Cat. No 9-452

DIAGNOSTIC KIT FOR DETERMINATION OF D-DIMER CONCENTRATION

OS – D-DIMER

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 concentration in a sample.

REAGENTS

Package

1-Reagent	1 x 57.5 ml
2- Reagent	1 x 22 ml
D-Dimer Diluent	2 x 125 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 Olympus AU400/AU640.
1-Reagent and 2-Reagent are ready to use.
For reagent blank 0.9% NaCl is recommended.

APPLICATION

Reagent ID: **099**

Specific Test Parameters

General | LIH | ISE | Range

Test name: **D-Dimer** Type: **Plasma** Operation: **Yes**

Sample:	Volume	5	µL	Dilution	0	µL	Pre-Dilution Rate:	1
Reagents: R1	Volume	150	µL	Dilution	0	µL	Min OD	Max OD
R2	Volume	50	µL	Dilution	0	µL	L -2.0000	H 2.5000

Reagent OD Limit:

Wavelength:	Pri.	540	Sec.	None	First L	-2.0000	First H 2.5000
Method:		End			Last L	-2.0000	Last H 2.5000
Reaction Slope:		+			Dynamic Range:		
Measuring Point 1:	First	0	Last	24	L		H
Measuring Point 2:	First	0	Last	13	Correlation Factor:		
Linearity:		%			A	1.000	B 0.000
No-Lag-Time:					On-board Stability Period:		

Specific Test Parameters

General | LIH | ISE | Range

Test name: **D-Dimer** Type: **Plasma**

Value/Flag: # Level L: # Level H: #

Normal Ranges:

	Sex	Age L Year	Age L Month	Age H Year	Age H Month	L	H
1.	#	#	#	#	#	#	#
2.	#	#	#	#	#	#	#
3.	#	#	#	#	#	#	#
4.	#	#	#	#	#	#	#
5.	#	#	#	#	#	#	#
6.	#	#	#	#	#	#	#
7. None Selected						#	#
8 Out of Range						#	#

	L	H		
Panic Value:	#	#	Unit: **µg/ml**	Decimal Places: **2**

Calibration Specific

General | ISE

Test name: **D-Dimer** Type: **Plasma**

Calibration Type: **7AB** Formula: **Spline** Counts: **1** Process: **CONC**

	Cal. No.	OD	CONC	Factor/OD-L	Factor/OD-H
Point 1:	#		**	-2.0000	2.5000
Point 2:	#		*	-2.0000	2.5000
Point 3:	#		*	-2.0000	2.5000
Point 4:	#		*	-2.0000	2.5000
Point 5:	#		*	-2.0000	2.5000
Point 6:	#		*	-2.0000	2.5000
Point 7:	#		*	-2.0000	2.5000

1-Point Cal.Point: with CONC-0 Slope Check: **None** Advanced Calibration: #

MB Type Factor: Calibration Stability Period:

\# User defined
* Calibrator value
** Saline should be used as calibrator 1

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.

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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