Instruction for Glycated Hemoglobin (HbA1c) Detection Kit (Nephelometry)

【Product Name】

Generic name: Glycated Hemoglobin (HbA1c) Detection Kit (Nephelometry)

Trade name: HbA1c

English name: Glycated Hemoglobin (HbA1c) Detection Kit (Nephelometry)

【Package】

Specification 1: 25T/kit	REF: 32026008
Specification 2: 2×25T/kit	REF: 32080008
Specification 3: 50T/kit	REF: 32027008
Specification 4: 100T/kit	REF: 32028008
Specification 5: 150T/kit	REF: 32029008
Specification 6: 200T/kit	REF: 32030008
Specification 7: 250T/kit	REF: 32031008
Specification 8: 300T/kit	REF: 32032008

【Intended Use】

For in vitro quantitative determination of the percentage content of glycated hemoglobin in human blood.

【Test Principle】

This detection kit bases on antigen-antibody reaction to directly test the HbA1c percentage of the total Hb. The total Hb of the sample which includes HbA1c's same non-specific absorption with the latex and becomes immobilized, when added in the complex of HbA1c specific monoclonal antibody and goat anti mouse IgG antibody, it forms latex - HbA1c - mouse anti human HbA1c monoclonal antibody - goat anti mouse IgG antibody complex, and the production amount of this complex is in positive correlation to the HbA1c percentage content. By detecting the reaction change at specific wavelengths and referring to the multi-point calibration curve, the HbA1c content in the whole blood can be calculated. The reagents are pre-calibrated, each specific calibration curve has been recorded into the magcard, and each detection kit is allocated with one magcard.

【Main Compositions】

1. Latex: 0.1% latex particles + phosphate buffer 20mmol/L
2. Diluent: distilled water
3. Antiserum: phosphate buffer 20mmol/L, sodium chloride 15.8g/L, mouse anti human HbA1c monoclonal antibody 1.5mg/L, sheep anti mouse IgG antibody 1mg/L
4. Magcard: polyvinyl chloride (PVC) plastic
5. Stirrer: stainless steel

【Storage and Validity Period】

The sealed detection kit can be stored at 2-8℃ for 12 months. Do not freeze. Once opened, the reagents stored at 2-8℃ are stable for 30 days.

【Applicable Instruments】

Applicable for PA50&PA54 Specific Protein Analyzer and PA120& PA200 Fully-auto Specific Protein Analyzer manufactured by Genrui Biotech Inc. to quantitatively test Glycated Hemoglobin (HbA1c) in human whole blood.

【Sample Requirements】

Gently shake to mix the whole blood with anticoagulant EDTA, take out 20μl from it to add into 1ml sample diluent for hemolysis.

Samples with clear interferent should eliminate the interferent and resample.

【Test Methods】

Bring all reagents to room temperature (18-25℃) before the use.

1. Test methods for PA50&PA54 Specific Protein Analyzer

1) Sample dilution: accurately add 1000μl diluent into the centrifuge tube, then add in 20μl whole blood, slightly shake it, 2 minutes later, it could be used to test.

2) After startup, the instrument displays the main measurement interface, select the test item and sample type at the item column (After the confirmation, it will default to this item and sample type in the future.).

3) Click "LOT" at the batch No. column to enter the card-swiping interface. Put the corresponding magcard onto the magnetic induction area, when a "di" sound heard, the magcard was successfully swiped, and the interface returns to the main measurement interface. For the same batch of reagents, no need to swipe the card again.

4) The instrument interface prompts "Input Cup!".

5) Take out one cuvette, put one stirrer into it, then use the pipettor to accurately add in 300μl HbA1c latex, then add in 10μl diluted sample.

6) Put the cuvette into the test channel, the instrument automatically stir for one time.

7) Wait for 1 minute, the instrument prompts "Please Add Antiserum", then use the pipettor to accurately add in 100μl HbA1c antiserum.

8) Immediately press the corresponding channel's start button, the instrument will stir automatically. When the test finished, the instrument will automatically display and print the test result.

9) After the test, take out the cuvette, the instrument prompts "Input Cup!", do the next test.

2. Fully-auto specific protein analyzer (PA120, PA200) detection methods are as follows

1) Login fully-auto specific protein analyzer PA120,PA200 PC software, put the magcard onto the magnetic induction area, the instrument will prompt the card is successfully swiped, for the same batch of reagents, only swipe the card once.

2) Login the main measurement interface, apply for testing according to the items and sample types to be tested.

3) Put the test sample in place, then put the corresponding reagents at the specified locations and Start the test, the instrument will automatically aspirate all the test samples and complete the measurement process. After the test is completed, you can view the measurement results and print the test results.

4) Please refer to PA120, PA200 manual for detailed description of instrument operation method.

【Reference Value】

Reference range: 4.2%-6.2%

【Explanation for the Test Results】

Glycated Hemoglobin (HbA1c) is the product of combining hemoglobin in erythrocytes of human blood with the blood glucose. The combination of blood glucose and hemoglobin to form glycated hemoglobin is an irreversible reaction and in direct proportion to the blood glucose concentration. The product will exist around 120 days, so it can be used to estimate the blood glucose concentration 120 days ago. The test of glycated hemoglobin could reflect patient's blood glucose control situation within recent 8-12 weeks.

【Calibration and QC】

1. Calibration

Use the appropriate HbA1c calibrator (recommended brand of Randox or other approved brands) and the calibration period is 30 days. Recalibration is needed when replacing the batch number of reagents.

2. QC

It is recommended to use QC with normal and pathological values to do the indoor quality control, the tested control value should be within the definite limits, if the value is out of control, the laboratory should take appropriate corrective measures.

3. QC Solution (optional)

3.1 Product Name: HbA1c QC

3.2 Package Specification

0.5ml/bottle

3.3 Intended Use

Intended for in vitro diagnostic use in the quality control of diagnostic assays.

3.4 Main Composition: HbA1c antigen

3.5 Storage and Validity Period

Please refer to the instruction of QC

3.6 Target and Limitation

Please refer to the label.

3.7 Test Method

Please refer to the instruction of QC

【Limitations for the Test Results】

The diagnosis and treatment cannot only depend on this test result, please consider the clinical history and other laboratory test results at the same time. It is suggested that each laboratory builds up its own reference range based on its own patient group.

【Product Performance Indicators】

1. Analysis sensitivity: ≤ 2%
2. Linearity range: 2%-15%, determination indicator: r ≥ 0.990
3. Measurement precision:

Repeatability: CV ≤ 5%, relative deviation of Detection Kit's inter batches (R) ≤ 5%

4. Accuracy: Bias% ≤ ±10%
5. Specificity:

When add in 525IU/ml rheumatoid factors, 540IU/ml anti streptolysin O, 400μmol/L bilirubin, ≤10mmol/L triglyceride, the test result Bias% ≤ ±10%

【Precautions】

—Only used for in vitro diagnostic, please refer to the Operation Manual.

—Do not use the expired reagents. Shake the antiserum reagent well before use.

—Do not use reagents of different batches together.

【Labels】

Label	Meaning
	Date of manufacture
	In vitro diagnostic medical device
	Manufacturer
	Biological risks
	Batch code
	Temperature limit
	Use-by date
	Authorized representative in the European Community
	Volume
	Consult instructions for use
	Do not re-use
	Keep away from sunlight
	Contains sufficient for <n>tests
	Catalogue number
	CE Marking

【Reference】

1. Tominaga M, Kobayashi I, Kuwa K, etal, Report of the Committee on Standardization of Laboratory Testing Related to Diabetes Mellitus, National Survey on Glycohemoglobin, J Japan Diabetes Society 2001, 44

2. 347-352 of the third version, November 2006, Clinical Chemistry Tests, the fourth article, The National Clinical Test Regulation of Operation, Medical administration department of Ministry of Health of the People's Republic of China

【Manufacturer】

Genrui Biotech Inc.

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

Web: www.genrui-bio.com

【Medical Devices' Manufacturing Permit No.】

Guangdong SFDA (State Food and Drug Administration) authorized Medical Device Manufacturing Permit No. 20041046

【Medical Devices' Product Registration】

Certificate No.

Guangdong SFDA 2014.2400415 (**Approved**)

【Product Standard Code】

YZB/Guangdong --- *0604-2014*

【Instruction Approved and Revised Date】

Approved date: February, 23th, 2018

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【Guarantee and Technical Support】

If invalid message repeats or need technical support, please contact Genrui Customer Service and Support Center

Lotus NL B.V.
Koningin Julianaplein 10, 1e Verd
2595AA, The Hague, Netherlands
Email :peter@lotusnl.com