



# HbA1c

## Fast Test Kit

### (Immunofluorescence Assay)

#### Instructions for Use

#### INTENDED USE

HbA1c fast test kit (Immunofluorescence Assay) is intended for the quantitative determination of Hemoglobin A1c (HbA1c) in human whole blood. This test is used as an aid for the monitoring of long-term blood glucose control in patients with diabetes mellitus. In addition, it can identify individuals who may be at risk for developing the diabetes mellitus.

For professional and laboratory use only.

#### SUMMARY

Diabetes mellitus is a serious, chronic disease, usually divided into two categories according to the disease cause, type 1 diabetes and type 2 diabetes. Type 1 diabetes is characterized by deficient insulin production in the body. People with type 1 diabetes require daily administration of insulin for survival. Type 2 diabetes results from the body's ineffective use of insulin. The majority of people with diabetes are affected by type 2 diabetes. Raised blood glucose, a common effect of uncontrolled diabetes, may, over time, lead to serious damage to the heart, blood vessels, eyes, kidneys and nerves. Good glycemic control can reduce the risk for developing or worsening diabetes complications. Hemoglobin A1c (HbA1c) is a specific glycosylated hemoglobin that results from the attachment of glucose to the N-terminal valine of the hemoglobin  $\beta$ -chain. The concentration of HbA1c depends on both the concentration of glucose in the blood and the life span of the erythrocyte. Thus, the concentration of HbA1c reflects the average glucose concentration over the previous 2–3 months.

Since the landmark clinical trials (DCCT, UKPDS) clearly demonstrated the relationship between glycemic control, HbA1c, and diabetic complications, the test has greatly improved through the IFCC/NGSP standardization and the ongoing efforts of the diagnostic industry. The HbA1c

concentration is now a reliable test and indispensable tool in both the routine blood glucose control and diagnosis of diabetes.

#### PRINCIPLE

The test uses an anti-human Hb monoclonal antibody conjugated with fluorescence and an anti-human HbA1c monoclonal antibody coated on the test line. After the sample has been applied to the test strip, the fluorescently labeled 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.

#### CONTENTS

Materials provided	Getein 1100/ Getein 208		Getein 1200/ Getein 1600	
	10 T/kit	25 T/kit	2*24 T/kit	2*48 T/kit
HbA1c 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 tubes	25 tubes	/	/
A1c diluent***	/	/	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

\* HbA1c test card

A test card consists of: Fluorescently labelled anti-human Hb monoclonal antibody, anti-human HbA1c monoclonal antibody.

\*\* Sample diluent

Sample diluent for Getein 1100/ Getein 208 in each tube mainly consists of:

Phosphate buffer matrix, surfactant, preservative.

\*\*\* A1c diluent

A1c diluent for Getein 1200/ Getein 1600 is an independent packing box mainly consists of:

- Phosphate buffer matrix, surfactant, preservative (25 mL/ bottle for Getein 1200, 25 mL/ bottle for Getein 1600),

- Box with pipette tips (96 tips/box),

- Mixing plate (1 piece/box).

**Note:**

- 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".
- Do not mix or interchange different batches of kits.

#### APPLICABLE ANALYZER

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

#### 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 208: 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

- For *in vitro* diagnostic use only.
- For professional and laboratory use only, not for near-patient test and self-testing.
- Do not use the test card if the foil pouch or the cartridge is damaged.
- Do not open pouches until performing the test.
- Handle all specimens as potentially infectious. The foil bag is nondegradable. Proper handling and disposal methods should be followed in accordance with local regulations.
- It is recommended that operators take necessary self-protection measures (work clothes, goggles and disposable gloves, etc) when touching kits or samples.

#### SPECIMEN COLLECTION AND PREPARATION

- Whole blood can be used as samples in the assay.
- EDTA can be used as the anticoagulant for whole blood.
- Whole blood is stable for 4 hours at room temperature (15~30°C), 3 days at 2-8°C and avoid cryopreservation.
- Specimens must be recovered to room temperature before testing and mix the blood sample thoroughly before testing.

#### TEST PROCEDURE

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

For Getein 1100:

- Confirm SD card lot No. in accordance with test kit lot No. It is required to perform "SD card" calibration when using a new batch of kits.
- Select the corresponding "Sample" on the analyzer according to the sample type (see the user manual of analyzer for details).
- Remove the test card from the sealed pouch before use. Horizontally place the test card.
- Deliver **10  $\mu$ L** of sample into one tube of sample diluent using disposable pipet or pipette, mix gently and thoroughly. Then drop **100  $\mu$ L** of sample mixture into the sample well on the test card.
- Reaction time: 5 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 208:

- Long press the Power Button to start the analyzer.
- The system will enter (Test) menu.
- Confirm SD card lot No. in accordance with test kit lot No.. Read the relevant information in the SD card for calibration.
- Insert test card according to the analyzer prompts.  
**Note:** Do not move the test card after it is inserted.
- Add sample according to the analyzer prompts. Then drop **20  $\mu$ L** of sample and drop it into sample diluent. Then drop **70  $\mu$ L** of sample mixture into the sample port on the test card.
- After sample adding, the system starts react-time countdown automatically.
- After the countdown is over, the result will be shown on

the screen.

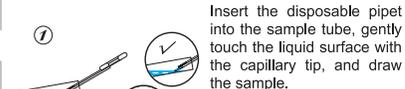
#### For Getein 1200/Getein 1600:

- (1) Each cartridge for Getein 1200/Getein 1600 contains a specific RFID card (SD 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, 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.

#### Note:

1. It is required to perform "SD card" calibration when using a new batch of kits for Getein 1100/ Getein 1160/Getein 1180.
2. The directions for using disposable pipet are as follows:

#### Directions to use disposable pipet

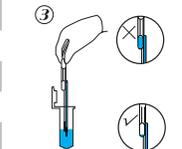


Insert the disposable pipet into the sample tube, gently touch the liquid surface with the capillary tip, and draw the sample.

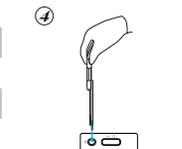
**Note: Do not immerse the exhaust pipe below the liquid level.**



Insert the disposable pipet (including the exhaust tube) into the dilution liquid, gently squeeze the suction bulb to perform 2-3 aspiration washing cycles, then mix the dilution manually.



Insert the disposable pipet (including the exhaust tube) into the dilution liquid, firmly squeeze the suction bulb to aspirate the mixed sample.



Squeeze the suction bulb and drop the mixed sample vertically into the sample well on the test card.

## 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. HbA1c Fast Test Kit (Immunofluorescence Assay) results are provided in %.

## 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	25g/L
Bilirubin	0.1g/L

## EXPECTED 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 determine the applicability of the reference value through experiments and establish its own reference ranges if necessary.

## PERFORMANCE CHARACTERISTICS

Measuring Range	2.00%-14.00%
Limit of Detection	≤2.00%
Within-Run Precision	≤10%
Between-Lot Precision	≤15%

## REFERENCES

1. Saaddine, Jinan B., et al. A Diabetes Report Card for the United States: Quality of Care in the 1990s[J]. Annals of Internal Medicine, 2002, 136(8):565-574.
2. Mbanya J C, Henry R R, Smith U. Presidents' statement on WHO recommendation on HbA1c for diabetes diagnosis. [J]. Diabetes Research & Clinical Practice, 2011, 93(3):310.

3. Weykamp C, John WG, Mosca A, Hoshino T, Little R, Jeppsson JO, Goodall I, Miedema K, Myers G, Reinauer H, Sacks DB, Slingerland R, Siebelder C. The IFCC Reference Measurement System for HbA1c: a 6-year progress report. Clin Chem. 2008 Feb;54(2):240-8.

## 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		Batch code
	Temperature limit		In vitro diagnostic medical device
	Contains sufficient for <n> tests		Authorized representative in the European Community/European Union
	CE mark		Do not use if package is damaged and consult instructions for use
	Catalogue number		Caution

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

Version: WIF22-S-22



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



CMC Medical Devices & Drugs S.L.  
 Add: C/ Horacio Lengo N° 18, CP 29006, Málaga,

Spain  
 Tel: +34951214054

Catalogue number	Applicable analyzer	Package specification
IF1017-10T	Getein 1100	10 T/kit
IF1017	Getein 1100	25 T/kit
IF6017-10T	Getein 208	10 T/kit
IF6017	Getein 208	25 T/kit
IF4017	Getein 1200	2*24 T/kit
IF4017-96T	Getein 1200	2*48 T/kit
IF2017	Getein 1600	2*24 T/kit
IF2017-96T	Getein 1600	2*48 T/kit