D-Dimer FS*

Diagnostic reagent for quantitative in vitro determination of D-dimer in plasma on photometric systems

Order information

Cat. No.	Kit size					
1 7268 99 10 935	R1	2 x	12 mL	+	R2	1 x 8 mL
1 7260 99 10 047		1 x	1 mL		TruCal D-Dimer	

Summary [1,2]

During plasma coagulation soluble fibrin is generated by the influence of thrombin on fibrinogen. The soluble fibrin is cross-linked to the vessel walls by factor XIIIa. When splitting this cross-linked fibrin, characteristic products called D-dimers are released.
Increased D-dimer concentrations are found in thrombotic diseases and microthrombotic events (e.g. in case of disseminated intravascular coagulation, DIC). D-dimer determination is mainly used to exclude deep vein thrombosis of the leg and pulmonary embolism.

Method

Particle enhanced immunoturbidimetric test

Principle

Determination of the D-dimer concentration by photometric measurement of antigen-antibody-reaction between antibodies against D-dimer bound to particles and D-dimer present in the sample.

Reagents

Components and Concentrations

R1:	Buffer	pH 8.5	0.38 mol/L
R2:	Particle suspension Polystyrene particle coated with monoclonal anti-human D-dimer antibody (mouse)	pH 7.5	< 1%

Storing Instructions and Reagent Stability

The reagents are stable up to the end of the indicated month of expiry, if stored at 2 – 8ºC and contamination is avoided after opening the vials. Do not freeze the reagents!

Warnings and Precautions

1. The reagents contain sodium azide (0.95 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes.
2. The reagents contain animal material. Handle the product as potentially infectious according to universal precautions and good clinical laboratory practices.
3. In very rare cases, samples of patients with gammopathy might give falsified results [5].
4. Heterophile antibodies in patient samples can cause falsified results.
5. Please refer to the safety data sheets and take the necessary precautions for the use of laboratory reagents. For diagnostic purposes, the results should always be assessed with the patient's medical history, clinical examinations and other findings.
6. For professional use only!

Waste Management

Please refer to local legal requirements.

Reagent Preparation

The reagents are ready to use.
The reagent R2 has to be mixed before the first use avoiding formation of foam.

Materials required but not provided

General laboratory equipment

Specimen

Citrate plasma

Stability[3]:			
	8 hours	at	20 – 25°C
	4 days	at	4 – 8°C
	6 months	at	–20°C

Freeze only once!
Discard contaminated specimens.

Assay Procedure for Analyzers

Application sheets for automated systems are available on request

Wavelength	570 nm
Optical path	1 cm
Temperature	37°C
Measurement	Against reagent blank

	Blank	Sample/calibrator
Sample/calibrator	-	30 µL
Dist. water	30 µL	-
Reagent 1	900 µL	900 µL
Mix, incubate for 3 – 5 min., then add:		
Reagent 2	300 µL	300 µL
Mix, read absorbance (A1) within 20 sec., incubate for 5 min, then read absorbance (A2) again.		

$\Delta A = (A2 - A1)$ sample or calibrator

Calculation

The D-dimer concentration of unknown samples is derived from a calibration curve using an appropriate mathematical model such as spline. The calibration curve is obtained with 5 calibrators at different levels and the added diluent for determination of the zero value.
Stability of calibration: 6 weeks

Calibrator and Controls

For calibration, use the DiaSys TruCal D-Dimer calibrator. Calibrator values are traceable to fibrinogen which was degraded by plasmin. DiaSys TruLab D-Dimer controls should be assayed for internal quality control. Each laboratory should establish corrective action in case of deviations in control recovery.

	Cat. No.	Kit size		
TruLab D-Dimer Level 1	5 9810 99 10 073	2	x	0.5 mL
TruLab D-Dimer Level 2	5 9820 99 10 073	2	x	0.5 mL

Performance Characteristics

Measuring Range

The test has been developed to determine D-dimer concentrations within a measuring range of 0.2 – 8.7 µg FEU/mL, at least up to the concentration of the highest calibrator. If values exceed this range, samples should not be diluted but released with > 8.7 µg FEU/mL.

Prozone Limit

No prozone effect was observed up to a D-dimer value of 50 µg FEU/mL.

Specificity/Interferences

Due to its antibodies, DiaSys D-Dimer FS is a specific immunoassay for human D-dimer. No interference was observed by conjugated and unconjugated bilirubin up to 60 mg/dL, hemoglobin up to 1000 mg/dL, lipemia up to 350 mg/dL triglycerides and rheumatoid factor up to 300 IU/mL. For further information on interfering substances refer to Young DS [4].

* fluid stable

Sensitivity/Limit of Detection

The lower limit of detection is 0.07 µg FEU/mL.

Precision (n= 20)

Intra-assay	Mean [µg FEU/mL]	SD [µg FEU/mL]	CV [%]
Sample 1	0.719	0.013	1.76
Sample 2	1.02	0.014	1.35
Sample 3	3.87	0.047	1.21

Inter-assay	Mean [µg FEU/mL]	SD [µg FEU/mL]	CV [%]
Sample 1	0.659	0.030	4.59
Sample 2	0.953	0.021	2.18
Sample 3	3.59	0.039	1.10

Method comparison

A comparison of DiaSys D-Dimer FS (y) to an immunoturbidimetric test (x) with 235 samples gave the following results:
y= 0.57 x + 0.133 µg FEU/mL; r = 0.985

Reference Range

Cut-off value for exclusion of the deep vein thrombosis of the leg:
< 0.5 µg FEU/mL
In a study* for determination of the cut-off value for D-dimer for exclusion of the deep vein thrombosis of the leg 250 patients were tested. 50 of the patients had confirmed thrombosis, 100 patients were suspected to have a thrombosis which has not been approved and 100 patients were not suspected to suffer from thrombosis.

The study gave the following result:
With the DiaSys D-Dimer FS test and a cut-off value of 0.5 µg FEU/mL, 49 thrombotic subjects out of 50 were found true positive and one thrombotic person was found false negative. Out of 200 non-thrombotic patients, 39 were found false positive and 161 were found true negative.

*The specimen for the study was characterized by Prof. Gualtiero Palareti, Angiologia e Malattie della Coagulazione “Marino Golinelli”, Bologna.

Each laboratory should check if the cut-off value is transferable to its own patient population and instruments and determine its own cut-off value if necessary.

Literature

1. Dati F, Metzmann E. Proteins Laboratory Testing and Clinical Use. Holzheim: DiaSys; 2005.p 376.
2. Thomas L. Clinical Laboratory Diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998 p. 633-5.
3. Guder WG, Zatwa B et al. The quality of Diagnostic Samples. 1st ed. Darmstadt: Git verlag, 2001: 26-7.
4. Young DS. Effects of Drugs on Clinical Laboratory Tests. 5th ed. Volume 1 and 2. Washington, DC: The American Association for Clinical Chemistry Press 2000.
5. Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: mechanisms, detection and prevention. ClinChemLabMed 2007;45(9):1240–1243.

Manufacturer

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