Hemoglobin A\textsubscript{1c} (HbA\textsubscript{1c} direct Latex Test)

<table>
<thead>
<tr>
<th>Cat.No</th>
<th>Package Size</th>
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<tbody>
<tr>
<td>837 400</td>
<td>2 x 23 ml R1 = Buffered Latex Reagent 15 ml R2 = Antiserum</td>
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**GENERAL**
Glycemic control in diabetes mellitus is done mainly by glucose determination, but also through quantitative determination of Hemoglobin A\textsubscript{1c} (HbA\textsubscript{1c}) in human blood. HbA\textsubscript{1c} indicates actual glucose levels over the preceding 3 months. HbA\textsubscript{1c} 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. HbA\textsubscript{1c} of the sample (= the antigen) is bound to the latex in the R1-compound. There it reacts with HbA\textsubscript{1c}-antibody. The reaction product is a measurable agglutination. This is proportional to HbA\textsubscript{1c}-concentration and is measured as absorbance A. The HbA\textsubscript{1c} 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.

- 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 A\textsubscript{1c} in whole blood with EDTA is stable for one week at 2-8°C.

To determine HbA\textsubscript{1c}, 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)**

<table>
<thead>
<tr>
<th>Hemolyzed Sample</th>
<th>Reagent R1</th>
<th>Reagent R2</th>
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<tbody>
<tr>
<td></td>
<td>3 µL</td>
<td>180 µL</td>
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Mix, incubate for 2 min, then add

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<tr>
<th>Reagent R2</th>
<th>60 µL</th>
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Mix, read absorbance A1, incubate for 5 min, then read immediately A2

**CALCULATION**
HbA\textsubscript{1c} 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 A\textsubscript{1c} 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 HbA\textsubscript{1c}.
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.