Hemoglobin A1c Assay Kit
(HbA1c)
Method: Latex Immunoturbidimetric Method

Cat. No	Package Size
GS9127T GM9127T GB9126T GX9127T	R1:1×60ml R2:1×20 ml
GS9127T/B GB9126T/B	R1:2×60 ml R2:2×20 ml
GH9127T GT9127T	R1:1×45 ml R2:1×15 ml
GD9127T	R1:24×3.8 ml R2:12×2.6ml

This assay kits apply to biochemistry analyzers: Hitachi7180/7170/7600/7080/7060/7020, Beckman AU400/AU680/AU5800, Bayer 1800, Dimension RXL Max, TBA40FR, etc. It is recommended that each laboratory should verify the results accordingly before testing.

Intended use

For quantitative determination of the HbA1c/Total Hemoglobin ratio(**%)** in human blood.

Clinical Significance

The concentration of HbA1c is representative of the mean blood glucose level over the preceding four to eight weeks. HbA1c in the blood of diabetic patients increases with rising blood glucose levels. Therefore it is described as a long term indicator of diabetic control unlike blood glucose which is only a short term indicator of diabetic control. HbA1c test can screen for and diagnose diabetes or risk of developing diabetes. It helps to evaluate how well the person's glucose levels have been controlled by treatment over time. This test is also used as a measure of risk for the development of gestational diabetes and diabetes complications.[1、2、3]

Assay Principle

This method utilizes the interaction of antigen and antibody to directly determine the HbA1c in whole blood. Total hemoglobin and HbA1c have the same unspecific absorption rate to latex particles. When mouse anti-human HbA1c monoclonal antibody is added (R2), latex-HbA1c-mouse anti human HbA1c antibody complex is formed. Agglutination is formed when goat anti-mouse IgG polyclonal antibody interacts with the monoclonal antibody. The measured absorbance is proportional to the HbA1c absorbed on to the surface of latex particals, which in turn is proportional to the percentage of HbA1c in the sample.

Reagent Composition

Contents	Concentration of Solutions
Reagent 1	
Glycine buffer	>15 mmol/L
Latex	>0.05%
Reagent 2	
Glycine buffer	>20 mmol/L
Goat anti-mouse IgG antibody	>0.05 mg/ml
Monoclonal mouse anti-human HbA1c antibody	>0.02 mg/ml

Sample Collection And Preparation

1. Whole blood collected with EDTA is satisfactory.
2. Anticoagulant whole blood samples are stable for two weeks at 2-8 ℃.
3. Refrigerated samples should place at the room temperature, operate before mixing fully. Please do not re-thawed.
4. Preparation of sample::

   To determine HbA1c, a hemolysate must be prepared for each sample:
   1) Dispense 1ml lysis into tubes labeled;
   2) Place 20ul of well mixed whole blood into the appropriately labeled tube, Mix;
   3) Allow to stand for 5 minutes or until complete lysis is evident. Hemolysates may be stored up to 10 days at 2-8° C.

Note: Human specimens and all materials that are in contact with samples should be handled and disposed of according to local and national laws and as if such samples are capable of transmitting infection.

Stability and Preparation of Reagents

1. The reagents should be stored at 2-8° C. Do not freeze. The reagents are stable when stored as instructed until the expiry date on the label.

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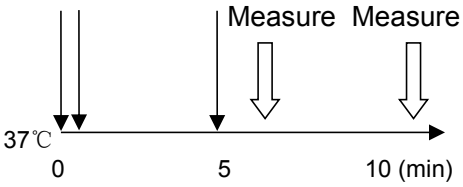
2. Please prevent cross-contamination if opened.
3. The on-board stability of reagents is about 30 days.

Assay Procedure
R1, R2 are ready-to-use.
Test Procedure for Analyzers (Hitachi 7180)
Assay Mode: 2 Point End 19-34
Wave Length (main/sub): 660nm/800nm
Sample:4μl
R1:150μl R2:50μl



Calibration
Gcell HbA1c Calibrator (GC-HbA1c) is recommended.

Calculation of Results

$$\text{Concentration} = \frac{\Delta A_{sample}\ /\text{min}}{\Delta A_{calibrator}\ /\text{min}} \times \text{Calibrator value}$$

Quality Control
For quality control, use Gcell Control(GQ-HbA1c) as daily quality control. Values should fall within a specific range. If these values fall outside the range and repetition excludes error, the following steps should be taken:
1. Check instrument settings and light source.
2. Check reaction temperature.
3. Check expiry date of kit and contents.
4. Check the quality of the water used for reagents reconstitution.

Reference Range
Normal value: 4-6%
It is recommended that each laboratory establish its own reference range to reflect the age, sex, diet and geographical location of the population.

Main Performance Characteristics

Precision

Sample Precision		GQ-1	GQ-2
NO.of Data Points		80	80
Mean(%)		5.56	11.98
Within-Run	SD	0.08	0.05
(S_r)	CV	1.5%	0.4%
Within-Laboratory	SD	0.11	0.18
(S_T)	CV	2.0%	1.5%

Linearity
Gcell HbA1c assay has a linear range from 4% to 16.0%.

When concentrations exceed the measurable range, dilute the test samples two-to three-fold with diluents (another test sample of known concentration (%) of HbA1c). Run the test again and calculate the concentrations using the following formula: HbA1C concentration (%) =[Retested HbA1C(%) × n] − [HbA1C(%) in the diluent × (n − 1)]
n = Dilution factor of the test sample (2 to 3).

Correlation
Tested the blood samples with Gcell HbA1c assay kit (Y) and a well-known brand kit (X) at the same time. The correlation formula is Y = 1.021X- 0.248, R^2 = 0.976, N=120.

Interference
The following analytes are tested and not to interfere:
Bilirubin: up to 50 mg/dL
Intralipid: up to 700 mg/dL
Ascorbic acid: up to 50 mg/dL

Sensitivity
For analysis sensitivity, the absorbance change (△A) should be between 0.0500～0.8000 under the percentage of 8.5%.

Safety Precautions and Warnings
1. For in vitro diagnostic use only. Do not pipette by mouth. Exercise the normal precautions required for handing laboratory reagents.
2. Reagents contain Sodium Azide. Avoid ingestion or contact with skin or mucous membranes. In case of skin contact, flush affected area with copious amounts of water. In case of contact with eyes or if ingested, seek immediate medical attention.

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3. Sodium Azide reacts with lead and copper plumbing, to form potentially explosive azides. When disposing of such reagents flush with large volumes of water to prevent azide build up. Exposed metal surfaces should be cleaned with 10% sodium hydroxide.
4. All specimens used in this test should be considered potentially infectious. Universal Precautions, as they apply at your facility, should be used for handling and disposing of materials during and after testing.

REFERENCES

1. Goldstein DE, Little RR, Lorenz RA, et al. Tests of glycemia in diabetes. Diabetes Care 1995;18:896-909.
2. The Diabetes Control and Complications Trial Research Group. The effect of intensive treatment of diabetes on the development and progression of long-term complications in insulin-dependent diabetes mellitus. N Engl J Med 1993;329:977-986.
3. American Diabetes Association, "Standards of Medical Care for Patients with Diabetes Mellitus", (Position statement), Diabetes Care, 21 (Suppl.1): S23 S31 (1998).
4. Pantheghini M, John WG on behalf of the IFCC Scientific Division. Implementation of haemoglobin A1c results traceable to the IFCC reference system: the way forward. Clin Chem Lab Med 2007; 45(8): 942-4.

INDEX OF SYMBOLS

	Manufacture
REF	Catalogue Number
LOT	Lot number
	Date of manufacture
	Use by (Expiration date)
IVD	For In-Vitro Diagnostic use only
2℃ 8℃	Stored at 2-8℃
	Attention: See instruction for use
EC REP	Authorized Representative in the European Company

Manufacture：Beijing Strong Biotechnology, Inc.

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