TruLab Lp(a)

Assayed quality control material for monitoring assay performance of quantitative in vitro determination of [Lp(a)]

Order Information
5 9840 99 10 046 Level 2 3 x 1 mL

Description
TruLab Lp(a) is a lyophilized control material for Lp(a) based on human blood material (serum). The Lp(a) concentration in TruLab Lp(a) Level 2 is in the pathological range.

Storage
The vials of TruLab Lp(a) both reconstituted and unopened must be stored at 2 – 8°C protected from light.

Stability
Unopened: Until the end of the indicated month of expiry
Reconstituted: At least 14 days

Proper storage and handling of this product must be observed.

Warnings and Precautions
1. Each individual blood donation used for production of TruLab Lp(a) 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. Contains sodium azide (0.9 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
The lyophilisate is vacuum sealed; therefore the vial should be opened very carefully to avoid loss of dried material. For reconstitution add exactly 1.0 mL of distilled water. Close the vial carefully and allow the control to stand for 30 minutes swirling occasionally. Avoid foaming! Do not shake!

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

Assay Values
Assay values may vary with different reagents and methodologies used. The assay values listed below are specific for this lot number of control only.

Assay value according to new standardization [mg/dL]

<table>
<thead>
<tr>
<th>Reagent</th>
<th>Lot No.</th>
<th>Expiry Date</th>
<th>Assay Value new Standardization</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>TruLab Lp(a) Level 2</td>
<td>27296</td>
<td>2021-06</td>
<td>49.0 mg/dL</td>
<td>39.2 – 58.8 mg/dL</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>490 mg/L</td>
<td>392 – 588 mg/L</td>
</tr>
</tbody>
</table>

Assay value according to IFCC (SRM 2B) standardization

<table>
<thead>
<tr>
<th>Reagent</th>
<th>Lot No.</th>
<th>Expiry Date</th>
<th>Assay Value</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>TruLab Lp(a) Level 2</td>
<td>27296</td>
<td>2021-06</td>
<td>116 nmol/L</td>
<td>92.8 – 139 nmol/L</td>
</tr>
</tbody>
</table>

Literature

Waste management
Please refer to local legal requirements.

Manufacturer
DiaSys Diagnostic Systems GmbH
Alte Strasse 9
65558 Holzheim
Germany

TruLab Lp(a) Level 2 844 9840 10 02 00 January 2017/6