TruLab HbA1c liquid
Assayed quality control material for monitoring assay performance of quantitative in vitro determination of hemoglobin A1c (HbA1c)

Order Information
5 9790 99 10 074 Level 1 4 x 0.25 mL
5 9790 99 10 060 Level 1 1 x 0.25 mL

Description
TruLab HbA1c liquid is a control based on human blood material (erythrocytes). The HbA1c concentration in TruLab HbA1c liquid Level 1 is normal.

Storage
The control both unopened and opened must be stored at 2 – 8°C, protected from light and heat.

Stability
Unopened and opened:
Maximum 15 months within the indicated period of shelf life if contamination and evaporation are avoided after having opened the bottles.

Proper storage and handling of this product must be observed.

Warnings and Precautions
1. Each individual blood donation used for production of TruLab HbA1c liquid was found to be non-reactive when tested with approved methods for HBsAg, anti-HIV 1+2 and anti-HCV. As there is no possibility to exclude definitely that products derived from human blood transmit infectious agents, it is recommended to handle the control with the same precautions used for patient specimens.
2. Please refer to the safety data sheets and take the necessary precautions for the use of calibrators and controls.
3. For professional use only!

Preparation
TruLab HbA1c liquid controls are ready to use. Controls must be treated the same way as patient samples. Please refer to the package insert of the reagent.

Target Values
The assay values were determined using DiaSys reagents oneHbA1c FS respectively oneHbA1c IS, calibrated by DiaSys TruCal HbA1c liquid. Assay values may vary slightly with different reagents. Control values according to DCCT/NGSP and according to IFCC have been derived from values according to IFCC by calculation [1–4]. The assay values listed below are specific for this lot number of control only.

Procedure
Please refer to the reagent package insert for instructions for use.

Literature

Waste management
Please refer to local legal requirements.

Manufacturer
DiaSys Diagnostic Systems GmbH
Alte Strasse 9 65558 Holzheim Germany

Target Values according to IFCC [mmol/mol]

<table>
<thead>
<tr>
<th>Lot No.</th>
<th>Expiry date</th>
<th>Test</th>
<th>Target value</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>TruLab HbA1c liquid Level 1</td>
<td>27565</td>
<td>2020-11</td>
<td>3-component system</td>
<td>42.9 mmol/mol</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2-component system</td>
<td>43.3 mmol/mol</td>
<td>34.6 – 52.0 mmol/mol</td>
</tr>
<tr>
<td></td>
<td></td>
<td>InnovaStar® (New Application)</td>
<td>41.4 mmol/mol</td>
<td>33.1 – 49.7 mmol/mol</td>
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<tr>
<td></td>
<td></td>
<td>InnovaStar®</td>
<td>25.4 mmol/mol</td>
<td>20.3 – 30.5 mmol/mol</td>
</tr>
</tbody>
</table>

Target Values according to DCCT/NGSP [%] have been derived from the values according to IFCC by calculation

<table>
<thead>
<tr>
<th>Lot No.</th>
<th>Expiry date</th>
<th>Test</th>
<th>Target value</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>TruLab HbA1c liquid Level 1</td>
<td>27565</td>
<td>2020-11</td>
<td>3-component system</td>
<td>6.08 %</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2-component system</td>
<td>6.11 %</td>
<td>5.32 – 6.91 %</td>
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<tr>
<td></td>
<td></td>
<td>InnovaStar® (New Application)</td>
<td>5.94 %</td>
<td>5.18 – 6.70 %</td>
</tr>
<tr>
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<td></td>
<td>InnovaStar®</td>
<td>4.47 %</td>
<td>4.01 – 4.94 %</td>
</tr>
</tbody>
</table>

Calculation formula:

\[ \text{HbA1c (NGSP)} = 0.0915 \times \text{HbA1c (IFCC)} + 2.15 \]

a: IFCC values in mmol/mol
b: NGSP values in %