



HbA1c Reagent Kit (Immunoturbidimetric Method)

Instructions for Use

REF CC1043

PRODUCT NAME

HbA1c Reagent Kit (Immunoturbidimetric Method)

PACKAGE SPECIFICATION

R1: 2x15 mL R2a: 1x0.5 mL R2b: 1x9.5 mL A1c Diluent: 2x50 mL
R1: 2x30 mL R2a: 1x1 mL R2b: 1x19 mL A1c Diluent: 3x65 mL
R1: 1x30 mL R2a: 1x0.5 mL R2b: 1x9.5 mL A1c Diluent: 2x50 mL
R1: 1x60 mL R2a: 1x1 mL R2b: 1x19 mL A1c Diluent: 3x65 mL
R1: 1x60 mL R2a: 2x0.5 mL R2b: 2x9.5 mL A1c Diluent: 3x65 mL
R1: 4x15 mL R2a: 2x0.5 mL R2b: 2x9.5 mL A1c Diluent: 4x60 mL

INTENDED USE

Used for the *in vitro* quantitative measurement of HbA1c in human blood cells. Mainly used clinically to assist in the diagnosis of diabetes and to monitor blood glucose levels. For professional and laboratory use only.

TEST PRINCIPLE

This kit determines the percentage of HbA1c in total hemoglobin (Hb) by an antigen-antibody reaction. The total Hb and HbA1c in the sample exhibit the same non-specific adsorption to the solid phase coated with latex. When the specific monoclonal antibody of HbA1c is added, a complex of latex HbA1c-mouse anti-human HbA1c monoclonal antibody is formed, which then agglutinates in the presence of goat anti-mouse IgG antibody. The degree of agglutination correlates with the amount of HbA1c bound to the latex surface. By measuring the absorbance and comparing with a standard HbA1c concentration curve, the percentage of HbA1c in the total Hb content of the sample can be determined.

MAIN COMPONENTS

Kit composition		Reagent components	Content
Reagent 1	R1	Latex	60 mL/L
		Glycine buffer	0.1 mol/L
Reagent 2	R2a	Goat anti-mouse IgG antibody	50 mg/L
		Glycine buffer	0.1 mol/L
	R2b	Mouse anti-human HbA1c monoclonal antibody	120 mg/L
		Glycine buffer	0.1 mol/L
A1c Diluent		H ₂ O	100 mL

The components in different batches of a multi-component kit are not interchangeable.

STORAGE AND SHELF LIFE

Reagents should be stored in tightly closed containers at 2°C-8°C, protected from light for a shelf life of 18 months. Once opened, they should be stored at 2°C-8°C, and the reagents remain valid for 42 days. Production date and expiration date: see details on the label.

APPLICABLE INSTRUMENTS

The kit is applicable to the following instruments: fully automatic biochemistry analyzers from Hitachi High-Tech (Shanghai) International Trading Co., Ltd., models: 7100, 7170, 7180, 7600, LABOSPECT 008 AS, 3100, 3500; fully automatic biochemistry analyzers from Beckman Coulter Commercial Enterprise (China) Co., Ltd., models: DXC800, AU480, AU680, AU5800; fully automatic biochemistry analyzers from

Canon Medical Systems (China) Co., Ltd., models: TBA-120FR, TBA-2000FR, TBA-FX8; fully automatic biochemistry analyzers from Shenzhen Mindray Bio-Medical Electronics Co., Ltd., models: BS-420, BS-490, BS-600, BS-800, BS-820, BS-2000; fully automatic biochemistry analyzers from Dirui Industrial Co., Ltd., models: CS-400, CS-600B, CS-1200; fully automatic biochemistry analyzers from Siemens Healthineers Diagnostics (Shanghai) Co. Ltd., models: 1800, 2400, ADVIA Chemistry XPT; fully automatic biochemistry analyzers from Roche Diagnostics (shanghai) Co., Ltd., models: cobas 6000 c 501, cobas 8000 c 502, 701, 702; clinical chemistry analyzers from Getein Biotech, Inc. models: CM-400, CM-430, CM-480, CM-600, CM-630, CM-680, CM-800, CM-830, CM-880, CM-2000, CM-1600, CM-1200, CM-1000; automatic biochemical analyzers from Changchun Blaser Medical Technology Co., LTD, models: BBA-400, BBA-300, BBA-480. If you need the application parameters of the fully automatic biochemistry analyzers, please contact our company.

SAMPLE REQUIREMENTS

After anticoagulation, take a 10µL sample from the blood cell layer that has been standing for more than 3 hours or from the blood cell layer after centrifugation at 2000 rpm for 2 minutes. Add the sample to 1mL of A1c diluent to hemolyze the cells. After hemolysis, the sample can be stored for 3 days at 15-25°C, for 7 days at 2-8°C and for 6 months at -20°C.

TEST PROCEDURE

- Reagent R1: R1 can be used directly after opening. It is packaged in two bottles, and can be selected according to the instrument.
Reagent R2: Prepare the working solution by mixing one bottle of R2a with one bottle of R2b. When opening R2a, take care to prevent the reagent from adhering to the cap. After transferring R2a and adding R2b, wash the empty R2a bottle several times with R2b to ensure all the R2a dissolves into R2b. Then, gently invert the bottle to thoroughly mix the reagent.
- Test conditions: (Different load parameters can be requested based on different testing instruments)

Primary/secondary wavelength	660 nm/800 nm	Calibration type	Nonlinearity
Sample/R1/R2	8/300/100 µL	Time of mixing serum + R1	1-5 min
Method	Two-point endpoint assay	Reaction time after addition of R2	5 min
Calibration method	Five-point calibration	Direction of reaction	Upward

(Absorbance (A) read by the instrument= $A_{\text{Primary wavelength}} - A_{\text{Secondary wavelength}}$)

Operating procedures:

Substances added	Blank tubes	Test tubes
Reagent 1	300 µL	300 µL
Sample	-	8 µL
Distilled water	8 µL	-
Mix well, incubate at 37°C for 300 s		
Reagent 2	100 µL	100 µL
Mix well, read the absorbance (A ₁) after 1 min, and read the absorbance (A ₂) after 300 s. $\Delta A = A_2 - A_1$		

- Calibration procedure: A calibrator from Getein is recommended.
- Quality control procedure: A quality control from Getein is recommended, and its measured value should be within the range of its label claim. If the result deviates from the range, find out the reason according to the steps below:
 - Check whether the parameter settings and light source are correct.
 - Check whether the cuvettes and sampling probes are clean.
 - Check whether water is contaminated, and bacterial growth will cause incorrect results.
 - Check reaction temperature.
 - Check the expiration date of the kit.
- Result calculation:
HbA1c concentration is determined by measuring the absorbance change ΔA of the test tube, utilizing a multi-point calibration curve and the non-linear calibration method.

REFERENCE RANGE

The reference range is 3.8-5.8%. The reference range is for reference only. Due to differences in factors such as geography, race, gender and age, it is recommended that each laboratory establish its own reference range.

RESULT INTERPRETATION

The professional is responsible for the review of the test results. The results may be affected by age, gender,

diet, and region of the individual being tested. If the result is within the reference range, it is considered normal; if it is out of the range, a retest should be conducted. If the test results are inconsistent with or contradict clinical symptoms, the cause should be analyzed and investigated.

LIMITATIONS

There is no interference with the measurement when bilirubin $\leq 648 \mu\text{mol/L}$ (40 mg/dL), ascorbic acid $\leq 50 \text{ mg/dL}$, carbamylated Hb $\leq 7.5 \text{ mmol/L}$, acetylated Hb $\leq 5.0 \text{ mmol/L}$, and chylous granule ≤ 2000 turbidity units.

PERFORMANCE CHARACTERISTICS

1. Appearance

Reagent 1 in the kit is an emulsion. Reagent 2a is a colorless or slightly yellow clear liquid, which may contain a small number of subvisible particles that do not affect the determination. Reagent 2b is a colorless or slightly yellow clear liquid, which may contain a small number of subvisible particles that do not affect the determination. A1c Diluent is a colorless clear liquid; Kit components should be complete and free from leakage of liquid.

2. Net content

The net content of liquid reagents should be not less than the labeled value.

3. Reagent blank absorbance

Reagent blank absorbance $A_{660\text{nm}} \leq 1.000$.

4. Accuracy

When using reference materials as samples for testing, the relative deviation of the measured results should not exceed $\pm 7\%$.

5. Linear range

Reagent linearity in the range of [3.0%, 14.0%] (NGSP unit):

a) The linear correlation coefficient (r) should not be less than 0.990;

b) Deviation from linearity: The absolute deviation should not fall outside the range of $\pm 0.5\%$ (NGSP unit) within the linear range of [3.0%, 7.0%] (NGSP unit); the relative deviation should not fall outside the range of $\pm 7\%$ within the linear range of (7.0%, 14.0%) (NGSP unit).

6. Analytical sensitivity

When testing samples with a concentration of 5% (NGSP unit), the absorbance difference should be ≤ 0.024 .

When testing samples with a concentration of 8.7% (NGSP unit), the absorbance difference should be between 0.004 and 0.151.

When testing samples with a concentration of 12.6% (NGSP unit), the absorbance difference should be between 0.010 and 0.181.

When testing samples with a concentration of 16.5% (NGSP unit), the absorbance difference should be between 0.012 and 0.216.

7. Precision

7.1 Repeatability

When testing samples at high and low concentration levels, the repeatability (coefficient of variation, CV) shall be no greater than 3.0%.

7.2 Between-run precision

The between-run precision should be no greater than 10.0%.

PRECAUTIONS

1. General precautions

1.1 This product is for *in vitro* diagnostic use only.

1.2 For clinical diagnosis, please make a comprehensive judgment based on the measurements, clinical symptoms and other findings.

1.3 Please use this product according to the IFU.

2. Precautions for operation

2.1 Please treat the specimens as dangerous substances that may be infected with HIV, HBV, HCV, etc. Please use disposable gloves to avoid or reduce the associated risk for infection.

2.2 If the reagents get into the eyes or mouth, or come into contact with the skin, rinse them quickly and thoroughly with

water, and receive medical treatment from a doctor when necessary.

3. Precautions for use

3.1 Please store the reagents according to the storage method, and avoid freezing. Please do not use frozen reagents whose quality may change.

3.2 Please do not use expired reagents whose test results may be inaccurate.

3.3 Please avoid adding reagents halfway during a test.

3.4 Please avoid direct sunlight during operation.

4. Precautions for waste disposal

Samples, waste liquids, etc. are potentially biologically contaminated. Operators should comply with the SOP for laboratory safety and dispose of waste liquids in accordance with local regulations for medical waste, infectious waste, industrial waste, etc.

5. Other precautions

5.1 On a fully automatic biochemistry analyzer, the linearity range is related to the ratio of the amount of a sample to the amount of a reagent and the time of measurement.

5.2 The amounts of the reagent and sample can be changed proportionally according to the requirements of different instruments.

5.3 Please do not use the reagent bottles for other purposes.

5.4 A result calculated with the k value is not as reliable as that obtained using the SRM (calibrator).
















5.5 Please do not mix reagents in different batches.

REFERENCE

1. Tietz NW et al. Clin Chem 1983, 29(5): 751
2. Tietz NW et al. Clin Chem Acta, 1983, 135: 339

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on HbA1c Reagent Kit (Immunoturbidimetric Method) are the most common ones appearing on medical devices and their packaging. They are explained in more details in the European Standard EN ISO 15223-1:2021.

Key to symbols used					
	Manufacturer		Use-by date		Catalogue number
	Date of manufacture		Batch code		Temperature limit
	<i>In vitro</i> diagnostic medical device		Keep away from sunlight		Biological risks
	Consult instructions for use or consult electronic instructions for use		Do not use if package is damaged and consult instructions for use		Authorized representative
	CE mark		This way up		Do not re-use



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