D-DIMER

Kit for quantitative determination of D-Dimer in the plasma

REF			IVD
SHD4DD			

USE OF TEST

D-dimer analysis is a test for the quantitative determination of degradation of fibrinogen / fibrin (D-dimer) products in human plasma. Measurement of D-dimer is used as an aid in the detection of intravascular clots and fibrinolysis. Only for in vitro diagnostic use.

SAMPLES

Plasma samples with 0.109 molar (~ 3.2%) Na citrate concentration can be used for D-dimer. Mix the sample gently by turning it gently before centrifuging. Centrifuge and separate plasma as soon as possible after collection. Samples can be stored at 2-8 ° C if analyzed within 4 days and 3 months if stored at -20 ° C. Defrost the samples at room temperature and mix thoroughly before use. Once thawed, the sample can not be reconstituted for analysis.

REAGENTS

Reagent 1: Tris buffer 100mm, pH 8.2

Reagent 2: Suspension of human antiserum D-Dimer covered of particles of latex(0,2%) of monoclonal antiserum mouse

HANDLING OF REAGENTS

Liquid reagents ready for use.

PRECAUTIONS AND WARNINGS

1. Do not use reagents, calibrators and controls after the expiration date on the label on the outer carton.
2. Samples containing materials of human origin must be treated as potentially infected with laboratory safety procedures. Avoid ingestion and contact with skin and eyes.
3. Do not mix reagents of different lots.
4. The reagent contains sodium azide <0.1%, NaN3, as a preservative. Sodium azide can react with lead and copper tubes to form highly explosive metal azide. For disposal, wash with a large amount of water to avoid the accumulation of azide.

PRESERVATION AND STABILITY OF PRODUCT

- Store kit at 2-8 ° C. DO NOT freeze reagents.
- The reagents are stable until the expiry date shown on the label, if contaminations and evaporations are avoided and stored in the light.

NECESSARY MATERIALS NOT SUPPLIED

- General laboratory equipment.

ANALITYCAL PROCEDURE

WAVELENGHT: 578 nm
TEMPERATURE OF REACTION: 37°C.
REACTION: Fixed-time

PROCEDURE HYDRA09

LEAK THE MINIMUM TEMPERATURE REACTORS 30 MIN BEFORE USE

1) **Dispense 270 µL of Reagent 1 in one of the supplied cuvettes.**
2) **Preheat the reagent containing cuvette.**
3) **Add 10 µL of sample and shake gently for a few seconds.**
4) **Incubate in the Photometer Incubation Room (Hydra09) and enter the Enter key.**
5) **Add 90 µL Reagent 2 and shake gently for a few seconds.**
6) **Insert the cuvette into the reading cell and wait for the end of the incubation period for the result**

CALCULATION

The Hydra 09 automatically performs the calculation of the results at the end Of incubation.

CALIBRATION

The reagents in the kit have already been calibrated. The calibration values Are contained in the Smart Card in the kit and are valid only for the lot Present on the Smart Card label. Each kit must be used with Your Smart Card supplied.

NOTE

A diagnosis can not be based on the result of a single test; But it must always be integrated and confirmed by clinical information and any other tests.

REFERENCE VALUES

Man - Woman < 0.50 µg/mL FEU

Reference values are to be considered as indicative because each laboratory should look for those of the population on which it operates. The test results should be interpreted together with the information from the patient's clinical evaluations.

CONSIDERATIONS ON DISPOSAL

The product is intended for use within professional analysis laboratories. For proper waste disposal refer to current regulations and safety data sheets.

INTERFERENCES:

Rheumatoid factor up to 50 IU / Ml

PERFORMANCE OF TEST

PRECISION IN THE SERIES N:10

	Sample 1	Sample 2
Media (µg/mL FEU)	0.920	1.84
CV%	5.22	4.39

PRECISION BETWEEN THE SERIES

	Sample 1	Sample 2
Media (µg/mL FEU)	0.903	3.616
CV%	8.31	4.71

LINEARITY:

The test is linear up to 5 mg / mL FEU.

COMPARISON BETWEEN METHODS

Parameters	Total of three sites
Pendence	0.979
95% CI	Da 0.909 a 1060
Intercept	-0.106
95%CI	Da -0.260 a 0.026
R^2	0.939

BIBLIOGRAPHY:

1. BJH Guideline. British Journal of Haematology. 124, 15-25.
2. Alan H.B. Wu. Tietz Clinical Guide to Laboratory Tests. Fourth Ed. Saunders Elsevier, 11830 Westline Industrial Drive, St. Louis, Missouri 63146. 2006; 328-329

SIMBOLS– 98/79/EC DIRECTIVE

Attenzione! Leggere le istruzioni	Size – No. Of determination		Manufacturer
For in vitro diagnostic use only	Expiry		Do not reuse
Store at --°C	Lot. #	REF	Code #

SELEO ENGINEERING S.R.L.
I TRAVERSA BUGNANO – ORTA DI ATELLA (CE) ITALY

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