a valid period of 24 months. Use the test card for Getein1100 within 1 hour once the foil pouch is opened.

For test card of Getein1600: 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.

Store the sample diluent/whole blood buffer at 0~30℃ with a valid period of 24 months.

Store the sample diluent/whole blood buffer at 2~8℃ for better results.

PRECAUTIONS

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

SPECIMEN COLLECTION AND PREPARATION

1. This test can be used for ***plasma and whole blood samples.*** ***Sodium citrate*** can be used as the anticoagulant for plasma and whole blood. Samples should be free of hemolysis.
2. Suggest using plasma for better results.
3. If testing will be delayed, plasma sample may be stored up to 3 days at 2~8℃ or stored at -20℃ for 1 month before testing (whole blood sample may be stored up to 3 days at 2~8℃).
4. Refrigerated or frozen sample should reach room temperature

and be homogeneous before testing. Avoid multiple freeze-thaw cycles.
5. Do not use heat-inactivated samples.
6. SAMPLE VOLUME *(for Getein1100): 100 µl*.

TEST PROCEDURE

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

For Getein1100:

3. Confirm SD card lot No. in accordance with test kit lot No.. Perform “SD Card Calib” calibration when necessary (Details refer to 8.5.2 of Getein1100 User Manual).
4. On the main interface of Getein1100, press "ENT" button to enter testing interface.
5. Remove the test card from the sealed pouch immediately before use. Label the test card with patient or control identification.
6. Put the test card on a clean table, horizontally placed.
7. 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 (or 3~4 drops of sample when using disposable pipet) into the sample port on the test card.
8. *Reaction time: 10 minutes.* Insert the test card into Getein1100 and press "ENT" button after reaction time is elapsed. The result will be shown on the screen and printed automatically.

For Getein1600:

9. Each cartridge for Getein1600 contains a specific RFID card which can calibrate automatically.
10. Place samples in the designed area of the sample holder, insert the holder and select the right test item, Getein1600 will do the testing and print the result automatically.

Notes:

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

TEST RESULTS

Getein1100/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/Getein1600.

EXPECTED VALUE

The expected normal value for D-Dimer was determined by testing samples from 500 apparently healthy individuals. The 95th percentile of the concentration for D-Dimer is 0.5 mg/L. (The probability that value of a normal person below 0.5 mg/L is 95%.)

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

PERFORMANCE CHARACTERISTICS

Measuring Range	0.1~10.0 mg/L
Lower Detection Limit	≤0.1 mg/L
Within-Run Precision	≤10%
Between-Run Precision	≤15%

Method Comparison:

The assay was compared with SIEMENS CA-7000 and its matching D-Dimer test kits with 200 plasma samples (60 positive samples and 140 negative samples). The correlation coefficient (r) for D-Dimer is 0.978.

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. Samples containing interferents such as rheumatoid factor, human anti-mouse antibody and heterophile antibody may influence the results. In this case, results of this test should be used in conjunction with clinical findings and other tests. The table below listed the maximum allowance of these potential interferents.

Interferent	Hemoglobin	Triglyceride	Bilirubin
Concentration (Max)	5 g/L	25 g/L	0.1 g/L

REFERENCES

1. Sarig G, Klil-Drori AJ, Chap-Marshak D, Brenner B, Drugan A. Activation of coagulation in amniotic fluid during normal human pregnancy.Thromb Res. 2011 Apr 18.
2. Roldán V, Marín F, Muiña B, Torregrosa JM, Hernández-Romero D, Valdés M, Vicente V, Lip GY. Plasma von Willebrand Factor Levels Are an Independent Risk Factor for Adverse Events Including Mortality and Major Bleeding in Anticoagulated Atrial Fibrillation Patients. J Am Coll Cardiol. 2011 Apr 11.
3. Sakamoto K, Yamamoto Y, Okamatsu H, Okabe M. D-dimer is helpful for differentiating acute aortic dissection and acute pulmonary embolism from acute myocardial infarction. Hellenic J Cardiol. 2011 Mar-Apr; 52(2):123-127.
4. EN ISO 18113-1:2009 *In vitro* diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements.
5. EN ISO 18113-2:2009 *In vitro* diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: *In vitro* diagnostic reagents for professional use (ISO 18113-2:2009).

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on D-Dimer 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 980:2008 and International Standard ISO 15223-1:2007.

Key to symbols used			
	Manufacturer		Expiration date
	Do not reuse		Date of manufacture
	Consult instructions for use	LOT	Batch code
	Temperature limitation	IVD	*In vitro* diagnostic medical device
	Sufficient for	EC REP	Authorized representative in the European Community
CE	CE mark		Do not use if package is damaged

Thank you for purchasing D-Dimer Fast Test Kit (Immunofluorescence Assay). Please read this user manual carefully before operating to ensure proper use.

Version: WIF05-S-02

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.bio-GP.com.cn

CE IVD

Ferritin

Fast Test Kit

(Immunofluorescence Assay)

User Manual

REF IF1077 for Getein1100
IF3077 for Getein1180
IF2077 for Getein1600

INTENDED USE

Ferritin Fast Test Kit (Immunofluorescence Assay) is intended for in vitro quantitative determination of ferritin in human serum and plasma samples. It can be used as an aid in the quantification of human ferritin and the diagnosis of iron deficiency anemia or iron overload related diseases.

SUMMARY

Ferritin has a molecular weight of 440 kD, depending on the iron content, and consists of a protein shell (apoferritin) that is composed of 24 subunits and an iron core containing an average of 2500 Fe^{3+} ions.
Latent iron deficiency is defined as a fall below the 12 ng/mL ferritin threshold. The two values are diagnostic even when the blood picture is still morphologically normal. A depressed ferritin level accompanied by hypochromic, microcytic anemia indicates manifest iron deficiency.
Elevated ferritin values are also encountered with the following tumors: acute leukemia, Hodgkin's disease and carcinoma of the lung, colon, liver, and prostate. Ferritin determinations have also proved to be of value in liver metastasis. Reasons for the elevated values could be cell necrosis, blocked erythropoiesis or increased synthesis in tumor tissue.

PRINCIPLE

The test uses an anti-human ferritin monoclonal antibody Ⅰ conjugated with fluorescence latex coated on the sample pad and another anti-human ferritin monoclonal antibody Ⅱ coated on the test line. After the sample has been applied to the test strip, the fluorescence latex-labelled anti-human ferritin antibody Ⅰ binds with the ferritin in sample and forms marked antigen-antibody complex. This complex moves to the test card detection zone by capillary action. Then marked antigen-antibody complex is captured on the test line by anti-human ferritin antibody Ⅱ. The fluorescence intensity of test line increases in proportion to the amount of ferritin in sample.
Then insert test card into Getein1100/Getein1180 Immunofluorescence Quantitative Analyzer/automatically inserted by Getein1600 Immunofluorescence Quantitative Analyzer (hereafter referred to as Getein1100, Getein1180 and Getein1600), the concentration of ferritin in sample will be measured and displayed on the screen. The value will be stored in Getein1100/Getein1180/Getein1600 and available for downloading. The result can be easily transmitted to the laboratory or hospital information system.

CONTENTS

1. A kit for Getein1100/1180 contains:
Package specifications: 25 tests/box, 10 tests/box
1) Getein Ferritin test card in a sealed pouch with desiccant
2) Capillary pipet
3) Sample diluent
4) User manual: 1 piece/box
5) SD card: 1 piece/box
2. A kit for Getein1600 contains:
Package specifications: 2×24 tests/box, 2×48 tests/box
Sealed cartridge with 24/48 Getein Ferritin test cards
User manual: 1 piece/box
Materials required for Getein1600:
1) Sample diluent: 1 bottle/box
2) Box with pipette tips: 96 tips/box
3) Mixing plate: 1 piece/box
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 (the end of pad is coated with fluorescence latex-labelled anti-human Ferritin monoclonal antibody Ⅰ), nitrocellulose membrane (test line is coated with another Ferritin monoclonal antibody Ⅱ and the control line C is coated with goat anti-mouse IgG antibody), absorbent paper and liner.
Note: Do not mix or interchange different batches of kits.

APPLICABLE DEVICE

Getein1100 Immunofluorescence Quantitative Analyzer
Getein1180 Immunofluorescence Quantitative Analyzer
Getein1600 Immunofluorescence Quantitative Analyzer

STORAGE AND STABILITY

Store the test card at 4~30°C with a valid period of 24 months. Use the test card for Getein1100/Getein1180 within 1 hour once the foil pouch is opened.
For test card of Getein1600: 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.
Store the sample diluent at 0~30°C with a valid period of 24 months.
Store the sample diluent at 2~8°C for better results.

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 hand-ling 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. Suggest using serum or plasma for better results.
3. If testing is delayed, serum and plasma samples may be stored up to 5 days at 2~8°C or stored at -20°C for 6 months before testing.
4. Refrigerated or frozen sample should reach room temperature and be homogeneous before testing. Avoid multiple freeze-thaw cycles.
5. Do not use heat-inactivated samples or hemolysis samples.
6. Sample volume (for Getein1100/Getein1180): ***10 μL.***

TEST PROCEDURE

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

For Getein1100:

3. Confirm SD card lot No. in accordance with test kit lot No.. Perform "SD card" calibration when necessary.
4. Enter testing interface of Getein1100.
5. Remove the test card from the sealed pouch immediately before use. Label the test card with patient or control identification.

6. Put the test card on a clean table, horizontally placed.
7. Using disposable pipet, deliver ***10 μL*** of sample into one tube of sample diluent, mix gently and thoroughly. Then drop ***100 μL*** of sample mixture into the sample port on the test card.
8. ***Reaction time: 15 minutes.*** Insert the test card into Getein1100 and start test after reaction time is elapsed. The result will be shown on the screen and printed automatically.

For Getein1180:

9. Confirm SD card lot No.in accordance with test kit lot No..Perform "SD card"calibration when necessary.
10. Enter testing interface of Getein1180.
11. Remove the test card form the sealed pouch immediately before use.Label the test card with patient or control identification.
12. Put the test card on a clean table,horizontally placed.
13. Using disposable pipet, deliver ***10 μL*** of sample into one tube of sample diluent, mix gently and thoroughly. Then drop ***100 μL*** of sample mixture into the sample port on the test card.
14. ***Reaction time: 15 minutes***. Insert the test card into Getein1180 immediately after sample loading. The analyzer will count down the reaction time and automatically test the card after reaction time is elapsed. The result will be shoe on the screen and printed automatically.

For Getein1600:

15. Each cartridge for Getein1600 contains a specific RFID card which can calibrate automatically.
16. Place samples in the designed area of the sample holder, insert the holder and select the right test item, 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/Getein1180.
3. Make sure the test card insertion is correct and complete.

TEST RESULTS

Getein1100/Getein1180/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/Getein1180/Getein1600.

Others: Dilute the sample which concentration is higher than the upper limit with negative samples, and the dilution ratio should be less than 50 times.

EXPECTED VALUE

The expected normal value for ferritin was determined by testing samples from apparently healthy male and women.

Group	Age	N	95% Reference Interval(ng/mL)
Male	20-60	254	30.00-400.00
Female	17-60	205	13.00-150.00

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

PERFORMANCE CHARACTERISTICS

Measuring Range	0.50 ~1000.00 ng/mL
Lower Detection Limit	≤0.50 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. Samples containing interferent may influence the results. The table below listed the maximum allowance of these potential interferent.

Interferent	Triglyceride	Bilirubin
Concentration(Max)	20g/L	0.1g/L

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3.Kell D B , Pretorius E . Serum ferritin is an important inflammatory disease marker, as it is mainly a leakage product from damaged cells[J]. Metallomics,

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DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on Ferritin 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 15223-1:2016.

Key to symbols used			
	Manufacturer		Use-by date
	Do not re-use		Date of manufacture
	Consult 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
	CE mark		Do not use if package is damaged
REF	Catalogue number		

Thank you for purchasing Ferritin Fast Test Kit (Immunofluorescence Assay).
Please read this user manual carefully before operating to ensure proper use.

Version: WIF84-S-05

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: en.bio-gp.com.cn

EC REP Lotus NL B.V.
Add: Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.
E-mail: peter@lotusnl.com
Tel: +31644168999

GP

IVD

fPSA Fast Test Kit

(Immunofluorescence Assay)

IF1072 for Getein 1100
IF5072 for Getein 1160
IF3072 for Getein 1180
REF IF2072 for Getein 1600
IF4072 for Getein 1200

Instructions for Use

INTENDED USE

fPSA Fast Test Kit (Immunofluorescence Assay) is intended for in vitro quantitative determination of free PSA in human serum and plasma samples. It is mainly used for dynamic monitoring of patients with malignant tumors to assist in judging the disease process or treatment effect. It cannot be used as a basis for early diagnosis of malignant tumors, and is not suitable for tumor screening in the general population.

This assay is intended to be used in conjunction with the Getein total PSA test as an aid in distinguishing prostate cancer from benign prostatic conditions in men age 50 years or older who have a digital rectal examination (DRE) that is not suspicious for prostate cancer and the Getein total PSA value between 4 ng/mL and 10 ng/mL.

SUMMARY

Prostate-specific antigen (PSA) is a single-chain glycoprotein with molecular weight of 34 kilodaltons. As a serine protease with chymotrypsin-like activity, PSA belongs to the kallikrein family. PSA exists as a free or complex form with protease inhibitors such as α-1-anti-chymotrypsin (ACT) in blood. PSA is produced mainly by the glandular epithelium of the prostate and is secreted into the seminal fluid in high concentrations. Low levels of PSA are found in the blood as a result of leakage of PSA from the prostate gland. The function of PSA is the proteolytic cleavage of gel forming proteins in the seminal fluid resulting in liquification of the seminal gel and increased sperm mobility.

PSA tests lack sufficient sensitivity and specificity to be considered ideal or absolutely diagnostic for screening or early detection because PSA is not specific for prostate cancer. PSA is organ specific, but has long been known to be elevated in non-malignant conditions such as benign prostatic hyperplasia (BPH). A number of studies have found that the percent of free PSA was significantly lower in patients having prostate cancer than those with benign disease or normal controls. The ratio fPSA/tPSA has subsequently been demonstrated to improve the sensitivity and specificity in patients with tPSA values in the "gray zone" of 4-10 ng/mL.

An equimolar tPSA determination is the prerequisite for reliable ratios. In patients receiving therapy, particularly hormone withdrawal therapy, the fPSA/tPSA ratio cannot be utilized to differentiate prostate hyperplasia from cancer of the prostate. Combining tests from different manufacturers to determine tPSA and fPSA can produce erroneous values, since total PSA tests may be standardized by differing methods or detect free PSA to differing degrees.

PRINCIPLE

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

Then insert test card into Getein 1100/Getein 1160/Getein 1180 Immunofluorescence Quantitative Analyzer/Automatically inserted by Getein 1200/Getein 1600 Immunofluorescence Quantitative Analyzer (hereafter referred to as Getein 1100, Getein 1160, Getein 1180, Getein 1200 and Getein 1600), the concentration of fPSA in sample will be measured and displayed on the screen. The value will be stored in Getein 1100/Getein 1160/Getein 1180/Getein 1200/Getein 1600 and available for downloading. The result can be easily transmitted to the laboratory or hospital information system.

CONTENTS

1. A kit for Getein 1100/Getein 1160/Getein 1180 contains:
Package specifications: 25 tests/kit, 10 tests/kit
1) Getein fPSA test card in a sealed pouch with desiccant
2) Disposable pipet
3) Sample diluent
4) Instructions for use: 1 piece/kit
5) SD card: 1 piece/kit

2. A kit for Getein 1200/Getein 1600 contains:
Package specifications: 2×24 tests/kit, 2×48 tests/kit
Sealed cartridge with 24/48 Getein fPSA test cards
Instructions for use: 1 piece/kit

Materials required for Getein 1200/Getein 1600:
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 (the junction of sample pad and nitrocellulose membrane is coated with fluorescence latex-labeled anti-human fPSA monoclonal antibody Ⅰ), nitrocellulose membrane (the test line is coated with another anti-human fPSA monoclonal antibody Ⅱ and the control line is coated with goat anti-mouse IgG antibody), absorbent paper and liner.

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

APPLICABLE DEVICE

Getein 1100 Immunofluorescence Quantitative Analyzer
Getein 1160 Immunofluorescence Quantitative Analyzer
Getein 1200 Immunofluorescence Quantitative Analyzer
Getein 1180 Immunofluorescence Quantitative Analyzer
Getein 1600 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 Getein 1100/Getein 1160/Getein 1180 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 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. For professional use only.
3. Do not use the kit beyond the expiration date.
4. Do not use the test card if the foil pouch or the cartridge is damaged.
5. Do not open pouches or the cartridge until ready to perform the test.
6. Do not reuse the test card.
7. Do not reuse the pipet.
8. Handle all specimens as potentially infectious. Proper handling and disposal methods should be followed in accordance with local regulations.
9. Carefully read and follow instructions for use to ensure proper test performance.

SPECIMEN COLLECTION AND PREPARATION

1. This test can be used for ***serum and plasma samples***, other bodily fluids may cause incorrect or inaccurate results.
2. **Heparin, sodium citrate and EDTA** can be used as the anticoagulant for plasma. Samples should be free of hemolysis.
3. The test should be performed within 4 hours after blood collection. If testing is delayed, serum and plasma samples may be stored up to 5 days at 2~8°C or stored at -20°C for 6 months before testing.
4. Refrigerated or frozen sample should reach 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. Collect specimens according to instructions for use.
2. Test card, sample and reagent should reach to room temperature before test.

For Getein 1100:
1. Confirm SD card lot No. in accordance with test kit lot No. Perform "SD card" calibration when necessary.
2. Remove the test card from the sealed pouch immediately before use. Label the test card with patient or control identification.
3. Put the test card on a clean table, horizontally placed.
4. 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.

5. ***Reaction time: 10 minutes.*** Insert the test card into Getein1100 and start test after reaction time is elapsed. The result will be shown on the screen and printed automatically.

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. Enter testing interface of Getein 1160/Getein 1180.
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 Getein 1160/Getein 1180 immediately after sample loading. The analyzer will count down the reaction time (10 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. Place the sample diluent at the correct position of Getein 1200/Getein 1600.
3. Place samples in the designed area of the sample holder, insert the holder and select the right test item, 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 is correct and complete.

TEST 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 instructions for use of Getein 1100/Getein 1160/Getein 1180/Getein 1200/Getein 1600.

Others: Measuring range of the fPSA test kit is 0.03-30.00 ng/mL. Dilute the sample which concentration is higher than the upper limit with negative samples, and the dilution ration should be less than 4 times.

EXPECTED VALUE

The expected normal value for free PSA was determined by testing samples from 250 apparently healthy individuals. The reference range of free PSA is 1.00 ng/mL calculated by using normal distribution methods (95th percentile).

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

PERFORMANCE CHARACTERISTICS

Measuring Range	0.03-30.00 ng/mL
Lower Detection Limit	≤ 0.03 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 interferent.

Interferent	Triglyceride	Bilirubin
Concentration (Max)	25 g/L	0.6 g/L

REFERENCES

1. Chen R, Huang Y, Cai X, et al. Age-Specific Cutoff Value for the Application of Percent Free Prostate-Specific Antigen (PSA) in Chinese Men with Serum PSA Levels of 4.0-10.0 ng/ml. PLoS One. 2015, 10 (6): e0130308.
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4. Salman J W, Schoots I G , Carlsson S V , et al. Prostate Specific Antigen as a Tumor Marker in Prostate Cancer: Biochemical and Clinical Aspects. Advances in Experimental Medicine and Biology, 2015, 867:93-114.

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on fPSA 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		Do not use if package is damaged and consult *instructions for use*
REF	Catalogue number		

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

Please read this instructions for use carefully before operating to ensure proper use.

Version: WIF74-S-07

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

GP

CE IVD

FSH

Fast Test Kit

(Immunofluorescence Assay)

IF1056 for Getein 1100
IF5056 for Getein 1160
IF3056 for Getein 1180
IF2056 for Getein 1600
IF4056 for Getein 1200

Instructions for Use REF

INTENDED USE

FSH Fast Test Kit (Immunofluorescence Assay) is intended for *in vitro* quantitative determination of FSH in human serum and plasma. The test is used as an auxiliary diagnosis for evaluating pituitary endocrine function and ovarian diseases. For professional and laboratory use only.

SUMMARY

Follicle stimulating hormone (FSH) is one of the hormones essential to pubertal development and the function of women's ovaries and men's testes. Like other glycoproteins, such as LH, TSH and HCG, FSH consists of subunits designated as alpha and beta. Hormones of this type have alpha subunits that are very similarly structurally, therefore the biological and immunological properties of each are dependent on the unique beta subunit.

In women, this hormone stimulates the growth of ovarian follicles in the ovary before the release of an egg from one follicle at ovulation. FSH levels are elevated after menopause, castration and in premature ovarian failure. In men, FSH stimulates seminiferous tubule testicular growth, and is involved in the early stages of spermatogenesis. Oligospermic males usually have elevated FSH levels. High levels of FSH in men may be found in primary testicular failure and Kinefelter syndrome. Elevated concentrations are also present in cases of starvation, renal failure, hyperthyroidism and cirrhosis.

FSH is a useful marker in the study of pituitary diseases, classification of pituitary tumors, and the differential diagnosis of primary and metastatic tumors of the pituitary.

PRINCIPLE

FSH Fast Test Kit (Immunofluorescence Assay) is a lateral flow immunoassay designed in a sandwich format. After the sample is applied to the test strip, the fluorescence-labelled FSH monoclonal antibody binds with the FSH in the sample to form a marked antigen-antibody complex. This complex moves to the detection zone on the test card by capillary action and is captured by another FSH monoclonal antibody. The fluorescence intensity of the test line increases in proportion to the amount of FSH in the sample. The fluorescent signal intensity can then be analyzed by an appropriate device to quantitatively detect the FSH in the sample.

APPLICABLE DEVICE

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

* FSH test card

A test card mainly consists of: Fluorescence-labelled FSH monoclonal antibody, FSH monoclonal antibody.

Consumables for Getein 1200/ 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 exposure to air. The valid period after opening is 7 days, it is recommended to put the cartridge back to the foil bag and reseal along the entire edge of zip-seal if not used up.

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 or the cartridge is damaged.
4. Do not open pouches or the cartridge until ready to perform the test.
5. Do not reuse the test card or pipet.
6. Handle all specimens as potentially infectious. Proper handling and disposal methods should be followed in accordance with local regulations.
7. Carefully read and follow instructions for use 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 and plasma 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 reach room temperature and be homogeneous before testing. Avoid multiple freeze thaw cycles.
5. Do not use heat-inactivated samples or hemolysis samples.
6. Sample volume (**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 "SD card" calibration when necessary.
2) Select the corresponding "Sample" on the analyzer according to the sample type (see the user manual of analyzer for details).
3) Remove the test card from the sealed pouch before use and put the test card on a clean table, horizontally placed.
4) Use disposable pipet or pipette to drop 100 µL of sample into the sample well on the test card.
5) Reaction time: **15 minutes**. Insert the test card into Getein 1100 and click on "Start" icon after reaction time is elapsed. The result will be shown on the screen and printed automatically.

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" on the analyzer according to the sample type (see the instructions of analyzer for details).
3) Remove the test card from the sealed pouch immediately before use and put the test card on a clean table, horizontally placed.
4) Use disposable pipet or pipette to drop 100 µL of sample into the sample well 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 displayed 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 consumables 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 insertion of test card and the sample are correct and complete.

TEST 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.

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. Some substances in blood as listed below may interfere with the test and cause erroneous results. The maximum allowance concentration of each is as follows:

Interferent	Concentration (Max)
Triglyceride	20.32 mmol/L
Bilirubin	171.0 umol/L
Hemoglobin	300mg/dL
Human serum albumin	3 g/dL

EXPECTED VALUE

The expected normal value for FSH was determined by testing blood samples from apparently healthy individuals. Reference range of FSH:

Group	No.		Reference Range (mIU/mL)
Male	220		1.22-19.25
Female	Mid-follicle	217	3.82-8.74
	Mid-cycle peak	195	4.59-22.59
	Mid-luteal phase	202	1.76-5.14
	Postmenopausal	197	16.01-114.08

It is recommended that each laboratory determine the applicability of the reference ranges through experimentation and establish their own laboratory-specific reference ranges if necessary.

PERFORMANCE CHARACTERISTICS

Measuring Range	0.20~150.00 mIU/mL
Limit of Detection	≤0.20 mIU/mL
Within-Run Precision	≤10%
Between-Lot Precision	≤15%

REFERENCES

1. Aurore C, Kalyane BN, Justine B, et al. Abnormally Elevated Follicle-Stimulating Hormone(FSH) Level in an Infertile Woman. Case Reports in Endocrinology, 2019, 2019.
2. Passing H, Bablok W, et al. A General regression procedure for method transformation [J]. J Clin Chem Clin Biochem, 1988, 26: 783-790.
3. Souvik SS, Amandeep V, Subeer M. Regulation of Hippo pathway components by FSH in testis [J]. Reproductive Biology, 2019.
4. Mia VG, Julia R, et al. Persistent organic pollutants as predictors of increased FSH: LH ratio in naturally cycling, reproductive age women [J]. Environmental Research 2018,164.
5. Piketty V, Kara E et al. Follicle-stimulating hormone (FSH) activates extracellular signal-regulated kinase phosphorylation independently of beta-arrestin- and dynamin-mediated FSH receptor internalization [J]. Reproductive Biology and Endocrinology 2006, 4(1).

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on FSH 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 FSH Fast Test Kit (Immunofluorescence Assay). Please read the instructions for use carefully before operating to ensure proper use. Please report any product problems or adverse events to the below manufacture or authorized representative in the European Community in time.

Version: WIF52-S-09

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

GP

CE IVD

fT3

Fast Test Kit

(Immunofluorescence Assay)

IF1067 for Getein 1100
IF5067 for Getein 1160
IF3067 for Getein 1180
REF IF2067 for Getein 1600
IF4067 for Getein 1200

Instruction for Use

INTENDED USE

fT3 Fast Test Kit (Immunofluorescence Assay) is intended for *in vitro* quantitative determination of free triiodothyronine (fT3) in human serum, plasma and whole blood. It is used as an aid in clinical routine diagnostics for the assessment of the thyroid status.

SUMMARY

Triiodothyronine (T3) is a thyroid hormone. It plays an important role in the body's control of metabolism. T3 circulates in the bloodstream as an equilibrium mixture of free and serum bound hormone. Free T3 (fT3) is the unbound and biologically active form, which represents only 0.2-0.4% of the total T3. The remaining T3 is inactive and bound to serum proteins, while the distribution of T3 between these binding proteins (thyroxine binding globulin, pre-albumin, albumin) is controversially discussed.
The detection of fT3 has the advantage of being independent of changes in the concentrations and binding properties of the binding proteins. Therefore, fT3 is a useful tool in clinical routine diagnostics for the assessment of the thyroid status. Free T3 measurements support the differential diagnosis of thyroid disorders, are needed to distinguish different forms of hyperthyroidism, and to identify patients with T3 thyrotoxicosis.

PRINCIPLE

The test kit is based on immunofluorescence competitive method to quantitatively detect the content of fT3 in human serum, plasma or whole blood.
The test uses an T3 monoclonal antibody conjugated with fluorescence and T3-BSA coated on the test line. After the sample has been applied to the test strip, the analyte competes with T3-BSA coated on the test line to bind to fluorescent labeled T3 monoclonal antibody and forms different antigen-antibody complexes respectively. The fluorescence intensity of test line has relationship with the amount of free T3 in sample.

CONTENTS

1. A kit for Getein 1100/Getein 1160/Getein 1180 contains:
Package specifications: 25 tests/kit, 10 tests/kit
1) Getein fT3 test card in a sealed pouch with desiccant
2) Disposable pipette
3) Reaction tube
4) Sample diluent 5
5) Instruction for use: 1 piece/kit
6) SD card: 1 piece/kit
2. A kit for Getein 1200/Getein 1600 contains:
Package specifications: 2×24 tests/kit, 2×48 tests/kit
Sealed cartridge with 24/48 Getein fT3 test cards
Instruction for use: 1 piece/kit
Materials required for Getein 1200/Getein 1600:
1) Sample diluent 5: 1 bottle/kit
2) Box with pipette tips: 96 tips/kit
3) Mixing plate: 1 piece/kit
3. A test card consists of:
A plastic shell and a reagent strip which is composed of a sample pad, nitrocellulose membrane , fluorescent labeled T3 monoclonal antibody, T3-BSA, polyclonal IgG antibody, absorbent paper and liner.
Note: Do not mix or interchange different batches of kits.

APPLICABLE DEVICE

Getein 1100 Immunofluorescence Quantitative Analyzer
Getein 1180 Immunofluorescence Quantitative Analyzer
Getein 1600 Immunofluorescence Quantitative Analyzer
Getein 1160 Immunofluorescence Quantitative Analyzer
Getein 1200 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 Getein 1100/Getein 1160/Getein 1180 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. For professional use only.
3. Do not use the kit beyond the expiration date.
4. Do not use the test card if the foil pouch is damaged.
5. Do not reuse the test card.
6. Do not reuse the disposable pipette.
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 instruction for use to ensure proper test performance.

SPECIMEN COLLECTION AND PREPARATION

1. This test can be used for ***serum, plasma and whole blood samples***. Heparin, EDTA and sodium citrate can be used as the anticoagulant for plasma and whole blood. Samples should be free of hemolysis.
2. Suggest using serum and plasma samples for better results.
3. The test should be performed within 4 hours after whole blood collection.
4. 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 (whole blood sample may be stored up to 3 days at 2~8°C).
5. Refrigerated or frozen sample should reach room temperature and be homogeneous before testing. Avoid multiple freezethaw cycles.
6. Do not use heat-inactivated samples or hemolysis samples.
7. SAMPLE VOLUME ***(Getein 1100/Getein 1160/Getein 1180): 100 µL***.

TEST PROCEDURE

1. Collect specimens according to instruction for use.
2. Test card, sample and reagent 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 "SD card" calibration when necessary.
2. Enter testing interface of Getein 1100.
3. Remove the test card from the sealed pouch immediately before use. Put the test card on a clean table, horizontally placed.
4. Using a pipette or disposable pipette, add ***100 uL*** sample to a reaction tube then ***100 uL*** sample diluent 5 to the same reaction tube, mix gently and thoroughly and wait for ***5-10 minutes***. Using a pipette or the same disposable pipette, deliver ***100 uL*** of the mixture into the sample well on the test card.

Note:
① It is necessary to squeeze the head of the disposable pipette when aspirating the liquid, ***make sure the liquid level is flush with the black scale line***, otherwise the sample volume will be inaccurate.
② It is recommended to wait ***5-10 minutes*** after mixing the samples, otherwise the test result will be inaccurate.

5. ***Reaction time: 15 minutes***. Insert the test card into Getein 1100 and click on "Start" icon after reaction time is elapsed. The result will be shown on the screen and printed automatically.

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. Enter testing interface of Getein 1160/Getein 1180.
3. Remove the test card from the sealed pouch immediately before use. Put the test card on a clean table,horizontally placed.
5. Using a pipette or disposable pipette, add ***100 uL*** sample to a reaction tube then ***100 uL*** sample diluent 5 to the same reaction tube, mix gently and thoroughly and wait for ***5-10 minutes***. Using a pipette or the same disposable pipette, deliver ***100 uL*** of the mixture into the sample well on the test card.

Note:
① It is necessary to squeeze the head of the disposable pipette when aspirating the liquid, ***make sure the liquid level is flush with the black scale line***, otherwise the sample volume will be inaccurate.
② It is recommended to wait ***5-10 minutes*** after mixing the samples, otherwise the test result will be inaccurate.

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 automati-

cally 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 5 at the correct position in Getein 1200/Getein 1600.
3. Place samples in the designed area of the sample holder, insert the holder and select the right test item, 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 insertion is correct and complete.

TEST 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 instruction for use of Getein 1100/Getein 1160/Getein 1180/Getein 1200/Getein 1600.

Others: Measuring range of the test kit is 0.60 pmol/L~ 50.00 pmol/L.

EXPECTED VALUE

The expected normal value for fT3 and was determined by testing samples from 254 apparently healthy individuals. The reference range of fT3 is 3.10 pmol/L~6.80 pmol/L calculated by using normal distribution methods (95% confidence interval).

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

PERFORMANCE CHARACTERISTICS

Measuring range	0.60 pmol/L~50.00 pmol/L
Low of Detection	≤ 0.60 pmol/L
Within-run Precision	≤ 15%
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 interferent.

Interferent	Triglyceride	Bilirubin
Concentration(Max)	20g/L	0.1g/L

REFERENCES

1. Bowerbank, S.L., Carlin, M.G., & Dean, J. (2019). A direct comparison of liquid chromatography-mass spectrometry with clinical routine testing immunoassay methods for the detection and quantification of thyroid hormones in blood serum. Analytical and Bioanalytical Chemistry, 411, 2839 - 2853.
2. Zhu, Lijie et al. “[Relationship of serum free T3 with the coronary artery calcification and major adverse cardiac events in patients with suspected coronary artery disease].” Zhonghua xin xue guan bing za zhi 42 12 (2014): 1017-21.
3. Julia K, Heike H, Bianca N. Enantiorecognition of triiodothyronine and thyroxine enantiomers using different chiral selectors by HPLC and micro-HPLC. J. Biochem Biophys Methods. 2008, 70(6):1254-1260.
4. Klee GG. Clinical usage recommendations and analytic performance goals for total and free triiodothyronine measurements. Clin Chem. 1996, 42(1):155-159.

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on the test kit 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 fT3 Fast Test Kit (Immunofluorescence Assay).

Please read this instruction for use carefully before operating to ensure proper use.

Version: WIF71-S-10

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

GP

CE IVD

fT4

Fast Test Kit

(Immunofluorescence Assay)

IF1068 for Getein 1100
IF5068 for Getein 1160
IF3068 for Getein 1180
REF IF2068 for Getein 1600
IF4068 for Getein 1200

Instructions for Use

INTENDED USE

fT4 Fast Test Kit (Immunofluorescence Assay) is intended for in vitro quantitative determination of free T4 in human serum, plasma and whole blood samples. This test can be used as an aid in the assessment of thyroid status.

SUMMARY

Thyroxine (T4) is the main thyroid hormone secreted into the bloodstream by the thyroid gland. Together with triiodothyronine (T3), it plays a vital role in regulating the body's metabolic rate, influences the cardiovascular system, growth and bone metabolism, and is important for normal development of gonadal functions and nervous system.

T4 circulates in the bloodstream as an equilibrium mixture of free and serum bound hormone. Free T4 (fT4) is the unbound and biologically active form, which represents only 0.03 % of the total T4. The remaining T4 is inactive and bound to serum proteins such as thyroxine binding globulin (TBG, 75%), pre-albumin (15%), and albumin (10%). The determination of free T4 has the advantage of being independent of changes in the concentrations and binding properties of these binding proteins; additional determination of a binding parameter (T uptake, TBG) is therefore unnecessary. Therefore, free T4 is a useful tool in clinical routine diagnostics for the assessment of the thyroid status. It should be measured together with TSH if thyroid disorders are suspected and is also suitable for monitoring thyrosuppressive therapy.

PRINCIPLE

The test kit is based on immunofluorescence competitive method to quantitatively detect the content of T4 in human serum, plasma or whole blood.

The test uses an T4 monoclonal antibody conjugated with fluorescence and T4-BSA coated on the test line. After the sample has been applied to the test strip, the analyte competes with T4-BSA coated on the test line to bind to fluorescent labeled T4 monoclonal antibody and forms different antigen-antibody complexes respectively. The fluorescence intensity of test line has relationship with the amount of free T4 in sample.

CONTENTS

1. A kit for Getein 1100/Getein 1160/Getein 1180 contains:
Package specifications: 25 tests/kit, 10 tests/kit
1) Getein fT4 test card in a sealed pouch with desiccant
2) Disposable pipette
3) Reaction tube
4) Sample diluent
5) Instruction for use: 1 piece/kit
6) SD card: 1 piece/kit

2. A kit for Getein 1200/Getein 1600 contains:
Package specifications: 2×24 tests/kit, 2×48 tests/kit
Sealed cartridge with 24/48 Getein fT4 test cards
Instruction for use: 1 piece/kit

Materials required for Getein 1200/Getein 1600:
1) Sample diluent: 1 bottle/kit
2) Box with pipette tips: 96 tips/kit
3) Mixing plate: 1 piece/kit

3. A test card consists of:
A plastic shell and a reagent strip which is composed of a sample pad, nitrocellulose membrane, fluorescent labeled T4 monoclonal antibody, T4-BSA, polyclonal IgG antibody, absorbent paper and liner.

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

APPLICABLE DEVICE

Getein 1100 Immunofluorescence Quantitative Analyzer
Getein 1180 Immunofluorescence Quantitative Analyzer
Getein 1600 Immunofluorescence Quantitative Analyzer
Getein 1160 Immunofluorescence Quantitative Analyzer
Getein 1200 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 Getein 1100/Getein 1160/Getein 1180 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 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. For professional use only.
3. Do not use the kit beyond the expiration date.
4. Do not use the test card if the foil pouch or the cartridge is damaged.
5. Do not open pouches or the cartridge until ready to perform the test.
6. Do not reuse the test card.
7. Do not reuse the disposable pipette.
8. Handle all specimens as potentially infectious. Proper handling and disposal methods should be followed in accordance with local regulations.
9. Carefully read and follow instruction for use to ensure proper test performance.

SPECIMEN COLLECTION AND PREPARATION

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

TEST PROCEDURE

1. Collect specimens according to instruction for use.
2. Test card, sample and reagent should be reached to room temperature before test.

For Getein 1100:
1. Confirm SD card lot No. in accordance with test kit lot No. Perform “SD card” calibration when necessary.
2. Remove the test card from the sealed pouch immediately before use. Put the test card on a clean table, horizontally placed.
3. Using a pipette or disposable pipette, add ***100 uL*** sample to a reaction tube then ***100 uL*** sample diluent to the same reaction tube, mix gently and thoroughly and wait for ***2-5 minutes***. Using a pipette or the same disposable pipette, deliver ***100 uL*** of the mixture into the sample well on the test card.

Note:
① It is necessary to squeeze the head of the disposable pipette when aspirating the liquid, ***make sure the liquid level is flush with the black scale line***, otherwise the sample volume will be inaccurate.
② It is recommended to wait ***2-5 minutes*** after mixing the samples, otherwise the test result will be inaccurate.

4. Reaction time: ***15 minutes***. Insert the test card into Getein 1100 and click on “Start” icon after reaction time is elapsed. The result will be shown on the screen and printed automatically.

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. Enter testing interface of Getein 1160/Getein 1180.
3. Remove the test card from the sealed pouch immediately before use. Put the test card on a clean table, horizontally placed.
4. Using a pipette or disposable pipette, add ***100 uL*** sample to a reaction tube then ***100 uL*** sample diluent to the same reaction tube, mix gently and thoroughly and wait for ***2-5 minutes***. Using a pipette or the same disposable pipette, deliver ***100 uL*** of the mixture into the sample well on the test card.

Note:
① It is necessary to squeeze the head of the disposable pipette when aspirating the liquid, ***make sure the liquid level is flush with the black scale line***, otherwise the sample volume will be inaccurate.
② It is recommended to wait ***2-5 minutes*** after mixing the samples, otherwise the test result will be inaccurate.

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. Place the sample diluent at the correct position of Getein 1200/Getein 1600.
3. Place samples in the designed area of the sample holder, insert the holder and select the right test item, 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 is correct and complete.

TEST 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 instruction for use of Getein 1100/Getein 1160/Getein 1180/Getein 1200/Getein 1600.

Others: Measuring range of the fT4 test kit is 0.30-100.00 pmol/L.

EXPECTED VALUE

The expected normal value for fT4 was determined by testing samples from 261 apparently healthy individuals. The reference range of fT4 is 12.00-22.00 pmol/L calculated by using normal distribution methods (99% confidence interval).

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

PERFORMANCE CHARACTERISTICS

Measuring Range	0.30-100.00 pmol/L
Lower Detection Limit	≤0.30 pmol/L
Within-Run Precision	≤15%
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 interferent.

Interferent	Triglyceride	Bilirubin
Concentration(Max)	20g/L	0.1g/L

REFERENCES

1. Kronenberg HM, Melmed S, Polonsky KS, et al. Williams Textbook of Endocrinology. Saunders Elsevier, Philadelphia, 12th edition, 2011, chapter 10, p. 301-311.
2. DeGroot LJ, Larsen PR, Hennemann G. Transport of Thyroid Hormone and Cell Uptake. The Thyroid and Its Diseases. Wiley and Sons, New York, 1984:62-65.
3. Wu AHB. Tietz Clinical Guide to Laboratory Tests. Saunders Elsevier, Philadelphia, 4th edition, 2006.
4. Brent GA. Thyroid Function Testing. Springer, Berlin, 1st edition, 2010.
5. US Department of Health and Human Services. Biosafety in Microbiological and Biomedical Laboratories. 5th ed. Washington, DC: US Government Printing Office; January 2007.
6. World Health Organization. Laboratory Biosafety Manual. 3rd ed. Geneva: World Health Organization; 2004.
7. Clinical and Laboratory Standards Institute. Protection of Laboratory Workers from Occupationally Acquired Infections: Approved Guideline-Third Edition. CLSI Document M29-A3. Wayne, PA: Clinical and Laboratory Standards Institute; 2005.

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on the test kit 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
Σ	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 fT4 Fast Test Kit (Immunofluorescence Assay).

Please read this instruction for use carefully before operating to ensure proper use.

Version: WIF72-S-11

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

CE IVD

HbA1c

Fast Test Kit

(Immunofluorescence Assay)

User Manual

Getein1100: Cat.# IF1017
Getein1600: Cat.# IF2017

INTENDED USE

HbA1c fast test kit is intended for the quantitative measurement of HbA1c in whole blood. This test is used as an aid for monitoring glycemic control in diabetics. In addition, it can identify people at risk of developing the disease and ongoing monitoring.

SUMMARY

Hemoglobin is the protein molecule in red blood cells with the main function transport oxygen and carbon dioxide in blood. HbA1c belongs to the glycated hemoglobin, a fraction formed by the attachment of various sugars to the Hb molecule and is proportional to average blood glucose concentration over the previous four weeks to three months. One advantage of using HbA1c for diagnosis is that the test does not require a fasting blood sample. Although HbA1c testing is mainly used for monitoring blood sugar control in patients with diabetes, the World Health Organization (WHO) now recommends that HbA1c can be used as a diagnostic test for diabetes, provided that stringent quality assurance tests are in place and assays are standardised to criteria aligned to the international reference values.

PRINCIPLE

The test uses an anti-human Hb monoclonal antibody conjugated with fluorescence latex and an anti-human HbA1c monoclonal antibody coated on the test line. After the sample has been applied to the test strip, the fluorescence latex-labelled anti-human Hb monoclonal antibody binds with the HbA1c and Hb in sample proportionally and forms marked antigen-antibody complex. The complex moves to the detection zone by capillary action. Then marked antigen-antibody complex is captured on the test line by the anti-human HbA1c monoclonal antibody. The fluorescence intensity of the test line increases in proportion to the amount of HbA1c in sample.

Then insert test card into Getein1100 Immunofluorescence Quantitative Analyzer/Getein1600 Immunofluorescence Quantitative Analyzer (hereinafter referred to as Getein1100 and Getein1600), the concentration of HbA1c in sample will be measured and displayed on the screen. The value will be stored in Getein1100/Getein1600 and available for downloading. The result can be easily transmitted to the laboratory or hospital information system.

CONTENTS

1. A kit for Getein1100 contains:
   Getein HbA1c test card in a sealed pouch with desiccant 25
   Disposable pipet 25
   A1c diluent 25
   SD card 1
   User manual 1
2. A kit for Getein1600 contains:
   Sealed cartridge with 24/48 Getein HbA1c test cards ··· 2
   User manual 1
   Package specifications:
   2×24 tests/kit, 2×48 tests/kit
   Materials required for Getein1600:
   A1c diluent..... 1
   Box with pipette tips 1
   Coated wells 1
3. A1c diluent composition:
   Phosphate buffered saline, proteins, detergent, preservative, stabilizer.
4. A test card consists of:
   A plastic shell and a reagent strip which is composed of a sample pad, nitrocellulose membrane (one end of the membrane is coated with a fluorescence latex-labelled anti-human Hb monoclonal antibody, the test line is coated with an anti-human HbA1c monoclonal antibody, and the control line 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
Getein1600 Immunofluorescence Quantitative Analyzer

STORAGE AND STABILITY

Store the test card at 4~30˚C with a valid period of 24 months.
Use the test card for Getein1100 within 1 hour once the foil pouch is opened.
Use the test card for Getein 1600 within 7 days once opened.
Store the sample diluent/whole blood buffer at 0~30˚C with a valid period of 24 months.
Store the sample diluent/whole blood buffer at 2~8˚C for better results.

PRECAUTIONS

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

SPECIMEN COLLECTION AND PREPARATION

1. This test can be used for ***whole blood samples. Heparin, sodium citrate and EDTA*** can be used as the anticoagulant under aseptic conditions.
2. The test is for human blood, other specimens or bodily fluids may not get accurate results.
3. The test should be performed within 4 hours after whole blood collection.
4. Samples could be kept for 7days at 2~8˚C and avoid cryopreservation.

5. Samples must be recovered to room temperature before testing.
6. SAMPLE VOLUME *(for Getein1100): 10 μl*.

TEST PROCEDURE

1. Collect specimens according to user manual.
2. Test card, sample should be brought to room temperature before testing.

For Getein1100:

3. Confirm SD card lot No. in accordance with test kit lot No.. Perform “QC (SD)” calibration when necessary (Details refer to 8.5.2 of Getein1100 User Manual).
4. On the main interface of Getein1100, press "ENT" button to enter testing interface.
5. Remove the test card from the sealed pouch immediately before use. Label the test card with patient or control identification.
6. Put the test card on a clean table, horizontally placed.
7. Using sample transfer pipette, deliver *10 μl* of sample into one tube of sample diluent, mix gently and thoroughly. Then drop *100 μl* of sample mixture (or 3~4 drops of sample mixture when using disposable pipet) into the sample port on the test card.
8. *Reaction time: 5 minutes.* Insert the test card into Getein1100 and press "ENT" button after reaction time is elapsed. The result will be shown on the screen and printed automatically.

For Getein1600:

9. Each cartridge for Getein1600 contains a specific RFID card which can calibrate automatically.
10. Place samples in the designed area of the sample holder, insert the holder and select the right test item, Getein1600 will do the testing and print the result automatically.

Notes:

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

TEST RESULTS

Getein1100/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/Getein1600.

EXPECTED RANGE OF VALUE

HbA1c concentration is determined using samples obtained from 345 apparently healthy individuals. The normal value for HbA1c is 3.8%-5.8% .
It is recommended that each laboratory establish its own expected values for the population it serves.

PERFORMANCE CHARACTERISTICS

Measuring Range	2%-14%
Lower Detection Limit	≤2%
Within-Run Precision (n=10)	≤10%
Between-Run Precision	≤15%

Accuracy: verify with comparison experiments, the correlation coefficient r ≥0.990, the relative error ≤20%.

LIMITATIONS

1. The result of the test should be evaluated in the context of all the clinical and laboratory data available. In those instances where the laboratory results do not agree with the clinical evaluation, additional tests should be performed accordingly.
2. Some substances in blood as listed below may interfere with the test and cause erroneous results. The maximum allowance concentration of them is as follows:

Interferent	Concentration (Max)
Triglyceride	25 g/L
Bilirubin	0.1 g/L

REFERENCES

1. Cagliero E, Levina E V, Nathan D M. Immediate feedback of HbA1c levels improves glycemic control in type 1 and insulin-treated type 2 diabetic patients[J]. Diabetes care, 1999, 22(11): 1785-1789.
2. Özdamar Ö, Gün i, Keskin U, et al. The role of maternal serumbeta-HbA1c and PAPP-A levels at gestational weeks 10 to 14 in the prediction of pre-eclampsia[J]. 2014.

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on HbA1c 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 980:2008 and International Standard ISO 15223-1:2007.

Key to symbols used			
	Manufacturer		Expiration date
	Do not reuse		Date of manufacture
	Consult instructions for use	LOT	Batch code
	Temperature limitation	IVD	*In vitro* diagnostic medical device
	Sufficient for	EC REP	Authorized representative in the European Community
CE	CE mark		Do not use if package is damaged

Thank you for purchasing HbA1c Fast Test Kit (Immunofluorescence Assay). Please read this user manual carefully before operating to ensure proper use.

Version: WIF22-S-02

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.bio-GP.com.cn