TruCal IgE

Calibrator for use in tests for quantitative in vitro determination of immunoglobulin E on photometric systems

Order Information
1 7230 99 10 059 5 x 1 mL

Description
TruCal IgE is a set of five liquid stable calibrators with different levels based on human blood material (serum) and containing biological additives from bovine origin.

Storage
The calibrator both opened and unopened must be stored at 2 – 8°C.

Stability
Unopened: Until the end of the indicated month of expiry
Opened: At least 6 weeks
Proper storage and handling of this product must be observed.

Warnings and precautions
1. Each individual blood donation used for production of TruCal IgE was found to be nonreactive 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. Contains sodium azide (0.95 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes.
3. Contains animal material. The calibrators should be handled as potentially infectious and with the same precautions used for patient specimens.
4. Please refer to the safety data sheets and take the necessary precautions for the use of calibrators and controls.
5. For professional use only!

Preparation
TruCal IgE calibrators are liquid and ready to use.

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

Calibrator Values
The assigned values of TruCal IgE calibrator have been made traceable to the WHO reference material IRP 75/502. Calibrator values listed below are specific for the indicated lot number only.

<table>
<thead>
<tr>
<th>Calibrator Level</th>
<th>Lot No.</th>
<th>Expiry date</th>
<th>Calibrator value</th>
</tr>
</thead>
<tbody>
<tr>
<td>TruCal IgE Level 1</td>
<td>29143</td>
<td>2021-11-30</td>
<td>50.0 IU/mL</td>
</tr>
<tr>
<td>TruCal IgE Level 2</td>
<td>29144</td>
<td>2021-11-30</td>
<td>100 IU/mL</td>
</tr>
<tr>
<td>TruCal IgE Level 3</td>
<td>29145</td>
<td>2021-11-30</td>
<td>200 IU/mL</td>
</tr>
<tr>
<td>TruCal IgE Level 4</td>
<td>29146</td>
<td>2021-11-30</td>
<td>500 IU/mL</td>
</tr>
<tr>
<td>TruCal IgE Level 5</td>
<td>29147</td>
<td>2021-11-30</td>
<td>1000 IU/mL</td>
</tr>
</tbody>
</table>

Waste management
Please refer to local legal requirements.

Manufacturer
DiaSys Diagnostic Systems GmbH
Alte Strasse 9 65558 Holzheim Germany

IVD CE