respons®920

D-Dimer FS*

Diagnostic reagent for quantitative in vitro determination of D-dimer in plasma on DiaSys respons®920

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

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. To avoid carryover interference, please take care of efficient washing especially after use of interfering reagents. Please refer to the DiaSys respons®920 Carryover Pair Table. Carryover pairs and automated washing steps with the recommended cleaning solution can be specified in the system software. Please refer to the user manual.
4. Samples containing heterophilic antibodies may cause falsely elevated results.
5. In very rare cases, samples of patients with gammopathy might give falsified results [5].
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. 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

Discard contaminated specimens. Freeze only once.

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 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	14 days
Calibration stability	5 days

Interfering substance	**Interferences < 10%**	**D-dimer [µgFEU/mL]**
Hemoglobin	up to 800 mg/dL	0.55
	up to 1100 mg/dL	1.66
Bilirubin, conjugated	up to 65 mg/dL	0.60
	up to 65 mg/dL	1.99
Bilirubin, unconjugated	up to 65 mg/dL	0.64
	up to 65 mg/dL	2.04
Lipemia (triglycerides)	up to 350 mg/dL	0.80
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]	0.80	1.08	3.79
Coefficient of variance [%]	5.93	2.68	1.74
Between run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [µg FEU/mL]	0.78	1.03	3.75
Coefficient of variance [%]	6.15	3.00	2.44

Method comparison (n=65)	
Test x	DiaSys D-Dimer FS (Hitachi 917)
Test y	DiaSys D-Dimer FS (respons®920)
Slope	0.954
Intercept	0.039 µg FEU/mL
Coefficient of correlation	0.994

** 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
Alte Strasse 9 65558 Holzheim Germany

* fluid stable

respons®920

D-Dimer FS

Application for plasma

Test Details			Test Volumes			Reference Ranges		
Test	:	DDI				Auto Rerun	:	☐
Report Name	:	D-Dimer				Online Calibration	:	☐
Unit	:	µg FEU/mL	Decimal Places	:	2	Cuvette Wash	:	☐
Wavelength-Primary	:	546	Secondary	:	0	Total Reagents	:	2
Assay Type	:	2-Point	Curve Type	:	Cubic spline	Reagent R1	:	DDI R1
M1 Start	:	20	M1 End	:	20	Reagent R2	:	DDI R2
M2 Start	:	30	M2 End	:	30			
Sample Replicates	:	1	Standard Replicates	:	3	Consumables/Calibrators:		
Control Replicates	:	1	Control Interval	:	0	Blank/Diluent	:	0
Reaction Direction	:	Increasing	React. Abs. Limit	:	*	Calibrator Level 1	:	**
Prozone Limit %	:	97*	Prozone Check	:	Lower	Calibrator Level 2	:	**
Linearity Limit %	:	0	Delta Abs. / Min.	:	0.00	Calibrator Level 3	:	**
Technical Minimum	:	*	Technical Maximum	:	*	Calibrator Level 4	:	**
Y = aX + b a=	:	1.00	b=	:	0.00	Calibrator Level 5	:	**

* Technical limits are automatically defined by the software via the upper and lower calibrator level.
** Enter calibrator value.

Test Details			Test Volumes		Reference Ranges
Test	:	DDI			
Sample Type	:	Plasma			

Sample Volumes

Normal	:	6.00	µL	Dilution Ratio	:	1	X
Increase	:	6.00	µL	Dilution Ratio	:	1	X
Decrease	:	6.00	µL	Dilution Ratio	:	1	X
Standard Volume	:	6.00	µL				

Reagent Volumes and Stirrer Speed

RGT-1 Volume	:	150	µL	R1 Stirrer Speed	: High
RGT-2 Volume	:	50	µL	R2 Stirrer Speed	: High

Sample Types

- ☑ Serum
- ☐ Urine
- ☐ CSF
- ☑ Plasma
- ☐ Whole Blood
- ☐ Other

Test Details			Test Volumes	Reference Ranges
Test	:	DDI		
Sample Type	:	Plasma		
Reference Range	:	DEFAULT		
Category	:	Male		

Reference Range

		Lower Limit (µgFEU/mL)	Upper Limit (µgFEU/mL)
Normal	:	0.00	0.50
Panic	:		

Sample Types

- ☑ Serum
- ☐ Urine
- ☐ CSF
- ☑ Plasma
- ☐ Whole Blood
- ☐ Other