



HbA1c Fast Test Kit (Immunofluorescence Assay)

Instructions for Use

REF IF5017 for Getein1160
IF3017 for Getein1180

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 potential diabetes and for later monitoring. For professional and laboratory use only.

SUMMARY

Hemoglobin (Hb) is the protein molecule in red blood cells with the main function of transporting oxygen and carbon dioxide in blood. HbA1c belongs to the glycosylated hemoglobin, a fraction formed by the attachment of various saccharides to the Hb molecule and is proportional to the average blood glucose concentration over the last 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 standardized to criteria aligned to the international reference values.

PRINCIPLE

Anti-human Hb monoclonal antibodies conjugated with fluorescence latex and anti-human HbA1c monoclonal antibodies are coated on the test line. After sample being added to the test strip, the fluorescence latex-labelled anti-human Hb monoclonal antibody binds to HbA1c and Hb in sample proportionally, forming marked antigen-antibody complex. The complex moves to the detection zone by capillary action. Then the 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. Fluorescent signals intensity

can be analyzed by applicable device thus the HbA1c in sample be detected quantitatively.

APPLICABLE DEVICE

Getein 1160 Immunofluorescence Quantitative Analyzer
Getein 1180 Immunofluorescence Quantitative Analyzer

CONTENTS

Materials provided	Component	10 T/kit	25 T/kit
HbA1c test card	Anti-human HbA1c monoclonal antibody and rabbit anti-mouse IgG antibody	10 pcs	25 pcs
Disposable pipet	/	10 pcs	25 pcs
Sample diluent	Phosphate buffer (20 mmol/L), proclin 300 (<0.1%)	10*0.25 mL/tube	25*0.25 mL/tube
Instructions for use	/	1 pc	1 pc
SD card	/	1 pc	1 pc

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.

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:

Use the test card within 1 hour once the foil pouch is opened.

PRECAUTIONS

- For *in vitro* diagnostic use only.
- Do not use the kit beyond the expiration date.
- Do not use the test card if the foil pouch or the cartridge is damaged.
- Do not open pouches or the cartridge until ready to perform the test.
- Samples must be added using the disposable pipet in the kit to avoid incorrect results. Do not reuse the disposable pipet.

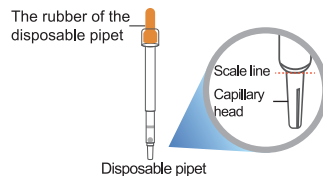
- Handle all specimens as potentially infectious. The foil bag is nondegradable. Proper handling and disposal methods should be followed in accordance with local regulations.
- Carefully read and follow instructions for use to ensure proper test performance.
- Extreme Hematocrit (below 25% or over 65%) may affect the test result.

SPECIMEN COLLECTION AND PREPARATION

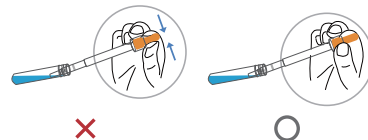
- This assay was designed and validated for use with human blood, other specimens or body fluids may not get accurate results.
- Whole blood samples** can be used in the assay. EDTA can be used as the anticoagulant under aseptic conditions.
- This assay should be performed within 4 hours after whole blood being collected.
- Specimens may be stored up to 3 days at 2~8°C and avoid cryopreservation.
- Specimens must be recovered to room temperature before testing.
- Mix the blood sample thoroughly before testing.

TEST PROCEDURE

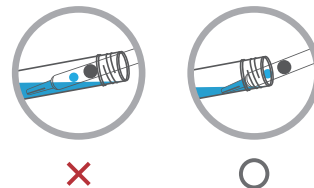
- User must carefully read and operate in strict accordance with the instructions for use before testing, otherwise reliable results cannot be guaranteed.
- Test kit and sample should be brought to room temperature before testing.
- Confirm SD card lot No.in accordance with the test kit lot No. , perform "SD card" calibration when necessary.
- Select the "W.B" on the analyzer according to the sample type.
- Remove test card and disposable pipet from the sealed pouch immediately before use and put them on a clean table, horizontally placed.
- Use disposable pipet to deliver 10 µL of sample into the sample diluent tube.



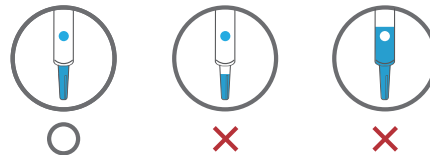
Note 1: Do not press the rubber of the disposable pipet with your finger during sampling.



Note 2: The capillary head of disposable pipet touches the sample level gently and draws the sample.

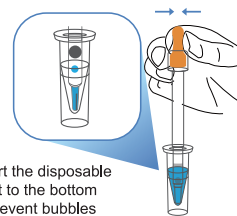


Note 3: Do not take too more or less samples than the scale line. If the sample is not sucked to the scale line, reinsert the disposable pipet into sample to the scale line to try again.



7. Insert the disposable pipet into the sample diluent tube to mix the sample by pressing the rubber of the disposable pipet for 4-6 times.

Note: Insert the disposable pipet to the bottom of tube to prevent bubbles.



8. Deliver the sample mixture by pressing the rubber of the disposable pipet and drop the sample mixture into the sample port "S" on the test card.

Note: Please add sample mixture immediately after mixing. Adding sample mixture in advance or delay may not get the correct test results.

9. Insert the test card into Getein 1160/Getein 1180 **immediately** after sample loading. The analyzer will count down the reaction time (5 minutes) and automatically test the card after reaction time is elapsed. The result will be shown on the screen and printed automatically.

LIMITATIONS

- The test results of this reagent are for clinical reference only, and cannot be used as the basis for diagnosis or exclusion of cases alone additional tests should be performed accordingly.
- 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	2500 mg/dL
Bilirubin	10 mg/dL

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 establish its own expected values for the population it serves.

PERFORMANCE CHARACTERISTICS

Measuring Range	3.50%-14.00%
Limit of Detection	≤3.50%
Within-Run Precision	≤8%

REFERENCES














- Cagliero E, Levina E V, Nathan D M. Immediate feedback of HbA1c levels improves glycemc control in type 1 and insulin-treated type 2 diabetic patients[J]. Diabetes care, 1999, 22(11): 1785-1789.
- 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.
- EN ISO 18113-1:2011 In vitro diagnostic medical

devices-Information supplied by the manufacturer (labelling)
- Part 1: Terms, definitions and general requirements.

- 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 <i>instructions for use</i> or consult <i>electronic instructions for use</i>		Batch code
	Temperature limit		<i>In vitro</i> 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 <i>instructions for use</i>
	Catalogue number		

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-SD5-01



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