Instruction for Glycated Hemoglobin (HbA1c) QC

【Product Name】

Glycated Hemoglobin (HbA1c) QC

【Package Specification】

Applicable for PA50&PA54		
REF No.	Level	Specification
32105079	QC(N)	0.5ml/bottle × 2
32105078	QC(H)	0.5ml/bottle × 2

Applicable for PA120		
REF No.	Level	Specification
32105081	QC(N)	0.5ml/bottle × 2
32105080	QC(H)	0.5ml/bottle × 2

【Intended Use】

HbA1c QC is designed for quality control of HbA1c detection by in vitro immune diagnostic system.

【Precaution】

This product is only used for in vitro diagnosis. Dispose the reagents according to the usual laboratory precautions.

Absorb the required amount for each use, and the remaining samples should not be returned to the original bottle.

If the quality control product is contaminated, the stability of the components will be decreased, it should be stop using and a new quality control product should be selected.

【Main Composition】

HbA1c antigen

【Storage and Stability】

The sealed detection kit can be stored at 2-8℃ for 12 months.

After reconstitution, the reagents stored at 2-8℃ (not frozen) can be stable for 10 days.

【Instructions for use】

The quality control product is dried frozen. The usage is as follows:

1. Open the bottle carefully, reconstitute the control using 0.5mL of deionized water.
2. Mix gently and stand 1 hour before use.
3. After sampling, cover the bottle cap as soon as possible and store it in a sealed condition of 2 ~ 8℃ in time.

Test methods for Semi-auto PA50/54 Specific Protein Analyzer

Take out one cuvette, add one stirrer, accurately transfer 300 μL of HbA1c latex, and 10 μL of HbA1c control. Put the cuvette into the test channel. Instrument automatically stirs once.

A minute later, a message “Please add antiserum” appears. Transfer accurately 100 μL of HbA1c antiserum by pipette. Immediately press the channel’s start button. Instrument automatically stirs. When test is finished, result is shown and printed out automatically.

Test methods for Fully-auto PA120 Specific Protein Analyzer

For specific usage, please refer to the corresponding kit instruction.

【Assignment】

Assigned the quality control product in the company laboratory, using kit and specific protein analyzer, the methodology was Nephelometry.

The assignment result is shown on the QC bottle label.

【Icon Illustration】

	Date of manufacture		Manufacturer
	In vitro diagnostic		Volume
	medical device		
	Biological risks		Catalogue number
	Batch code		Main component
	Use-by date		Temperature limit
	Authorized representative in the European Community		CE Marking

【Manufacturer】

 Genrui Biotech Inc.

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Web: www.genrui-bio.com

【Medical Device Manufacturing Enterprise Permit No.】

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

【Guarantee and Technical Support】

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