TruCal Protein high

Calibrator for use in tests for quantitative in vitro determination of various serum proteins on photometric systems

Order Information
5 9200 99 10 037 3 x 1 mL

Description
TruCal Protein high is a liquid stable calibrator based on human blood material (plasma).

Storage
The unopened and opened bottles of TruCal Protein must be stored at 2 – 8°C.

Stability
Unopened: Until the end of the indicated month of expiry
Opened: At least 12 weeks

Proper storage and handling of this product must be observed.

Warnings and Precautions
1. Each individual blood donation used for production of TruCal Protein 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. Contains sodium azide (0.95 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes.
3. Please refer to the safety data sheets and take the necessary precautions for the use of calibrators and controls.
4. For professional use only!

Preparation
TruCal Protein is liquid and ready to use.
For calibration 5 calibrator levels are required. Prepare five calibrator levels using TruCal Protein high and NaCl solution 0.9% (9 g/L) according to the instructions in the table below.

Note: Homogenize diluted levels by thorough mixing and use them immediately.

<table>
<thead>
<tr>
<th>Level</th>
<th>Lot No.</th>
<th>Expiry date</th>
<th>Dilution</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Undiluted+NaCl 0.9%</td>
</tr>
<tr>
<td>Level 1</td>
<td>1 + 15</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Level 2</td>
<td>1 + 7</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Level 3</td>
<td>1 + 3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Level 4</td>
<td>1 + 1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Level 5</td>
<td>25870</td>
<td>2021-01</td>
<td>Undiluted</td>
</tr>
</tbody>
</table>

Calibrator values

<table>
<thead>
<tr>
<th>Calibrator values</th>
<th>Albumin [g/L]</th>
<th>C3c [mg/dL]</th>
<th>C4 [mg/dL]</th>
<th>IgA [mg/dL]</th>
<th>IgG [mg/dL]</th>
<th>IgM [mg/dL]</th>
<th>Prealbumin [mg/dL]</th>
<th>Transferrin [mg/dL]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level 1</td>
<td>4.87</td>
<td>19.7</td>
<td>5.08</td>
<td>56.4</td>
<td>195</td>
<td>56.2</td>
<td>7.79</td>
<td>31.5</td>
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<tr>
<td>Level 2</td>
<td>9.74</td>
<td>39.4</td>
<td>10.2</td>
<td>113</td>
<td>391</td>
<td>112</td>
<td>15.6</td>
<td>63.1</td>
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<td>Level 3</td>
<td>19.5</td>
<td>78.8</td>
<td>20.3</td>
<td>226</td>
<td>781</td>
<td>225</td>
<td>31.2</td>
<td>126</td>
</tr>
<tr>
<td>Level 4</td>
<td>39.0</td>
<td>158</td>
<td>40.6</td>
<td>451</td>
<td>1563</td>
<td>449</td>
<td>62.4</td>
<td>252</td>
</tr>
<tr>
<td>Level 5</td>
<td>77.9</td>
<td>315</td>
<td>81.2</td>
<td>902</td>
<td>3125</td>
<td>899</td>
<td>125</td>
<td>505</td>
</tr>
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</table>

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

Calibrator Values
The assigned values of TruCal Protein have been made traceable to the ERM®-DA470k/IFCC reference material. Calibrator values listed below are specific for this lot number of calibrator only.

Literature

Waste management
Please refer to local legal requirements.

Manufacturer
DiaSys Diagnostic Systems GmbH
Alte Strasse 9
65558 Holzheim Germany

IVD