TruCal HbA1c liquid
Calibrator set for use in tests for quantitative in vitro determination of hemoglobin A1c (HbA1c) on photometric systems

Order Information
1 3320 99 10 043 4 x 0.25 mL

Description
TruCal HbA1c liquid is a set of four liquid-stable calibrators with different levels based on human blood material (erythrocytes). The calibrator set is to be used for calibration of the DiaSys test oneHbA1c FS (Cat. No. 1 3329).

Storage
The calibrators 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 TruCal 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 calibrator 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
The TruCal HbA1c liquid calibrator set is ready to use. Calibrators must be treated the same way as patient samples. Please refer to the package insert of the reagent.

Waste management
Please refer to local legal requirements.

Calibrator Values
The calibrator values have been made traceable to the approved IFCC reference method. Values according to DCCT/NGSP in % have been derived from the values according to IFCC by calculation [1–4]. Calibrator values listed below are specific for this lot number of calibrator only.

Literature

Manufacturer
DiaSys Diagnostic Systems GmbH
Alte Strasse 9
65558 Holzheim Germany

Calibrator values according to IFCC

<table>
<thead>
<tr>
<th>Calibrator Value</th>
<th>Lot No.</th>
<th>Expiry Date</th>
<th>3-component system</th>
<th>2-component system</th>
</tr>
</thead>
<tbody>
<tr>
<td>TruCal HbA1c liquid Level 1</td>
<td>29651</td>
<td>2021-11-30</td>
<td>29.0 mmol/mol</td>
<td>30.0 mmol/mol</td>
</tr>
<tr>
<td>TruCal HbA1c liquid Level 2</td>
<td>29652</td>
<td>2021-11-30</td>
<td>71.3 mmol/mol</td>
<td>71.9 mmol/mol</td>
</tr>
<tr>
<td>TruCal HbA1c liquid Level 3</td>
<td>29653</td>
<td>2021-11-30</td>
<td>119 mmol/mol</td>
<td>116 mmol/mol</td>
</tr>
<tr>
<td>TruCal HbA1c liquid Level 4</td>
<td>29654</td>
<td>2021-11-30</td>
<td>145 mmol/mol</td>
<td>145 mmol/mol</td>
</tr>
</tbody>
</table>