GP

CE IVD

HbA1c
Fast Test Kit
(Immunofluorescence Assay)

IF1017 for Getein 1100
IF4017 for Getein 1200
IF6017 for Getein 208
IF2017 for Getein 1600

Instructions for Use REF

INTENDED USE

HbA1c fast test kit is intended for the quantitative measurement of HbA1c in human whole blood samples. This test is used as an aid for monitoring glycemic control in diabetes. In addition, it can identify people who are at risk of developing diabetes and need continuous 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 saccharides 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 Getein 1100 Immunofluorescence Quantitative Analyzer/Getein 208 Hand-held Integrated System/automatically inserted by Getein 1200/Getein 1600 Immunofluorescence Quantitative Analyzer (hereinafter referred to as Getein 1100, Getein 208, Getein 1200 and Getein 1600), the concentration of HbA1c in sample will be measured and displayed on the screen. The value will be stored in Getein 1100/Getein 208/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 208 contains:

Package specifications: 25 tests/kit, 10 tests/kit
1) Getein HbA1c test card in a sealed pouch with desiccant
2) Capillary pipet
3) Sample diluent
4) User manual: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
1) Sealed cartridge with 24/48 Getein HbA1c test cards
2) User manual: 1 piece/kit

Materials required for Getein 1200/Getein 1600:
1) A1c diluent: 1 bottle/kit
2) Box with pipette tips: 96 tips/kit
3) Mixing plate: 1 piece/kit

3. Sample diluent/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

Getein 1100 Immunofluorescence Quantitative Analyzer
Getein 1200 Immunofluorescence Quantitative Analyzer
Getein 208 Hand-held Integrated System
Getein 1600 Immunofluorescence Quantitative Analyzer

STORAGE AND STABILITY

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

Use the test card for Getein 1100/Getein 208 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 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 ***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℃ and avoid cryopreservation.
5. Samples must be recovered to room temperature before testing.
6. SAMPLE VOLUME ***(Getein 1100): 10 μL***.
   (for Getein 208): 20 μL.

TEST PROCEDURE

1. Collect specimens according to user manual.
2. Test card, 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. Enter testing interface of Getein 1100.
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 ***10 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 (for disposable capillary pipet using, please refer to the directions in the package).
6. ***Reaction time: 5 minutes.*** Insert the test card into Getein 1100 and press "ENT" button or click on “Start” icon after reaction time is elapsed. The result will be shown on the screen and printed automatically.

For Getein 208:

1. Long press the Power Button to start the analyzer.
2. The system will enter (Test) menu.
3. Confirm SD card lot No.in accordance with test kit lot No.. Read the relevant information in the SD card for calibration.
4. Insert test card according to the analyzer prompts.

Note: Do not move the test card after it is inserted.

5. Add sample according to the analyzer prompts. Then draw ***20 μL*** of sample and drop it into sample diluent. Then drop ***70 μL*** of sample mixture into the sample well on the test card.
6. After sample adding, the system starts react-time countdown automatically.
7. After the countdown is over, the result will be shown on the screen.

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 A1c diluent 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 208.
3. Make sure the test card and the sample insertion is correct and complete.

TEST RESULTS

Getein 1100/Getein 208/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 208/Getein 1200/Getein 1600.

EXPECTED RANGE OF VALUE

HbA1c concentration is determined using samples obtained from 345 apparently healthy individuals. The normal value for HbA1c is 3.80%-5.80%.
It is recommended that each laboratory establish its own expected values for the population it serves.

PERFORMANCE CHARACTERISTICS

Measuring Range	2.00%-14.00%
Lower Detection Limit	≤2.00%
Within-Run Precision (n=10)	≤10%
Between-Run Precision	≤15%

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.
3. EN ISO 18113-1:2011 In vitro diagnostic medical devices-Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements.
4. EN ISO 18113-2:2011 In vitro diagnostic medical devices-Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use.

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

Version: WIF22-S-19

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