CE IVD

GLU/HbA1c Test Kit

User Manual

REF DC1002 for Getein 3608/3600
DC2002 for Getein 200
DC3002 for Getein 208
DC4002 for Getein 3200/3208

INTENDED USE

GLU/HbA1c Test Kit is intended for *in vitro* quantitative determination of blood glucose (GLU) and hemoglobin A1c (HbA1c) in human whole blood or fingertip blood sample. This test is used as an aid for monitoring glycemic control in diabetes.

SUMMARY

Glucose is a type of sugar. It is your body's main source of energy. Glucose moves from your bloodstream into your cells. Too much or too little glucoses in the blood can be a sign of a serious medical condition. A blood glucose test measures the glucose levels in your blood to find out if your blood levels are in the healthy range. It is often used to help diagnose and monitor diabetes.

Hemoglobin is a protein in your red blood cells that carries oxygen through your body. When glucose builds up in your blood, it binds to the hemoglobin in your red blood cells. The hemoglobin A1c test measures the amount of blood sugar bound to hemoglobin and shows what the average amount of blood sugar has been over the past 2 to 3 months. An HbA1c test can be used to check for diabetes, and distinguish short-term stress-induced glucose rise from diabetes. It can be used to monitor your glucose levels and evaluate the clinical treatment effect of diabetes.

PRINCIPLE

This test kit consists of a dry chemical detection area for GLU detection and a dry immunofluorescence detection area for detection of HbA1c.

The dry chemical detection area contains a GLU reaction membrane which has reaction enzymes and a chromogen pair, a filter membrane and a diffusion layer. After the sample is loaded, it is filtered and permeated through the diffusion and filter membranes, then it reacts with the enzyme on the reaction membrane to produce H_2O_2. The combination of H_2O_2, 4-aminoantipyrine, chromogenic reagent and peroxidase produces colored compounds. The dry chemical detection area is equipped with a GLU detection hole. The biochemical immunofluorescence analyzer collects the signal concentration of colored compounds which is positively correlated with the GLU concentration to obtain the result.

The dry immunofluorescence detection area is coated with the highly specific and sensitive mouse anti-human HbA1c monoclonal antibody (AntiHbA1c) on the test line and the fluorescent (YG) labeled mouse anti-human hemoglobin monoclonal antibody (AntiHB) at the junction of the lower edge of the chromatography membrane and the sample pad. The quality control area is coated with rabbit anti-mouse immunoglobulin G (IgG) antibody. After the sample is applied to the test card, the fluorescent labeled anti-human Hb monoclonal antibody (AntiHB) binds with HbA1c and Hb in the sample proportionally and forms complexes YG-AntiHB-HB and YG-AntiHB-HbA1c. The complexes move to the detection zone by capillary action. Then YG-AntiHB-HbA1c is captured by HbA1c monoclonal antibody (AntiHbA1c) in detection area. The fluorescence intensity of test line increases in proportion to the amount of HbA1c in sample.

CONTENTS

1. Each kit contains:

Package specification for Getein 200/208: 1 test/box, 3 tests/box, 5 tests/box, 10 tests/box, 25 tests/box, 50 tests/box, 100 tests/box

Package specification for Getein3200/3208: 1×5 tests/box, 2×5 tests/box, 3×5 tests/box, 4×5 tests/box, 1×12 tests/box, 2×12 tests/box, 3×12 tests/box, 4×12 tests/box, 1×24 tests/box, 2×24 tests/box, 3×24 tests/box, 4×24 tests/box

Package specification for Getein 3600/3608: 1×5 tests/box, 2×5 tests/box, 3×5 tests/box, 1×10 tests/box, 2×10 tests/box, 3×10 tests/box, 1×15 tests/box, 2×15 tests/box, 3×15 tests/box, 1×20 tests/box, 2×20 tests/box, 3×20 tests/box, 1×24 tests/box, 2×24 tests/box, 3×24 tests/box, 1×30 tests/box, 2×30 tests/box, 3×30 tests/box, 1×40 tests/box, 2×40 tests/box, 3×40 tests/box, 1×47 tests/box, 2×47 tests/box, 3×47 tests/box, 1×48 tests/box, 2×48 tests/box, 3×48 tests/box

1) Getein GLU/HbA1c test card in a sealed pouch with desiccant
2) Sample diluent for Getein 200/208
3) User manual: 1 piece/box
4) SD card: 1 piece/box
5) Disposable pipet (optional)

2. Sample diluent composition (300 μL/tube):

Phosphate (20-200 mmol/L), dodecyl trimethyl ammonium bromide (0.2 - 1.0%), tween 20 (0.5 - 1%).

3. A test card consists of:

A plastic shell and a test strip. The test strip is composed of a dry chemical detection area and a dry immunofluorescence detection area.

Composition	Reaction Membrane	Main Ingredients	Content
Dry Chemistry	GLU	Glucose oxidase Peroxidase 4-aminoantipyrine MAOS	≥ 200 KU/L ≥ 500 KU/L 14 mmol/L 20 mmol/L
Dry Immunofluorescence	HbA1c	C line (Rabbit anti-mouse IgG antibody) Sample pad (Mouse anti-human hemoglobin monoclonal antibody) NC membrane (Mouse anti-human HbA1c monoclonal antibody)	1.5 - 2.5 mg/mL 1.5 - 4 mg/mL 2 - 5 mg/mL

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

APPLICABLE DEVICE

Getein 200/208 Hand-held Integrated System
Getein 3200/3208/3600/3608 Integrated System

STORAGE AND STABILITY

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

Use the test card for Getein 200/208 within 1 hour once the foil bag is opened. For test card of Getein 3200/32083600/3608: if the cartridge is opened, it could be stable within 24 hours once exposed to air. If the test cards cannot be used up at once, it is recommended that unused test cards are sealed and stored in the original foil pouch of the cartridge for no more than 7 days.

Seal and store the Sample diluent at 0 ~ 37°C with a valid period of 18 months. After opening, the validity period is 1 month.

PRECAUTIONS

1. Straws should not be mixed to avoid cross contamination.
2. After the cartridge is unsealed, it should be used as soon as possible to avoid being placed in the air for a long time, which may cause damp.
3. The cartridge can be sealed and stored at room temperature. The cartridge stored at low temperature should be brought up to room temperature before use.
4. This product contains animal-derived ingredients (such as antibodies). Please wear gloves during use of the product and avoid direct skin contact with test cards.
5. If the product is unsealed, its storage will not be affected until the end of the validity period after being placed at a temperature not higher than 37°C for 7 days.
6. For professional use only. For in vitro diagnostic use only.
7. GLU determination is traceable to the national standard reference material (GBW10062) and HbA1c determination is traceable to the national standard reference material (BW3625 and BW3626).
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. Whole blood samples can be used for the test. Other body fluids and samples may not give accurate results.
2. Heparin, sodium citrate and EDTA can be used as the anticoagulant. Samples should be free of hemolysis.
3. Fresh blood should be collected under sterile conditions. Samples at different times have different clinical significance. Details refer to "EXPECTED VALUE".
4. Tests should be performed within 2 hours after blood collection. If testing is delayed, whole blood samples can be stored up to 3 days at 2 ~ 8°C and should not be frozen.

5. Samples should be brought up to room temperature before testing. Do not use heat-inactivated or hemolysis samples.
6. SAMPLE VOLUME (for Getein 200/208): **20 μL**

TEST PROCEDURE

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

For Getein 200/208

3. Confirm that SD card lot No. matches test kit lot No. Perform "SD card" calibration when necessary.
4. Take out the test card from the sealed pouch before use. Label the test card with patient or control identification.
5. Insert the test card when Getein 200/208 prompts "Insert test card". Then draw 20 μL of sample and drop it into 300 μL of Sample diluent and mix thoroughly. Then drop 100±20 μL of sample mixture into the sample port on the test card.
6. Reaction time: ≤ 5 minutes. The result will be shown on the screen when the reaction is complete.

For Getein 3200/3208/3600/3608

Each cartridge for Getein 3200/3208/3600/3608 contains a specific RFID card which can calibrate automatically.

Place sample tubes in the designated area of the analyzer, and select the right test item. Getein 3200/32083600/3608 will start the automatic testing process and show the test results on the screen.

SD card traceability and calibration - This kit is calibrated with the working calibrator provided by Getein Biotech. The calibration curve is programmed into the SD card as the preset curve.

Quality control test: In order for the analyzer and test kit to function properly, and to ensure the correct test method, it is recommended to use the GLU/ HbA1c control material provided by Getein Biotech to check system performance and perform quality control procedure. Please refer to the instruction manual of the GLU/ HbA1c control material for details. If control products from other suppliers are utilized, the precision of the control products must be determined and within the acceptable range of Getein 200/208 and Getein 3200/3208/3600/3608.

Notes:

1. Calibration with SD card is required when using a new batch of kits.
2. Make sure the test card and the sample insertion is correct and complete.

TEST RESULTS

Getein 200/208 and Getein 3200/3208/3600/3608 can display the result on the screen. For additional information, please refer to the user manual of your instrument.

Others: The detection range of GLU is 2.00 - 25.00 mmol/L and the detection range of HbA1c is 2.0 - 14.0%. Dilute the sample with normal saline when GLU concentration is higher than the upper limit of detection, and the maximum dilution factor is 2.

EXPECTED VALUE

The expected normal values for GLU and HbA1c are determined by testing whole blood samples from 345 apparently healthy individuals.

The reference range for HbA1c is 4.0 - 5.8%; the normal reference value for fasting blood glucose is 5.88 mmol/L (95th percentile), and the reference value for 2 hours postprandial blood glucose is 7.8mmol/L (95th percentile).

It is recommended that each laboratory determine the applicability of the reference ranges through experiments and establish its own reference ranges if necessary.

PERFORMANCE CHARACTERISTICS

Detection range:
GLU 2.00 - 25.00 mmol/L HbA1c 2.0 - 14.0%
Minimum Detection Limit:
GLU ≤ 2.00 mmol/L HbA1c ≤ 2.0%
Repeatability: CV≤10%
Difference between batches: CV≤15%
Accuracy (relative deviation) ≤ 20%

LIMITATIONS

1. This kit is only for *in vitro* diagnostic use.
2. 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.
3. Interferents in the sample may have an influence on the test results. The table below lists the maximum allowable value of the potential interferent.

Interferent	Vitamin C	Triglyceride	Bilirubin
Concentration (Max)	5.68 mmol/L	25 g/L	0.1 g/L

4. Test results may be lower or higher than normal for patients with anemia or polycythemia.
5. The hook effect will not occur even when HbA1c content is as high as 40%.

REFERENCES

1. Ozdamar O, Gun I, Keskin U, et al. The role of maternal serum beta-HbA1c and PAPP-A levels at gestational weeks 10 to 14 in the prediction of pre-eclampsia. Pak J Med Sci. 2014, 30(3): 568 -573.
2. American Diabetes Association: Standards of Medical Care in Diabetes-2012. Diabetes Care 35 (Suppl. 1), S11-S63, 2012.

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on GLU/HbA1c Test Kit 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 GLU/HbA1c Test Kit Please read this user manual carefully before operating to ensure proper use.

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