respons®910

D-Dimer FS*

Diagnostic reagent for quantitative in vitro determination of D-dimer in plasma on DiaSys respons®910

Order Information

Cat. No. 1 7268 99 10 921
4 twin containers for 100 determinations each
Cat. No. 1 7268 99 10 926
1 twin container for 100 determinations

Method

Particle enhanced immunoturbidimetric test

Principle

Determination of 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 particle 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. Heterophile antibodies in patient samples can cause falsified results.
4. In very rare cases, samples of patients with gammopathy might give falsified results [5].
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. Avoid formation of foam. The bottles are placed directly into the reagent rotor.

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

For calibration, DiaSys TruCal D-Dimer calibrator is recommended. The calibrator value is 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 action 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 up to 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**	0.35 µg FEU/mL D-Dimer
No prozone effect up to 50 µg FEU/mL D-Dimer	
On-board stability	15 days
Calibration stability	5 days

Interfering substance	**Interferences < 10%**	**D-dimer [µg FEU/mL]**
Hemoglobin	up to 350 mg/dL	0.507
	up to 1200 mg/dL	1.09
Bilirubin, conjugated	up to 60 mg/dL	0.452
	up to 60 mg/dL	2.74
Bilirubin, unconjugated	up to 20 mg/dL	0.497
	up to 60 mg/dL	1.52
Lipemia (triglycerides)	up to 350 mg/dL	0.794
	up to 450 mg/dL	2.44
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]	0.48	1.09	3.66
Coefficient of variance [%]	6.54	4.17	2.32
Between run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [µg FEU/mL]	0.92	1.97	4.27
Coefficient of variance [%]	5.06	1.79	2.15

Method comparison (n=26)	
Test x	DiaSys D-Dimer FS (Hitachi 917)
Test y	DiaSys D-Dimer FS (respons®910)
Slope	0.939
Intercept	0.019 µg FEU/mL
Coefficient of correlation	0.995

** according to NCCLS document EP17-A, vol. 24, no. 34

Reference Range

Cut-off value for exclusion of the deep vein thrombosis:
< 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 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 Laboratory 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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* fluid stable

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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.

Identification	
This method is usable for analysis:	Yes
Twin reaction:	No
Name:	DDI
Shortcut:	
Reagent barcode reference:	708
Host reference:	708

Technic	
Type:	Fixed time kinetic
First reagent:[µL]	150
Blank reagent	Yes
Sensitive to light	
Second reagent:[µL]	50
Blank reagent	No
Sensitive to light	
Main wavelength:[nm]	546
Secondary wavelength:[nm]	
Polychromatic factor:	
1 st reading time [min:sec]	05:00
Last reading time [min:sec]	08:00
Reaction way:	Increasing
Linear Kinetics Substrate depletion: Absorbance limit	
Linearity: Maximum deviation [%]	
Fixed Time Kinetics Substrate depletion: Absorbance limit	
Endpoint Stability: Largest remaining slope	
Prozone Limit [%]	

Reagents	
Decimals	
Units	

Sample	
Diluent	DIL A (NaCl)
Hemolysis:	
Agent [µL]	0 (no hemolysis)
Cleaner	
Sample [µL]	0
Technical limits	
Concentration technical limits-Lower	0.2000
Concentration technical limits-Upper	8.7000
SERUM	
Normal volume [µL]	6.0
Normal dilution (factor)	1
Below normal volume [µL]	
Below normal dilution (factor)	
Above normal volume [µL]	2.0
Above normal dilution (factor)	1
URINE	
Normal volume [µL]	6.0
Normal dilution (factor)	1
Below normal volume [µL]	
Below normal dilution (factor)	
Above normal volume [µL]	2.0
Above normal dilution (factor)	1
PLASMA	
Normal volume [µL]	6.0
Normal dilution (factor)	1
Below normal volume [µL]	
Below normal dilution (factor)	
Above normal volume [µL]	2,0
Above normal dilution (factor)	1
CSF	
Normal volume [µL]	6.0
Normal dilution (factor)	1
Below normal volume[µL]	
Below normal dilution (factor)	
Above normal volume [µL]	2.0
Above normal dilution (factor)	1
Whole blood	
Normal volume [µL]	6.0
Normal dilution (factor)	1
Below normal volume[µL]	
Below normal dilution (factor)	
Above normal volume [µL]	2.0
Above normal dilution (factor)	1

Results	
Decimals	2
Units	µg FEU/mL
Correlation factor-Offset	0.0000
Correlation factor-Slope	1.0000

Range	
Gender	All
Age	
SERUM	
URINE	
PLASMA	>= <=0.50
CSF	
Whole blood	
Gender	
Age	
SERUM	
URINE	
PLASMA	
CSF	
Whole blood	

Contaminants
Please refer to r910 Carryover Pair Table

Calibrators details	
Calibrator list	**Concentration**
Cal. 1/Blank	0
Cal. 2	*
Cal. 3	*
Cal. 4	*
Cal. 5	*
Cal. 6	*
	Max delta abs.
Cal. 1	0.0100
Cal. 2	0.0100
Cal. 3	0.0100
Cal. 4	0.0100
Cal. 5	0.0200
Cal. 6	0.0300
Drift limit [%]	10.0

Calculations	
Model	X
Degree	3

* Enter calibrator value