D-DIMER ASSAY

The D-Dimer Assay is a powerful diagnostic tool that assists in the detection of intravascular coagulation and fibrinolysis. Published study shows thrombus formation is normally followed by an immediate fibrinolytic response. The resultant generation of plasmin causes the release of fibrin degradation products (predominantly containing D-Dimer) into circulation.[1]

Diazyme's latex enhanced immunoturbidimetric method offers excellent analytical performance, improving laboratory efficiency and workflow. 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.

DIAZYME D-DIMER ASSAY ADVANTAGES

- Excellent correlations compared to existing commercial D-Dimer assays
- Excellent low limit of quantitation: 0.15 µg/mL FEU
- Fast test results (under 10 minutes) for a rapid turnaround time
- Liquid stable format requires no reagent preparation
- Wide range of instrument parameters available for simplifying implementation

REGULATORY STATUS

510(k) Cleared; EU: CE IVD

DIAZYME
Innovations in Clinical Diagnostics

D-DIMER ASSAY

Dual Vial
Liquid Stable

ASSAY SPECIFICATIONS

Method	Latex Enhanced Immunoturbidimetric
Sample Type & Volume	• Human Na Citrate Plasma Sample Volume 8 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
Linearity	0.15 to 8.0 µg/mL FEU
LOD LOB LOQ	0.06 µg/mL FEU 0.09 µg/mL FEU 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

1. BJH Guideline. British Journal of Haematology. 124, 15-25.

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 7.47µg/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	Level 2	Level 3
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	Level 2	Level 3
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	Level 2	Level 3
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	Level 2	Level 3
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

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