

TruCal D-Dimer

Calibrator for the DiaSys test for quantitative in vitro determination of D-dimer on photometric systems

Order information

Cat. No.: 1 7260 99 10 047

1 vial lyophilisate for preparation of 1 mL ready-to-use, undiluted calibrator + 2 x 2.5 mL diluent

Description

TruCal D-Dimer is a lyophilized calibrator based on human blood material (serum) for determination of D-dimer with the DiaSys reagent D-Dimer FS. It contains biological additives from bovine origin.

Storage

The calibrators both opened 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

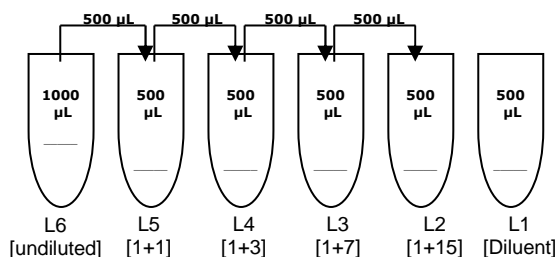
1. The diluent contains sodium azide (0.95 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes.
2. Each individual blood donation used for production of TruCal D-Dimer was found to be non-reactive when tested with FDA-approved methods or methods cleared in compliance with the European Directive 98/79/EC, Annex II, List A for HBsAg, anti-HIV and anti-HCV. As there is no possibility to exclude definitely that products derived from human blood components transmit infectious agents, it is recommended to handle the calibrator with the same precautions used for patient specimens.
3. TruCal 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 1 mL of diluent. Close the vial carefully and allow the calibrator to stand for 30 minutes swirling occasionally. Avoid foaming! Do not shake!

The calibration curve is obtained with five calibrators at different levels and the added diluent for determination of the zero value.

The following levels have to be prepared diluting the calibrator with diluent (concentrations are stated below):



Note : After each dilution step the calibrator samples should be homogenized by thorough mixing. For each dilution step, use new pipette tips to avoid carry-over.

Procedure

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

Calibrator Values

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.

Calibrator values listed below are specific for this lot number of calibrator only.

Literature

1. Stenman UH. Standardization of immunoassays. In: Price CP, Newman DJ, editors. Principles and practice of immunoassay. New York: Stockton Press; 1997.p.243-68.
2. Biosafety in Microbiological and Biomedical Laboratories. U.S. Department of Health and Human Services, Washington 1993 (HHS Publication No. [CDC] 93-8395).

Waste management

Please refer to local legal requirements.

Manufacturer

DiaSys Diagnostic Systems GmbH
Alte Strasse 9
65558 Holzheim Germany



| | Lot No. | Expiry date | Calibrator value |
|----------------|---------|-------------|------------------|
| TruCal D-Dimer | 33444 | 2024-08-31 | 10.7 µg FEU/mL |

Concentrations of the dilution steps for TruCal D-Dimer in µg FEU/mL:

| L6 | L5 | L4 | L3 | L2 | L1 |
|------|------|------|------|------|------|
| 10.7 | 5.35 | 2.68 | 1.34 | 0.67 | 0.00 |