Instruction for Glycosylated Hemoglobin (HbA1c) Test Kit (Immunofluorescence)

1. Product Name

Generic name: Glycosylated Hemoglobin (HbA1c) Test Kit (Immunofluorescence)

Trade name: HbA1c

2. Package

Specification 1: 25T/kit REF: 52026008

Specification 2: 50T/kit REF: 52027008

Quality Control (optional):

Level 2: 0.5mL × 1 REF: 52105024

3. Intended Use& Indication

For *in vitro* quantitative determination of HbA1c content in human whole blood.

Clinically used for Prediction, screening, and helpful for diagnosis of diabetes.

Products for professional use only.

4. Test Principle

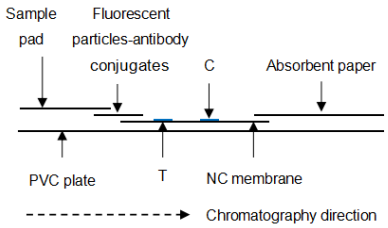
When the test sample is added to the sample port on the test card, HbA1c and Hb in the sample combines with mouse anti-human HbA1c and Hb monoclonal antibodies which are coupled to fluorescent particles to form fluorescent particles - antibody - antigen complexes. This immune complex reaches to the test area (T) along the nitrocellulose membrane and combines with the pre-coated mouse anti-human HbA1c monoclonal antibody, its fluorescence intensity is proportional to the HbA1c content in the sample. The remaining fluorescent antibody particle reaches the quality control area (C), and combines with the pre-coated goat anti-human Hb monoclonal antibody to present a quality control line. The ratio of HbA1c to Hb was calculated by the fluorescence signal intensity. If the sample does not contain HbA1c the test area (T) will not appear fluorescence.

5. Main components & Additional Required Equipment

The test kit consists of test card, magcard, sample diluent and the instruction.

(1).The test card is made up by a card housing and a test strip. And the test strip is formed by a sample pad, glass fiber (coated with conjugate of HbA1c antibody with fluorescent particles, and conjugate of Hb antibody with fluorescent particles), nitrocellulose membrane (section T coated with HbA1c monoclonal antibody and section C coated with Hb monoclonal antibody), absorbent paper, and PVC plate. See figure 1.

Figure 1 Schematic diagram of test strip



(2). Magcard: containing the calibration curve for this batch of reagent.

(3). Diluent: main composition is phosphate buffer (PBS), also containing preservative.

(4).Equipment: applicable to FA50 Quantitative Immunoassay Analyzer manufactured by Genrui Biotech Inc.

Note: Compositions of different batches are not interchangeable.

6. Accessories Required But Not Provided

(1) Pipettes and pipette tips: 100 μL.

(2) Timer.

7. Special Storage & Transport Conditions

(1) The test kit is kept in sealed aluminum foil bag and can be stored at 2-30℃. The unopened pack is valid for 18 months from the date of manufactured. Once opened, it is valid for 1 hour. The diluent cannot be frozen.

(2) Transport at 2-30℃.

8. Sample Requirements

(1) The optimal sample is fresh non-hemolyzed whole blood. Venous blood is recommended to be used for testing.

(2) Complete the sample test within 24h at room temperature after the sample is collected. Keep sample refrigerated at 2-8℃ for not more than 3 day, whole blood samples should not be frozen.

(3) Bring the samples to room temperature (18-25℃) before the test.

(4) It is recommended to use EDTA as anticoagulant.

9. Test Procedure

Carefully read the reagent instruction before using the test kit and strictly follow the instruction to ensure reliable results. Bring all reagents to room temperature (18-25℃) before use.

(1) Startup: Click “STD Mode” in the main menu to enter the measurement interface, click “Item” to select the desired test item and click “Type” to select the sample type.

(2) Click “Lot No.” to enter the card swiping interface, place magcard of the corresponding item to the magnetic induction zone, when hearing a “di” sound, the magcard is swiped successfully. Make sure the magcard and the test card are from the same batch (Note: reagents are precalibrated and specific calibration curve parameters for each batch of reagents have been stored in the magcard.).

(3) Sampling:

Add 10μL of whole blood into a centrifuge tube with 1000μL of the sample diluent, mix thoroughly for 1 min. Take 100μL diluted sample, drop vertically to the sample port on the test card directly and start timing.

(4) Insert it into the analyzer’s test slot (the sample port end toward the inside). Click “Measure”, the instrument will automatically detect and print out the results after 15 minutes (If using “Fast Mode”, keep it for 15 minutes and quickly insert into the analyzer’s test slot).

10. Reference Interval

Reference range: 4.0% ~ 6.0%

Note: Blood glucose level should be taken into consideration for diagnosis. Due to populations it is recommended that each lab establish its own reference range.

11. Explanation for Test Results

1) When fluorescent strips appear on the control area (C), the analyzer will

automatically capture and analyze the fluorescence light signals to provide quantitative results.

(2) When the control area (C) does not appear fluorescent strips, the analyzer will not detect the fluorescence. The analyzer will alarm automatically to indicate that either the operation is incorrect or the test card is damaged. In this case, carefully read the instructions again and re-test with a new test card. If the problem still exists, immediately stop using products of this batch and contact your supplier.

(3) When the sample test results are greater than 14%, the instrument displays > 14%, when the test results are less than 3%, the instrument displays <3%.

(4) This test kit does not produce Hook Effect within 20%.

12. Detection Limit

(1) This test kit is for *in vitro* diagnostic use only.

(2) Diagnosis and treatment can not only rely on this test result, it should be taken into account the patients' clinical history and other laboratory test results. Each laboratory is recommended to establish its own reference range based on the local population.

13. Interfering Substance

Bilirubin, cholesterol and triglycerides in samples can interfere with the test results, the maximum allowable concentrations of bilirubin is 2mg/mL, cholesterol is 15mg/mL, triglycerides is 30mg/mL,

14. Product Performance Indicators

(1) Analysis sensitivity: ≤ 3%.

(2) Linearity range: 4%-14% (Linear correlation coefficient: r ≥ 0.990)

(3) Measurement precision: Within run repeatability: CV ≤ 10%,

Between run repeatability: CV ≤ 15%

(4) Accuracy: -10%≤ Bias% ≤+10%.

(5) The Interference test: -10%≤ Bias% ≤+10%.

15. Precautions

(1) Once opened, use the test cards as soon as possible, otherwise it may cause moisture. Do not re-use the test card.

(2) Components in test kit of different batches cannot be used interchangeably.

(3) For substances containing sources of infection or suspected of containing sources of infection, there should be proper bio-safety assurance procedures. Pay attention to the following matters:

a) Wear gloves when handling sample or reagent for disinfection.

b) Disinfect spilled sample or reagent with disinfectant.

c) Disinfect or handle potential contamination sources of all samples or reagents in accordance with local regulations.

16. Explanation of graphic symbol

	Consult Instructions for use		Temperature Limitation
LOT	Lot No.		Expiry Date
IVD	*In Vitro* Diagnostic Reagent	CE	CONFORMITE EUROPEENNE
	Production Date		Biohazard
	Manufacturer		Volume
Σ	Contains sufficient for < n>tests		Keep away from sunlight
	Do not re-use		Dark dry preservation
EC REP	Authorized representative in the European community	REF	Catalogue number

17. Reference

Paolo Metus, Nicoletta Ruzzant, Piero Bonvicin, et al. Immunoturbidimetric assay of glycated hemoglobin. [J] Journal of Clinical Laboratory Analysis, 1999, 13:5-8.

18. Metrological Traceability

The kit was traced to the HbA1c Test Kit produced by Sysmex Co., Ltd, and G8 HPLC produced by Tosoh Corporation.

19. Help Information

If you need help please contact after sales.

20. Manufacturer

Genrui Biotech Inc.

Address: 4-10F, Building 3, Geya Technology Park, Guangming District, 518106, Shenzhen, China.

Web: www.genrui-bio.com

21. Instruments & Applications

Genrui's Immunofluorescence products, designed to work in automated lab environment, which are compatible with the FA50 Quantitative Immunoassay Analyzers. There may or may not be an application developed for your particular instrument, please visit the instrument section of our website.

IVD CE EC REP Wellkang Ltd Suite B, 29 Harley Street LONDON, W1G 9QR, U.K. www.CE-Marking.EU