


HbA1c Assay (Immunoturbidimetric)

IVD For *in-vitro* diagnostic use only

Store at 2° to 8°C



INTENDED USE

HbA1c Assay Kit is for calibrating results in the quantitative determination of human hemoglobin A1c (HbA1c) in blood by automated immunoassay. For *in vitro* diagnostic use only.

INTRODUCTION

Throughout the circulatory life of the red cell, Hemoglobin A1c is formed continuously by the adduction of glucose to the N-terminal of the hemoglobin beta chain. This process, which is non-enzymatic, reflects the average exposure of hemoglobin to glucose over an extended period. In a classical study, Trivelli et al1 showed Hemoglobin A1c in diabetic subjects to be elevated 2-3 fold over the levels found in normal individuals. Several investigators have recommended that Hemoglobin A1c serve as an indicator of metabolic control of the diabetic, since Hemoglobin A1c levels approach normal values for diabetics in metabolic control. Hemoglobin A1c has been defined operationally as the "fast fraction" hemoglobins (HbA1a, A1b, A1c) that elute first during column chromatography with cation-exchange resins. The non-glycosylated hemoglobin, which consists of the bulk of the hemoglobin has been designated HbA0. The present procedure utilizes an antigen and antibody reaction to directly determine the concentration of the HbA1c.

PRINCIPLE OF THE METHOD

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. The amount of agglutination is proportional to the amount of HbA1c absorbed on to the surface of latex particles. The amount of agglutination is measured as absorbance. The HbA1c value is obtained from a calibration curve.

REAGENTS

Reagent	Component	Concentration
R1	Gly Buffer	15mmol/L
	Latex	0.1%
R2	IgG Antibody	0.08g/L
	Gly Buffer	60mmol/L
	HbA1c Antibody	0.05g/L
Hemolysing Solution	Distilled Water	
HBA1c Calibrator	Diluted human red cell solution	See label

PRECAUTIONS AND WARNINGS

- Although this product has been tested and found non-reactive for Hepatitis B Surface Antigen (HBsAG) and HIV, there is no known test can offer assurance that products derived from human blood will not transmit disease. Therefore, all human serum products and patient specimens should be handled in the same manner as an infectious agent.
- Avoid skin and eye contact. Avoid ingestion.
- Disposal of the used material in accordance with local guidelines. Avoid pollution and reuse.
- Do not use the product if interior package is damaged during shipment.
- The possibility of reagent instability or deterioration may be considered if there is precipitation, visible exudate, turbidity, microorganism growth; calibration results do not meet the appropriate standard specification, or control values out of range.
- Exercise the normal precautions required for handling all laboratory reagents.
- Wear protective clothing and disposable gloves while handling the kit reagents.
- Wash hands thoroughly after performing the test.
- Use in ventilated area.
- For acids, include appropriate warnings for spills such as "wipe up spills immediately and flush with water" and "should the reagent contact eyes or skin, flush with copious amounts of water and consult a physician
- For biological spills, indicate appropriate disinfectants and disinfection procedure.
- Dispose all specimens and components of the kit as potentially infectious agents.

- Do not use the kit or any kit component past the indicated expiry date.
- Do not use any other reagents from different lots in this test, unless the reagent is designated to be used with other lots of the same kit.
- Avoid microbial contamination of reagents.
- The reagents must be used only for the purpose intended by suitably qualified laboratory personnel, under appropriate laboratory conditions.

PREPARATION OF THE REAGENT

- R1, R2, and Hemolysing Solution are ready to use.
- HbA1c Calibrator: add 250µL distilled water to each vial, and let it stand for 30 minutes at room temperature.

STORAGE AND STABILITY

- All reagents are stable for 24 months. Do not use the reagents past their expiration date.
- R1 and R2 are stable for 4 weeks after opening when stored at 2-8°C.
- Lyophilized Calibrator/Control are stable for 7 days after reconstitution.

SPECIMEN COLLECTION AND HANDLING

Using an anticoagulant tube, collect 10 µl of red cells from the blood cell layer of a sample which has been standing for more than 3 hours, or from the blood cell layer which has been centrifuged for 2 minutes at 2000 rpm. Add 1ml of hemolysing solution or distilled water into the red cells. The sample is stable for 10 days at 4°C, when prevented from light.

PROCEDURE

R1&R2: Ready for use

Wavelength : 660 nm (800 nm) new line Temperature : 37°C

Cuvette: 1cm

Test Method: 2P End

	Blank Tube	Calibration Tube	Sample Tube
D.W	4ul	—	—
Sample	—	—	4 ul
Calibrator	—	4 ul	—
R1	150 ul	150 ul	150 ul
Mix thoroughly and incubate for 100~300 seconds at 37°C			
R2	50 ul	50 ul	50 ul

Mix thoroughly and read the Absorbance when incubate for 300 seconds at 37 °C, zero setting for blank tube, and calculate $A_{\text{calibrator}}$ and A_{sample} .

CALIBRATION

It is recommended to use the HbA1c Calibrators for calibration.

Dissolve the lyophilized calibrator with 250 µL distilled water, balance 10 minutes in room temperature, and then dilute to 6 levels calibrators.

Calibration Method: Spline

CALCULATIONS

When concentration (%) of test samples exceeds the measurable range, dilute the test sample by 2-3 times with HbA1c calibrator (STD-2)

Concentration of HbA1c = (retested HbA1c% × n) - (HbA1c% of the sample / a calibrator used for the dilution × (n-1))

N = Dilution factor of the test sample (2-3) newline

Expected Value

4.6-6.2% (NGSP)

Each lab should set up its own reference range or evaluate this range.

PERFORMANCE CHARACTERISTICS

Appearance: R1 is a milky white suspension, no agglomerate; R2 is a colorless or light yellow clear liquid, no precipitation or flocculent suspension; Hemolytic agent is a colorless clear liquid, no precipitation or floc suspension;

Reagent blank absorbance: at a wavelength of 600 nm, 37 °C, 1 cm light path, the reagent blank absorbance ≤ 2.0.

Reagent blank limit: reagent blank limit ≤ 1.5%.

Analytical sensitivity: When the reagent was tested for a 5.5% glycated is hemoglobin sample, the absorbance difference (ΔA) ≥ 0.01 under the specified parameters.

Liner range: reagents in the range of [3.0%, 15.0%] :

- The linear correlation coefficient r should be ≥ 0.990.
- In the range of [3.0%, 7.0%], the linear absolute deviation should not exceed ± 0.5%.

Within the range of [7.0%, 15.0%], the linear relative deviation should not exceed ± 7.0%.

Accuracy: With a certified reference test kit, the relative deviation should not exceed ± 7.0%.

Repeatability: Test control substances at different concentrations, repeat test 10 times each, the coefficient of variation (CV) was ≤ 3.0%.

Inter-batch difference: Three batches of reagents were tested with control substances in the range of 4.0% to 6.5%, and the relative difference between batches was ≤ 10%.

INTERFERENCE

















- Lipemia (Intralipid): no interference up to 1400mg/dl of intralipid.
- Vc: no interference up to 100mg/dl of Vc.
- Bilirubin: no interference up to 20mg/ dl.

REFERENCES

- Weichselbaum T E. Amer J Clin Path, 1946, 16:40
- Szasz G, E W Busch. Paper presented at 3rd Eur Congr Clin Chem, Brighton/England, June 3~8 (abstract), 1979
- Tietz N W. Textbook of Clinical Chemistry, 2nd Edition, W B Saunders Company, Philadelphia, 1994:2202

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	Catalogue Number		Temperature limit
	In Vitro diagnostic medical device		Caution
	Contains sufficient for <n> tests and Relative size		Consult instructions for use (IFU)
	Batch code		Manufacturer
	Fragile, handle with care		Use-by date
	Manufacturer fax number		Do not use if package is damaged
	Manufacturer telephone number		Date of Manufacture
	Keep away from sunlight		Keep dry