Hemoglobin A_{1c}

(HbA_{1c} direct Latex Test)

Cat.No	Package Size	
837 400	2 x 23 ml R1 = Buffered Latex Reagent	15 ml R2 = Antiserum

GENERAL

Glycemic control in diabetes mellitus is done mainly by Glucose determonation, but also through quantitative determination of Hemoglobin A1c (HbA1c) in human blood : HbA1c indicates actual glucose levels over the preceding 3 months. HbA1c in diabetic subjects can be elevated 2-3 fold over normal and on the other hand approaches normal values when they are under metabolic control.

PRINCIPLE

Hemolyzed blood is used as sample material.
HbA1c of the sample (= the antigen) is bound to the latex in the R1-compound. There it reacts with HbA1c-antibody.
The reaction product is a measurable agglutination.
This is proportional to HbA1-concentration and is measured as absorbance A.
The HbA1c value is derived from a calibration curve.

REAGENTS

Storage

Store all reagents refrigerated at 2-8°C.
Unopened reagents are stable up to the expiration date printed on the labels.

Preparation of Reagents

R1 and **R2** are ready for use .

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Stability after opening :
At least 1 month at 2 – 8°C,
when contamination is strictly avoided

Additional Reagents

Calibration Set
Control Set
Lysing Reagent

SAMPLES

Collect venous blood with EDTA.

Storage and Stability:

Hemoglobin A1c in whole blood with EDTA is stable for one week at 2-8°C.[5]

To determine HbA1c, a hemolysate must be prepared from each sample:

1. Dispense 2ml of Lysing Reagent into test tubes and label as Controls, Patients, etc.
2. Add 20ul of well mixed (!) whole blood samples respectively of Calibrators and Controls .
   (Note: Calibrators and Controls have to be treated exactly like the patient samples!)
3. Let incubate at room temperature for minimum 5 min.
4. *Stability:*
   Hemolysates may be stored up to 3 days at 2-8°C

ANALYTICAL PROCEDURE

This reagent is made esp. for use on automated analyzers. Applications are available on request.

Wavelength	660nm
Temperature	37 °C

	Hemolyzed Sample (Patient, Calibrators, Control)
Hemolyzed Sample	3 µl
Reagent R1	180 µl
Mix, incubate for 2 min, then add	
Reagent R2	60 µL
Mix, read absorbance A1, incubate for 5 min, then read immediately A2	

CALCULATION

HbA1c results are determined using a calibration curve based on a suitable mathematical procedure and the Greiner Calibration Set.

QUALITY CONTROL

We suggest the use Greiner Hemoglobin A1c Control Set with assayed values respectively ranges.

EXPECTED VALUES

Recommended Values are
< 6% for non-diabetics
6 - 9% for diabetics under glycemic control
Up to 20% for diabetics out of glycemic control

Note:
Each laboratory should establish its own expected values. The given values can only be an average indication .

LIMITATIONS

1. Results may be inconsistent in patients e.g.with opiate addiction, lead-poisoning, alcoholism, ingestion of large doses of aspirin.
2. Elevated levels(> 10%) of HbF may lead to underestimation of HA1c.
3. Hemoglobin variants HbS, HbC and HbE do not interfere in this assay. There is also no interference by labile intermediates , and uremia does not interfere, too.

PRECAUTIONS

1.The reagent is for in vitro diagnostic use only.
2.All human specimens should be regarded as potentially biohazardous. Therefore, universal precautions should be
used in specimen handling (gloves, lab garments, avoid aerosol production, etc.)

PERFORMANCE DATA

These data are collected, and are available from Greiner. All data correspond to the requirements of the IVD directive. The data will be printed in rev.1 of this IFU.

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