BioMajesty

D-Dimer FS*

Diagnostic reagent for quantitative in vitro determination of D-dimer in plasma on BioMajesty JCA-BM6010/C

Order Information

Cat. No. 1 7268 99 10 966
R1: 2 x 100 tests
R2: 2 x 100 tests

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	pH 7.5	< 1%
	Polystyrene particles coated with monoclonal anti-human D-dimer antibody (mouse)		

Storage Instructions and Reagent Stability

The reagents are stable up to the end of the indicated month of expiry, if stored at 2 – 8°C and contamination is avoided. 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. Samples containing heterophilic antibodies may cause falsely elevated results.
4. In very rare cases, samples of patients with gammopathy might give falsified results [5].
5. Heterophile antibodies in patient samples can cause falsified results.
6. 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.
7. 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.
The bottles are placed directly into the reagent trays.

Specimen

Citrate plasma

Stability [1]:

8 hours	at	20 – 25°C
4 days	at	4 – 8°C
6 months	at	–20°C

Freeze only once!
Discard contaminated specimens.

Calibrators and Controls

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

	Cat. No.	Kit size
TruCal D-Dimer	1 7260 99 10 047	1 x 1 mL
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 of 0.2 – 8.7 µg FEU/mL D-dimer 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.	
Limit of detection**	0.06 µg FEU/mL D-dimer
No prozone effect up to 50 µg FEU/mL D-dimer	
On-board stability	6 weeks
Calibration stability	4 weeks

Interfering substances	**Interferences ≤ 10%**	**D-Dimer concentration**
Conjugated bilirubin	up to 60 mg/dL	1,12 µg FEU/mL
Unconjugated bilirubin	up to 60 mg/dL	1,09 µg FEU/mL
Hemoglobin	up to 860 mg/dL	0,55 µg FEU/mL
Hemoglobin	up to 1200 mg/dL	1,06 µg FEU/mL
Lipemia (triglycerides)	up to 370 mg/dL	0,97 µg FEU/mL
For further information on interfering substances refer to Young DS [2].		

Precision			
Within run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [µg FEU/mL]	0.637	1.04	1.64
Coefficient of variance [%]	2.71	1.34	0.935
Between run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [µg FEU/mL]	0.617	1.05	4.18
Coefficient of variance [%]	4.43	2.36	2.29

Method comparison (n=122)	
Test x	D-Dimer FS (Hitachi 917)
Test y	D-Dimer FS (BM6010/C)
Slope	1.04
Intercept	–0.03 µg FEU/mL
Coefficient of correlation	0.999

** lowest measurable concentration which can be distinguished from zero mean + 3 SD (n=20) of an analyte free specimen

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. Guder WG, Zawta B et al. The Quality of Diagnostic Samples. 1st ed. Darmstadt: GIT Verlag; 2001; p. 26-7.
2. 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.
3. Dati F, Metzmann E. Proteins Laboratory Testing and Clinical Use. Holzheim: DiaSys; 2005 p. 376.
4. Thomas L. Clinical Laboartory Diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998 p. 633-5.
5. Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: mechanisms, detection and prevention. ClinChemLabMed 2007;45(9):1240–1243.

Manufacturer

IVD CE

DiaSys Diagnostic Systems GmbH
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BioMajesty

D-Dimer FS

Chemistry code 10 726

Application for plasma samples

This application was set up and evaluated by DiaSys. It is based on the standard equipment at that time and does not apply to any equipment modifications undertaken by unqualified personnel.

Analytical Conditions	
R1 volume	80
R2e volume	0
R2 volume	26.7
R1 diluent vol	0
R2e diluent vol	0
R2 diluent vol	0
Sample vol (S)	2.7
Sample vol (U)	2.7
Reagent 1 mix	strong
Reagent 2e mix	weak
Reagent 2 mix	strong
Reaction time	10

Endpoint Method	
Re.absorb (u)	9.999
Re.absorb (d)	-9.999

Calculation Method Setting	
M-DET.P.I	0
M-DET.P.m	36
M-DET.P.n	37
S-DET.P.p	22
S-DET.P.r	23
Check D.P.I.	0
Limit value	0.003
Variance	10
Reac.type	Inc

Sub-analy. Conditions	
Name	DDI
Digits	2
M-wave L.	596
S-wave.L	****
Analy.mthd.	EPA
Calc.mthd.	MSTD
Qualit. judge	No

Reaction Rate Method	
Cycle	2
Factor	2
E2 corre	Not do
Blank (u)	9.999
Blank (d)	-9.999
Sample (u)	9.999
Sample (d)	-9.999

Analysis Test Condition Setting (M)		
Sample Type	**Serum**	**Urine**
Reac. sample vol.	2.7	2.7
Diluent method	No dil	No dil
Undil. sample vol.	0	0
Diluent volume	0	0
Diluent position	0	0

Prozone	
Prozone form	No
Prozone limit	9.999
Prozone judge	Upper limit
Judge limit	9.999
M-DET.P.m	0
M-DET.P.n	0
S-DET.P.p	0
S-DET.P.r	0

MULTI-STD Setting

Formula	Spline	**Axis Conv**	No conv
Blank	Blank-any value	**Points**	6

	FV	Reac. smp. vol.	Dil. method	Dil. smp. vol.	Diluent vol.	Diluent pos.	STD H	STD L
BLK	#	2.7	No dil	0	0	0	9.999	-9.999
1	#	2.7	No dil	0	0	0	9.999	-9.999
2	#	2.7	No dil	0	0	0	9.999	-9.999
3	#	2.7	No dil	0	0	0	9.999	-9.999
4	#	2.7	No dil	0	0	0	9.999	-9.999
5	#	2.7	No dil	0	0	0	9.999	-9.999

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