Instruction for HbA1c QC

【Product Name】

Generic name: HbA1c QC

English name: HbA1c Quality Control (L, H)

【Package Specification】

0.5mL/bottle

【Intended Use】

These products are control substances designed for accuracy maintenance of hemoglobin A1c tests. They are best suited for accuracy control of the latex Nephelometry assay.

【Test Principle】

Not Applicable.

【Main Composition】

Glycosylated albumin

【Accessories Required But Not Provided】

None

【Storage and Validity Period】

The QC can be stored for 12 months at 2-8℃ without sunshine. It is stable for 10 days at 2~8℃ after reconstituted.

The products should be transported with outer package.

【Applicable Instruments】

Applicable for PA50&PA54 Specific Protein Analyzer manufactured by Genrui Biotech Inc.

【Sample Requirements】

Not Applicable.

【Test Methods】

1. Reconstitute each control vial using 0.5mL of deionized water. Mix gently and stand 1 hour before use.
2. To a cuvette, add one stirrer, accurately transfer 300 μL of HbA1c latex, and 10 μL of 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.

【Target and Limitation】

Please refer to the label.

【Interpretation of Test Results】

Not Applicable.

【Calibration and QC】

Not Applicable.

【Limitations of Testing Methods】

Not Applicable.

【Performance Indicator】

Not Applicable.

【Precaution】

1. Please seal it properly after using, to avoid long-time exposure in the air.
2. This product is for in vitro diagnostic use only, please refer to the instruction for usage.
3. If the reagent is carelessly spattered onto the skin, eyes, etc., flush with clean water immediately, and if mistakenly swallowed, seek medical advice.
4. Do not use the solution when package is damaged.

【Icon Illustration】

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
	Catalogue number
	CE Marking
	Volume
	Main component

【Training information】

Please refer to the training manual.

【Help information】

If you need help please contact after-sales.

【Trouble shooting】

Please contact after-sales.

【References】

Not Applicable.

【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.

【Instruction Approved and Revised Date】

Approved date:

Revised date:

【Guarantee and Technical Support】

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