TruLab D-Dimer

Assayed quality control material for monitoring the assay performance of quantitative in vitro determination of D-Dimer

Order information
Cat. No.: 5 9810 99 10 073 Level 1
2 vials lyophilisate for preparation of 2 x 0.5 mL control + 1 x 2.5 mL diluent

Description
TruLab D-Dimer is a lyophilized control for D-dimer based on human blood material (serum) for use with the DiaSys reagent D-Dimer FS. The control contains biological additives from bovine origin.

Storage
The controls both unopened and reconstituted must be stored at 2 – 8°C.

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. The diluent for the reconstitution of TruLab D-Dimer contains sodium azide (0.95 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes.
2. Each individual blood donation used for production of TruLab D-Dimer 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.
3. TruLab D-Dimer contains animal material. The controls 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
The lyophilisate is vacuum sealed; therefore the vial should be opened very carefully to avoid loss of dried material. For reconstitution add exactly 0.5 mL of diluent. 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.

Target value
The assay values were determined with the reagent D-Dimer FS using the TruCal D-Dimer calibrator. The calibrator value is traceable to fibrinogen, which was degraded by plasmin. The value was defined by means of clinically characterized samples in such a way that the cut-off for diagnosis of the deep vein thrombosis of the leg (DVT) has a value of 0.5 µg FEU/mL.

The assay values listed below are specific for this lot number of control only.

Waste management
Please refer to local legal requirements.

Literature

Manufacturer
DiaSys Diagnostic Systems GmbH
Alte Strasse 9
65558 Holzheim
Germany

<table>
<thead>
<tr>
<th>TruLab D-Dimer Level 1</th>
<th>Lot No.</th>
<th>Expiry date</th>
<th>Assay value</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>28629</td>
<td>2021-11-30</td>
<td>1.30 µg FEU/mL</td>
<td>1.04 – 1.56 µg FEU/mL</td>
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