

D-DIMER ASSAY

Dual Vial Liquid Stable

Diazyme's D-Dimer Assay is a cost effective dual vial liquid stable reagent system intended for the in vitro quantitative determination of fibrinogen/ fibrin degradation products (D-Dimer) in human plasma. The D-Dimer Assay is a powerful diagnostic tool that assists in the detection of intravascular coagulation and fibrinolysis. Diazyme's latex enhanced immunoturbidimetric method offers excellent analytical performance, improving laboratory efficiency and workflow.

DIAZYME D-DIMER ASSAY ADVANTAGES

- Fast test results (under 10 minutes) for a rapid turnaround time
- Excellent correlations compared to existing commercial D-Dimer assays
- Wide range of instrument parameters available for facilitating and simplifying implementation
- Liquid stable format requires no reagent preparation, saving time and reducing sample handling

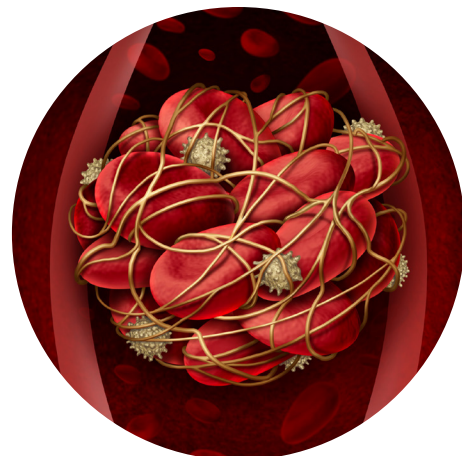
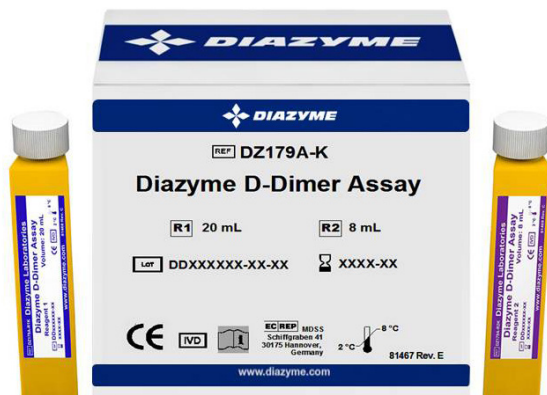
REGULATORY STATUS

510(k) Cleared



AVAILABLE INSTRUMENT SPECIFIC PACKAGING

- Roche
- Hitachi



D-DIMER ASSAY

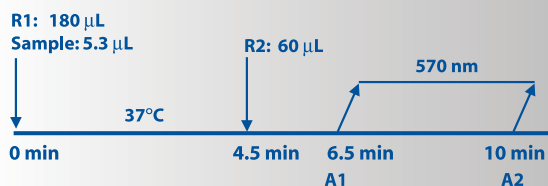
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ASSAY SPECIFICATIONS

Method	Latex Enhanced Immunoturbidimetric
Sample Type & Volume	• Human Plasma Sample Volume 5.3 µL
Method Correlation	N = 128 y-intercept = 0.106 Slope = 0.979 R ² = 0.939 Samples ranged from 0.17 - 7.95 µg/mL FEU in comparison with an existing commercial D-Dimer assay method
Linear Range	0.15 to 8.0 µg/mL FEU
LOB	0.06 µg/mL FEU
LOD	0.09 µg/mL FEU
LOQ	0.15 µg/mL FEU
Calibration Levels	6-Point Calibration
Reagent On-Board Stability	Opened: 4 weeks when stored at 2-8°C

D-Dimer Assay Procedure*



*Analyzer Dependent

**Saline is not provided, but needed to calibrate the assay

A five point D-Dimer calibrator (DZ179A-CAL) is provided separately.

Parameter questions for D-Dimer Assay should be addressed to Diazyme technical support.

Please call 858.455.4768 or email support@diazyme.com

ASSAY PRECISION

The precision of the Diazyme D-Dimer Assay was evaluated according to Clinical Laboratory Standards Institute EP5-A guideline. In the study, three levels of pooled citrated plasma specimens containing 0.60 µg/mL, 2.41 µg/mL and 5.88 µg/mL FEU, respectively. The low plasma sample was unaltered. The other two plasma samples were spiked with D-Dimer stock solution to targeted concentrations and assayed. Three levels of D-Dimer controls containing 0.97, 2.99 and 7.47 µg/mL FEU, respectively were also tested with 2 runs per day with duplicates over 20 working days with three lots of reagent and three lots of calibrators. The results are shown below:

Plasma Samples Within-Run Precision (all results using 240 Data Points N)

	Level 1 0.60 µg/mL FEU	Level 2 2.41 µg/mL FEU	Level 3 5.88 µg/mL FEU
Mean (µg/mL FEU)	0.60	2.41	5.88
SD (µg/mL FEU)	0.03	0.05	0.08
CV%	5.0%	2.0%	1.4%

Plasma Samples Total Precision

	Level 1 0.60 µg/mL FEU	Level 2 2.41 µg/mL FEU	Level 3 5.88 µg/mL FEU
Mean (µg/mL FEU)	0.60	2.41	5.88
SD (µg/mL FEU)	0.04	0.07	0.19
CV%	6.2%	2.7%	3.2%

Control Samples Within-Run Precision

	Level 1 0.97 µg/mL FEU	Level 2 2.99 µg/mL FEU	Level 3 7.47 µg/mL FEU
Mean (µg/mL FEU)	0.97	2.99	7.47
SD (µg/mL FEU)	0.03	0.05	0.11
CV%	2.9%	1.6%	1.4%

Control Samples Total Precision

	Level 1 0.97 µg/mL FEU	Level 2 2.99 µg/mL FEU	Level 3 7.47 µg/mL FEU
Mean (µg/mL FEU)	0.97	2.99	7.47
SD (µg/mL FEU)	0.04	0.08	0.27
CV%	4.4%	2.8%	3.6%

ASSAY INTERFERENCE

The following substances do not interfere with this assay at the levels tested (less than 10% bias):

Hemoglobin:	up to 500 mg/dL	Bilirubin Conjugated:	up to 40 mg/dL
Bilirubin:	up to 40 mg/dL	Ascorbic acid:	up to 176 mg/dL
Triglycerides:	up to 1000 mg/dL	Rheumatoid Factor :	up to 100 IU/mL
Heparin:	up to 1.5 IU/mL	HAMA:	up to 490 ng/mL

DIAZYME LABORATORIES

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