HbA1c CONTROL
Lot: 0000000

<table>
<thead>
<tr>
<th>Cat. No.</th>
<th>Pack Name</th>
<th>Packaging (Content)</th>
</tr>
</thead>
<tbody>
<tr>
<td>XSYS0055</td>
<td>HBA1C CON L</td>
<td>1 x 0.25 ml</td>
</tr>
</tbody>
</table>

**INTENDED USE**
HbA1c liquid control is a human–based control. The HbA1c concentration in HbA1c Control Low is normal.

**STORAGE AND STABILITY**
The controls both unopened and reconstituted must be stored at 2 – 8 °C, protected from light and heat.
Unopened and opened: until the end of the indicated month of expiry if contamination and evaporation are avoided after having opened the bottles.
Proper storage and handling of this product must be observed.

**WARNINGS AND PRECAUTIONS**
Reagent of the kit is not classified like dangerous but contains less than 0.1% sodium azide classified as very toxic and dangerous substance for the environment.
Each individual blood donation used for production of HbA1c control 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.

**PREPARATION**
HbA1c control is ready to use. Controls must be treated the same way as patient samples. Please refer to the package insert of the reagent HbA1c, Cat. No. XSYS0054
Control preparation:
- Hemolyzing Solution (R3) 500 µl
- Control 10 µl
Mix and allow to stand for 5 minutes or until complete lysis is apparent.

**PROCEDURE**
Please refer to the reagent package insert for instructions for use.

**ASSAY VALUES**
HbA1c control values according to DCCT/NGSP in % and according to IFCC in mmol/mol have been derived from percentage values according to IFCC by calculation.

**WASTE MANAGEMENT**
Please refer to local legal requirements.

**LITERATURE**

**ASSIGNED VALUES**

**Target values according to IFCC (mmol/mol)**

<table>
<thead>
<tr>
<th>Lot No.</th>
<th>Expiry Date</th>
<th>Target Value</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>HbA1c Control Low</td>
<td>xxxxxx mm/yyyy</td>
<td>3-component system xx.x mmol/mol</td>
<td>xx.x – xx.x mmol/mol</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2-component system xx.x mmol/mol</td>
<td>xx.x – xx.x mmol/mol</td>
</tr>
</tbody>
</table>

**Target values according to DCCT/NGSP (%)**

<table>
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<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>HbA1c Control Low</td>
<td>xxxxxx mm/yyyy</td>
<td>3-component system x.xx %</td>
<td>x.xx – x.xx %</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2-component system x.xx %</td>
<td>x.xx – x.xx %</td>
</tr>
</tbody>
</table>

**USED SYMBOLS**

- **REF** Catalogue Number
- **LOT** Lot Number
- **IVD** In vitro Diagnostics
- **CONT** Content
- **Manufacturer**
- **See Instruction for Use**
- **Storage Temperature**

**QUALITY SYSTEM CERTIFIED ISO 9001 ISO 13485**

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