

Glycosylated Hemoglobin Test Reagent Kit

【Intended Use】

For the quantitative determination of HbA1c in human blood.

【Specification】

800Tests

Component	Active Ingredient
Eluent A: 800ml; 1320ml	Buffer, NaCl, Preserver
Eluent B: 500ml; 920ml	Buffer, NaCl, Preserver
Hemolysis: 1950ml; 2990ml	Buffer, NaCl, Surfactant, Preserver
Pre-Column(1pcsx2)	/
Chromatography Column (1pcsx2)	/
Pump Tube Cassette (1pcsx1)	/
Paper rolls(1pcsx8)	/

【Principle】

Ion Exchange Chromatography. After preparing the hemolysate, where the labile fraction is eliminated, hemoglobins are retained by a cationic exchange resin. HbA1c is specifically eluted after washing away the HbA1a+b, and is quantified by direct photometric reading at 415nm.

【Storage】

Stable at 5°C-35°C until the expiry date on the label. Direct exposure to sunshine avoided. Stable for 60 days after open-vial.

【Applicable Instrument】

HA-1500 automated HbA1c Analyzer, or compatible HbA1c Analyzers.

【Specimen】

Whole blood collected by standard procedure, and anti-coagulated by EDTA-K₂ or EDTA-Na₂. Specimens are stable for 7 days at 2-8°C.

【Procedure to Replace the Reagent Kit】

1. Place the Eluent A, Eluent B and Hemolysis tubing into the reagent bottle, and ensure that they are fitted correctly.
2. Install the Microcolumn on the analyzer.
3. Start the analyzer, the reagents will be filled in automatically.

【Reference Range】

NGSP: 4.0%~6.0%.

【Quality Control】

It is recommended to use the Hemoglobin A1c Controls (two levels) to verify the performance of the measurement procedure.

Each laboratory should establish its own internal Quality Control scheme and procedures for corrective action if controls do not recover within the acceptable tolerances.

【Product Performance】

1. accuracy: ≤5.0%
2. Precision: Within run: CV≤3.0%(n=20), batches accuracy range ≤6%(n=3).

【Diagnostic Characteristics】

HbA1c is the product of the irreversible condensation of glucose with the N-terminal residue of the β-chain of hemoglobin A. The HbA1c concentration in blood is directly proportional to the mean concentration of glucose prevailing in the previous 6-8 weeks (eAG), equivalent to the lifetime of the erythrocytes, as stated in the formulas below.

$$eAG \text{ (mg / dL)} = 28.7 \times \text{HbA1C\%} - 46.7$$

$$eAG \text{ (mmol / L)} = 1.59 \times \text{HbA1C\%} - 2.59$$

HbA1c levels are a valuable adjunct to glucose determinations in the assessment and follow up of individuals with diabetes mellitus, providing much more reliable information for glycemia monitoring than do determinations of glucose. Numerous studies have shown

that diabetes related complications may be reduced by the long term monitoring and tight control of blood glucose levels. However, it is not reliable for the diagnosis of diabetes.

Clinical diagnosis should not be made on the findings of a single test result, but should integrate both clinical and laboratory data.

【Precautions】

1. This kit is for professionals and in vitro diagnostic use only.
2. Use the reagents before expiry.
3. Different batches of reagents shouldn't be mixed together for use.
4. Reagents storage and validity please see the package insert.
5. Please refer to the local legal requirements for waste management.
6. Wear gloves and goggles when practicing the analysis.
7. Do not contact the reagents directly. Rinse with copious water to rinse in case of skin or eye contact. Seek medical advice if necessary.

【References】

1. Tietz NW. Clinical guide to laboratory tests, 3rd ed. Saunders Co, 1999.
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.

