

# TruLab D-Dimer

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

### Order information

Cat. No.: 5 9820 99 10 073 Level 2  
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 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

1. Röhle G, Siekmann L. Quality assurance of quantitative determination. In: Thomas L, editor. Clinical laboratory diagnostics. 1<sup>st</sup> ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p. 1393-1401.
2. Biosafety in Microbiological and Biomedical Laboratories. U.S. Department of Health and Human Services, Washington 1993 (HHS Publication No. [CDC] 93-8395).

### Manufacturer

DiaSys Diagnostic Systems GmbH  
Alte Strasse 9  
65558 Holzheim  
Germany



	Lot No.	Expiry date	Assay value	Range
TruLab D-Dimer Level 2	38615	2027-09-30	4.96 µg FEU/mL	3.97 – 5.95 µg FEU/mL