

## D-Dimer FS\*

### Order Information

#### Cat. No.

1 7268 99 10 921

1 7268 99 10 926

#### Kit size



400 (4 x 100)



100 (1 x 100)

### Intended Use

Diagnostic reagent for quantitative in vitro determination of D-dimer, a fibrin degradation product (FDP), in human citrate plasma on automated respons<sup>®</sup>910. Determination of D-dimer is used to exclude thrombotic events like deep vein thrombosis or pulmonary embolism in conjunction with a clinical probability assessment in outpatients who do not exceed the cut-off value.

### Summary

Thrombosis is the formation of a blood clot in the human body. A blood clot consists of a fibrin mesh that stabilizes a cluster of erythrocytes and platelets [1]. D-dimer is a small protein fragment that appears in plasma during fibrinolysis, the degradation process of a fibrin mesh. In this process, the enzyme plasmin catalyzes the breakdown of the fibrin mesh and produces so-called fibrin degradation products, including D-dimer [2]. Thus, fibrinolysis prevents uncontrolled growth of blood clots and D-dimer can be used as an indicator of activated coagulation and fibrinolytic system. Under normal physiological conditions, circulating D-dimer levels are typically low; however, pathologically elevated levels are observed in conditions characterized by increased fibrin formation and fibrinolytic activity like venous thromboembolism (VTE), preeclampsia and certain conditions of cancer and infections. Furthermore, high levels may indicate the presence of disseminated intravascular coagulation (DIC). Since elevated D-dimer levels can be attributed to various causes, a measured value can never be used for a specific diagnosis [3]. In conjunction with patients history and profile, D-dimer values below the cut-off (0.5 µg FEU/mL) are used to exclude a deep vein thrombosis (DVT) and pulmonary embolism (PE) with high sensitivity [4]. To overcome the lack of reference material or methods, clinical studies are conducted to determine cut-off values and diagnostic value, thereby providing evidence for exclusion diagnostics [5]. In addition, for patients with a history of thrombosis, D-dimer levels can be used to help predicting the risk of recurrence and monitoring effectiveness of anticoagulation therapy [6].

### Method

Particle enhanced immunoturbidimetric test

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

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

### Storage and Stability

Reagents are stable up to the date of expiry indicated on the kit, if stored at 2 – 8°C and contamination is avoided. Do not freeze.

The open-vial stability of the reagent is 15 months until expiry date.

### Warnings and Precautions

- The reagents contain sodium azide (0.95 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes.
- The reagents contain material of biological origin. Handle the product as potentially infectious according to universal precautions and good clinical laboratory practice.
- In very rare cases, samples of patients with gammopathy might give falsified results [7].
- Heterophile antibodies in patient samples can cause falsified results.
- In case of product malfunction or altered appearance that could affect the performance, contact the manufacturer.

- Any serious incident related to the product must be reported to the manufacturer and the competent authority of the Member State where the user and/or patient is located.
- Please refer to the safety data sheets (SDS) 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.
- For professional use only.

### Waste Management

Refer to local legal requirements for chemical disposal regulations as stated in the relevant SDS to determine the safe disposal.

Warning: Handle waste as potentially biohazardous material. Dispose of waste according to accepted laboratory instructions and procedures.

### Reagent Preparation

The latex enhanced reagent 2 in respons<sup>®</sup> bottle has to be mixed up by successive inversions before first use. Avoid formation of foam.

### Materials Required

General laboratory equipment

### Specimen

Human citrate plasma

Only use suitable tubes or collection containers for specimen collection and preparation.

When using primary tubes, follow the manufacturer's instructions.

Stability [8]:

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

Only freeze once. Discard contaminated specimens.

### Calibrators and Controls

DiaSys TruCal D-Dimer is recommended for calibration. Calibrator values are traceable to fibrinogen, which was degraded by plasmin. Use DiaSys TruLab D-Dimer Level 1 and Level 2 for internal quality control. All target values of the controls are traceable to DiaSys reagent/calibrator system. Quality control must be performed after calibration. Control intervals and limits have to be adapted to the individual requirements of each laboratory. Results must be within the defined ranges. Follow the relevant legal requirements and guidelines. Each laboratory should establish corrective action in case of deviations in control recovery.

	Cat. No.	Kit size
TruCal D-Dimer (+ diluent)	1 7260 99 10 047	1 x 1.0 mL 2 x 2.5 mL
TruLab D-Dimer Level 1 (+ diluent)	5 9810 99 10 073	2 x 0.5 mL 1 x 2.5 mL
TruLab D-Dimer Level 2 (+ diluent)	5 9820 99 10 073	2 x 0.5 mL 1 x 2.5 mL

### Performance Characteristics

Measuring range from 0.34 µg FEU/mL up to 8.7 µg FEU/mL, depending on the concentration of the highest calibrator. Linearity is given within ± 10%. If values exceed this range, samples should not be diluted but released with > 8.7 µg FEU/mL.

Limit of detection**	0.266 µg FEU/mL
Limit of quantitation**	0.34 µg FEU/mL
No prozone effect up to 50 µg FEU/mL.	
Onboard stability	15 days
Calibration stability	5 days

Interference by	Interferences ≤ 10% up to	Analyte concentration [µg FEU/mL]
<b>Bilirubin</b> (conjugated)	60 mg/dL	0.452
	60 mg/dL	2.74
<b>Bilirubin</b> (unconjugated)	20 mg/dL	0.480
	60 mg/dL	1.52
<b>Hemolysis</b>	350 mg/dL	0.507
	1200 mg/dL	1.09
<b>Lipemia</b> (triglycerides)	350 mg/dL	0.794
	450 mg/dL	2.44

For further information on interfering substances, refer to the literature [9,10].

Precision			
Repeatability (n=20)	Sample 1	Sample 2	Sample 3
Mean [µg FEU/mL]	0.485	1.09	3.66
CV [%]	6.54	4.17	2.32
Between day (n=20)	Sample 1	Sample 2	Sample 3
Mean [µg FEU/mL]	0.918	1.97	4.27
CV [%]	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 <sup>®</sup> 910)
Slope	0.939
Intercept	0.019 µg FEU/mL
Coefficient of correlation	0.995

\*\* according to CLSI document EP17-A, Vol. 24, No. 34

## 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 reference ranges are transferable to its own patient population and determine own reference ranges if necessary.

## Literature

- Weisel, J. W., & Litvinov, R. I. Red blood cells: the forgotten player in hemostasis and thrombosis. *Journal of Thrombosis and Haemostasis*. 2019;17(2):271-282.
- Dati F, Metzmann E. *Proteins Laboratory Testing and Clinical Use*. Holzheim: DiaSys; 2005.p 376.
- Thomas L. *Clinical Laboratory Diagnostics* [Internet]. Prof. Lothar Thomas; 2024 [cited 2024 Jun 07]. <https://www.clinical-laboratory-diagnostics.com/>
- Soheir S. Adam, Nigel S. Key, Charles S. Greenberg; D-dimer antigen: current concepts and future prospects. *Blood* 2009; 113 (13): 2878–2887.
- Favresse, J., Lippi, G., Roy, P. M., Chatelain, B., Jacqmin, H., ten Cate, H., Mullier, F. D-dimer: Preanalytical, analytical, postanalytical variables, and clinical applications. *Critical Reviews in Clinical Laboratory Sciences*. 2018;55(8):548–577.
- Palareti, G., Cosmi, B., Legnani, C., Tosetto, A., Brusi, C., Iorio, A., et al. D-dimer testing to determine the duration of anticoagulation therapy. *New England Journal of Medicine*. 2006;355(17):1780-1789.
- Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: mechanisms, detection and prevention. *ClinChemLabMed* 2007;45(9):1240-1243.
- Guder WG, da Fonseca-Wollheim F, Heil W, et al. *The Quality of Diagnostic Samples*, German United Society for Clinical Chemistry and Laboratory Medicine. 3rd ed; 2010.
- 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.
- Young DS. *Effects on Clinical Laboratory Tests - Drugs Disease, Herbs & Natural Products*, <https://clinfx.wiley.com/aaccweb/aacc/>, accessed in March 2024. Published by AACC Press and John Wiley and Sons, Inc.

Additions and/or changes in the document are highlighted in grey. Deletions are communicated via customer info by stating the edition no. of the package insert/instruction for use.



DiaSys Diagnostic Systems GmbH  
Alte Strasse 9 65558 Holzheim  
Germany  
[www.diasys-diagnostics.com](http://www.diasys-diagnostics.com)

\* Fluid Stable

## D-Dimer FS

### 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:[ $\mu$ L]	150
Blank reagent	Yes
Sensitive to light	
Second reagent:[ $\mu$ L]	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 [ $\mu$ L]	0 (no hemolysis)
Cleaner	
Sample [ $\mu$ L]	0
Technical limits	
Concentration technical limits-Lower	0.3400
Concentration technical limits-Upper	8.7000
SERUM	
Normal volume [ $\mu$ L]	6.0
Normal dilution (factor)	1
Below normal volume [ $\mu$ L]	
Below normal dilution (factor)	
Above normal volume [ $\mu$ L]	2.0
Above normal dilution (factor)	1
URINE	
Normal volume [ $\mu$ L]	6.0
Normal dilution (factor)	1
Below normal volume [ $\mu$ L]	
Below normal dilution (factor)	
Above normal volume [ $\mu$ L]	2.0
Above normal dilution (factor)	1
PLASMA	
Normal volume [ $\mu$ L]	6.0
Normal dilution (factor)	1
Below normal volume [ $\mu$ L]	
Below normal dilution (factor)	
Above normal volume [ $\mu$ L]	2.0
Above normal dilution (factor)	1
CSF	
Normal volume [ $\mu$ L]	6.0
Normal dilution (factor)	1
Below normal volume [ $\mu$ L]	
Below normal dilution (factor)	
Above normal volume [ $\mu$ L]	2.0
Above normal dilution (factor)	1
Whole blood	
Normal volume [ $\mu$ L]	6.0
Normal dilution (factor)	1
Below normal volume [ $\mu$ L]	
Below normal dilution (factor)	
Above normal volume [ $\mu$ L]	2.0
Above normal dilution (factor)	1

Results	
Decimals	2
Units	$\mu$ g FEU/mL
Correlation factor-Offset	0.0000
Correlation factor-Slope	1.0000

Range	
Gender	All
Age	
SERUM	
URINE	
PLASMA	#
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

# Editable by user