D-Dimer Assay

CE REF **C179D**
R1 1x30ml+R2 1x10ml
Turbidimetry

Configuration
The D-Dimer Assay reagent is provided in packaging configuration:
IVD

Store 2 - 8ºC.

INTENDED USE
In vitro test for the quantitative determination of D-Dimer in human plasma on automated clinical chemistry analyzers for Clinical laboratories.

PRINCIPLE OF THE METHOD
Increase of D-Dimer in blood testifies the blood clot is formed and fibrinlytic activity has functioned. It is known that high value of D-Dimer is indicated in diseases such as malignant tumor, vascular disease.

Principle
The D-dimer contained in the sample reacts with the latex sensitized with anti-human D-dimer monoclonal antibody (mouse) and forms aggregates, which are determined optically for calculation of D-dimer concentration.

REAGENTS

Diluent (R1)	Tris buffer 100 mM, NaN3 0.1%, pH 8.3 Surfactant 0.95 g/L.
Antibody (R2)	Suspension of anti-human D-Dimer mouse monoclonal antibody coated, pH 7.5, Latex particles (0.2%).PBS Buffer 0.1 mmol/l

CALIBRATION
The assay is calibrated to the Reference Material CRM 470/RPPHS (Institute of Reference of Materials and Measurements, IRMM). It must be used the CALIBRATOR (Cat. No. 179CAL) to calibrate the reagent. The reagent (both mono reagent and bireagent) should be recalibrated every month, when the controls are out of specifications, and when changing the reagent lot or the instrument settings.

QUALITY CONTROL
It is recommended to use D-Dimer Quality Control (Cat. No. 179CTL) or BioRad / Siemens level 1 and level 2 for daily quality control.
Two levels of controls should be assayed at least once a day.
Values obtained should fall within a specified range.
Each laboratory should establish its own internal Quality Control.

PREPARATION
Reagents: Ready to use.

It is recommended to use the D-Dimer Calibrators (Cat. No. 179CAL) for calibration. Dissolve the lyophilized D-Dimer calibrator with 1ml distilled water, balance 10 minutes in room temperature, then dilute to 6 levels calibrators as follows,.

Calibrator dilution	1	2	3	4	5	6
Calibrator (µL)	--	10	25	50	75	100
NaCl 9 g/L (µL)	100	90	75	50	25	-
Factor	0	0.1	0.25	0.5	0.75	1.0

Calibration frequency
Recalibration is recommended:
• As a blank calibration after 24 hours
• As a blank calibration after reagent bottle change
• As a two point calibration every 30 days if the reagent always on-board
• As a two point calibration after reagent lot change
• As a two point calibration if required following quality control

Procedures
Calibration verification: Not necessary

STORAGE AND STABILITY
All the components of the kit are stable until the expiration date on the label when stored tightly closed at 2-8ºC and contaminations are prevented during their use. Do not use reagents over the expiration date.
Reagent deterioration: The presence of particles and turbidity.
Do not freeze; frozen Antibody or Diluent could change the functionality of the test.
The final concentration of the components is below the limits imposed by Regulation (EC) No. 1272/2008 - CLP (and subsequent amendments) and Directive 88/379/CEE and subsequent amendments to the classification-packaging and labeling of dangerous substances.

SAMPLES
In order to obtain a plasma sample for measurement, mix 1 part of citric acid (0.11mol/L) with 9 parts of venous whole blood to avoid air bubbles. Centrifuge immediately, not less than 3000 rpm (1500*g), centrifuge for 10 minutes, and collect the upper plasma.

Sample stability:
It can be stored for 4 hours (fresh) under +15-25℃; it can be stored for 1 month under -18℃.

PROCEDURE
Reagent preparation:
R1: Ready for use; R2: Ready for use.
Reaction parameters + Reaction curve
Basic parameters of automatic biochemical instruments
Two-point endpoint method or fixed-time method :

	Blank	Sample/calibrator
Sample/calibrator	-	5 µL
Dist. Water	5 µL	-
Reagent 1	300 µL	300 µL
Mix, incubate for 3 - 5 min., then add:		
Reagent 2	100 µL	100 µL
Mix, read absorbance (A1) within 20 sec. incubate for 5 min then read absorbance (A2) again.		

Gesan has instruction sheets for several automatic analyzers. Instructions for many of them are available on request.

CALCULATIONS

The analyzer automatically calculate the analyte concentration of each sample.

REFERENCE VALUES[4]

Samples with a D-Dimer concentration ≤ 0.50 µg/ml are considered normal. Use of an 8 µg/ml cut-off value is recommended for the VTE exclusion.
The reference range should be determined by each hospital to confirm with the characteristics of the region being tested.

PERFORMANCE CHARACTERISTICS

0.2 µg/mL～20.0 µg/mL

Determine the samples with higher concentrations via the rerun function. In the event of a rerun the upper limit of the assay ranges is increased to approximately 20 µg/mL.
These values are dependent on the lot specific values of the calibrators in use.

EP5	CV (%)		
	1.13 µg/mL	3.22 µg/mL	7.28 µg/mL
Total	8.2%	5.2%	3.5%
Within Run	1.7%	1.5%	1%
Between Run	2.2%	1.9%	2.4%
Between Day	7.7%	4.6%	2.3%

6. Accuracy: Results obtained using this reagent (y) were compared to those obtained using an immunoturbidimetric method from Bayer. 20 samples ranging from 0.2 to 20 µg/mL of D-Dimer were assayed. The correlation coefficient (r) was 0.97 and the regression equation y = 1.16x – 12.2.

The results of the performance characteristics depend on the used analyzer.

INTERFERENCES
1. Lipemia (Intralipid): no interference up to 250 mg/dl of intralipid.
2. Haemoglobin: no interference up to 500 mg/ dl.
3. Bilirubin: no interference up to 40mg/ dl.

NOTES
1. Clinical diagnosis should not be made on findings of a single test result, but should integrate both clinical and laboratory data.

BIBLIOGRAPHY

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4. Dati F et al. Eur J Clin Chem Clin Biochem 1996; 34: 517-520.
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CE — CE Mark (98/79 CE regulation)
IVD — in vitro medical device
LOT — Batch Code
Use by
Storage temperature limits
Read instruction for use
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