Cat. No 4-246 and 4-446

PRESTIGE 24i D-DIMER

DIAGNOSTIC KIT FOR DETERMINATION OF D-DIMER CONCENTRATION

INTRODUCTION
FDPs (Fibrin and Fibrinogen Degradation Products) are generic name for several degradation products that are formed as the result of plasmin mediated, proteolytic degradation of fibrin and fibrinogen. FDP assay become important test to diagnose or monitor fibrinolytic disorder, especially disseminated intravascular coagulation (DIC). But FDP assay also detects the degradation products of fibrinogenolysis. D-dimer assay is more specific for fibrinolysis because it can only be produced as the result of plasmin mediated, proteolytic degradation of fibrin.

METHOD PRINCIPLE
D-dimer assay is a turbidimetric immunoassay that utilizes latex particles sensitized with antibodies. In the presence of D-dimer, the particles aggregate.
The turbidity measured is directly proportional to the D-dimer sample concentration.

REAGENTS
Package

	Cat. No 4-246 (24-TRAY)	**Cat. No 4-446 (36-TRAY)**
1-Reagent	1 x 40 ml	1 x 23 ml
2-Reagent	1 x 15 ml	1 x 9 ml
D-Dimer Diluent	2 x 40 ml	2 x 40 ml

Buffer (1-Reagent), latex (2-Reagent) and D-Dimer Diluent stored at 2-10°C are stable until expiry date printed on the package. The reagents are stable for 4 weeks on board the analyser at 2-10°C. Do not freeze the reagents. Protect from light and contamination!

Concentrations in the test

Tris(hydroxymethylo)aminomethane	0.38 mol/l
suspension of latex particles sensitized with anti-D-Dimer antibodies (mouse)	0.2 w/v%

Warnings and notes
- Products for in vitro diagnostic use only.
- The reagents must be used only for the intended purpose, by suitably qualified laboratory personnel, under appropriate laboratory conditions.
- Products contain sodium azide (< 0.1%) as a preservative. Avoid contact with skin and mucous membranes.
- Allow the reagents to equilibrate at the room temperature before use.
- Swirl the latex reagent (2-Reagent) well before use.
- Do not mix different lots of reagent.
- Do not add new reagent to the remaining reagent.
- Pay attention not to contaminate cuvettes with dust or detergents.
- In buffer reagent (1-Reagent) might appear turbidity but it has no influence on assay results.
- Immunoassay cannot deny non-specific reaction and rarely occurs prozone effect when assay samples containing unusually high D-dimer level.

SPECIMEN
Plasma.
Nine volumes of fresh blood are collected in one volume of 0.11M trisodium citrate, followed by centrifugation at 3000 x g for 10-30 minutes. Use supernatant as plasma sample.
Samples containing more than 20 µg/ml FEU D-dimer should be reassayed, using a 1:10 sample dilution with D-Dimer Diluent.
Plasma samples might be stored 8 hours at room temperature (20-25°C), 4 days in temperature 4-8°C and 6 months in -20°C.
Nevertheless it is recommended to perform the assay with freshly collected samples!

PROCEDURE
These reagents may be used in automatic analysers Prestige 24i, Biolis 24i, Sapphire 400 and Prestige 24i Premium, Biolis 24i Premium, Sapphire 400 Premium.
1-Reagent and 2-Reagent are ready to use.
1-Reagent put on basic position in reagent tray.
2-Reagent put on start position in reagent tray.
For reagent blank 0.9% NaCl is recommended.

REFERENCE VALUES [1]

plasma	< 0.5 µg/ml FEU (< 500 µg/l FEU)

It is recommended for each laboratory to establish its own reference ranges for local population.
Unit converter:
1µg/ml DDU (D-Dimer Unit) = 2µg/ml FEU (Fibrynogen Equivalent Unit)

QUALITY CONTROL
For internal quality control it is recommended to use the CORMAY D-DIMER CONTROLS (Cat. No 4-459) with each batch of samples.
For the calibration of automatic analysers systems the CORMAY D-DIMER CALIBRATOR (Cat. No 4-259) is recommended. The calibration curve should be prepared every 4 weeks, with change of reagent lot number or as required e.g. quality control findings outside the specified range.

PERFORMANCE CHARACTERISTICS
These metrological characteristics have been obtained using the automatic analysers BS-400 and TBA80FR. Results may vary if a different instrument is used.

- **Sensitivity:** 0.3 µg/ml FEU.
- **Linearity:** up to 20 µg/ml FEU.

For higher concentrations dilute the sample with D-Dimer Diluent in the ratio of 1 to 10 and repeat the assay. Multiply the result by 11.

- **Specificity / Interferences**

Haemoglobin up to 0.49 g/dl, conjugated bilirubin up to 20.6 mg/dl, free bilirubin up to 18.3 mg/dl, RF up to 500 IU/ml do not interfere with the test.

- **Precision**

Repeatability (run to run) n = 20	Mean [µg/ml]	SD [µg/ml]	CV [%]
level 1	2.50	0.05	1.97
level 2	9.20	0.54	5.91
Reproducibility (day to day) n = 20	Mean [µg/ml]	SD [µg/ml]	CV [%]
level 1	2.60	0.11	4.38
level 2	8.99	0.48	5.36

- **Method comparison**

A comparison between CORMAY kit (y) and another commercially available kit based on latex turbidimetric method (x) and dedicated for coagulometers, using 24 samples gave following results:
y = 0.9911x – 0.0514 µg/ml FEU;
R = 0.920 (R – correlation coefficient)

WASTE MANAGEMENT

Please refer to local legal requirements.

APPLICATION for Prestige 24i, Biolis 24i and Sapphire 400

Item name	27	D-Dim

Data information

Units	µg/ml
Decimals	1

Analysis

Type	RATE
Main W.Length1	570
Sub W.Length2	
Method	Latex

Corr

Slope		Inter
Y= 1.000	X+	0.000

Calibration

Type	Spline		
Standard			
#1	*	#4	*
#2	*	#5	*
#3	*	#6	*

Normal Range

	Male		Female	
	Low	High	Low	High
Serum				
Urine				
Plasma	0	0.5	0	0.5
CSF				
Dialysis				
Other				

Item name	27	D-Dim

Aspiration

Kind	Double

	Volume	
Sample	5	µl
Reagent1	150	
Reagent2	50	

Third Mix.	ON
R1 Blank	Water-Blank

Monitor

0 Level Point	1
Span	3.000

Data Process

Read

	Start	End
Main	34	40
Sub		

Factor

Blank correction	

Absorbance Limit

Low	-3.000
High	3.000

Endpoint Limit	2.000
Linear Check (%)	40%

Dilution

Diluent	100:Dil2

Prozone Check

	Start	End	Limit (%)	
First				
Second				Low
Third				Low

Item name	27	D-Dim

Auto Rerun SW

OFF

Auto Rerun Range (Result)

	OFF	OFF
	Lower	Higher
Serum		
Urine		
Plasma		
CSF		
Dialysis		
Other		

Auto Rerun Condition (Absorbance)

Absorbance Range	
Lower	OFF
Higher	OFF

Prozone Range	OFF

APPLICATION for Prestige 24i Premium, Biolis 24i Premium and Sapphire 400 Premium

Item No.	27	Item Name	D-Dimer	Optical

Data information

Units	µg/ml
Decimals	1

Analysis

Type	RATE method
Main Wave Length	570 nm
Sub Wave Length	
Method	Latex

Correlation

Slope		Intercept
Y= 1	X+	0

Calibration

Type	Spline1				
Std sample conc.					
Blank	0	#1	*	#2	*
#3	*	#4	*	#5	*
#6	*				

Item No.	27	Item Name	D-dimer	Optical

Aspiration

Kind	Double

Vol.

Kind	Vol.	Add	Units
Sample	6	5	µl
Reagent 1	210	10	µl
Reagent 2	65	10	µl

Blank value

Water Blank

Reaction Monitor

0 Level Point	1
Span	3

Third mixing

ON

Data Process

Read

	Start	End
Main	36	42
Sub		

Abs.Limit Low -3 ~ High 3

Correction value

Blank correction	1
End Point Limit	2
Linear Check (%)	80

Prozone Check

	Start	End	Limit (%)	
First				
Second				Low

Item No.	27	Item Name	D-dimer	Optical

Normal Range

	Male		Female	
	Low	High	Low	High
Serum				
Urine				
Plasma	0	0.5	0	0.5
CSF				
Dialysis				
Other				

Panic Range

	Male		Female	
	Low	High	Low	High
Serum				
Urine				
Plasma				
CSF				
Dialysis				
Other				

Item No.	27	Item Name	D-dimer	Optical

Auto Rerun SW

OFF

Auto Rerun Range (Conc.)

	First Dil	Low			High		
		Re	Value	Dil	Re	Value	Dil
Serum							
Urine							
Plasma							
CSF							
Dialysis							
Other							

Auto Rerun Condition (Absorbance)

Lower	OFF
Higher	OFF

Auto Rerun Condition (Prozone)

OFF

Dilution

100:Dil2

LITERATURE

1. Alan H. B. Wu, Tietz Clinical Guide to Laboratory Tests, W.B. Saunders Company, 4th edition, 332 (2006)
2. World Health Organization, Use of anticoagulants in diagnostic laboratory investigations, Geneva 2002
3. Dembińska-Kieć A, Naskalski J, Diagnostyka Laboratoryjna z Elementami Biochemii Klinicznej, VOLUMED, Wrocław 1998

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