D-DIMER ASSAY

Dual Vial Liquid Stable

Diazyme's D-Dimer Assay is a cost effective dual vial liquid stable reagent 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

- Excellent performance on VITROS® 5600 Integrated System and VITROS® 4600 Chemistry System
- Fast test results (9 minutes) for a rapid turnaround time
- Wider linear range reduces the need for repeat testing
- Liquid stable format requires no reagent preparation, saving time and reducing sample handling

REGULATORY STATUS

510(k) Cleared

CE

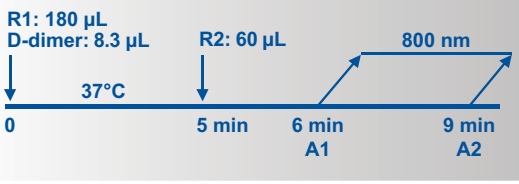
D-DIMER ASSAY
Dual Vial Liquid Stable

DIAZYME

ASSAY SPECIFICATIONS

Method	Latex Enhanced Immunoturbidimetric
Sample Type & Volume	Human Plasma Sample Volume 8.3 µL
Linear Range	0.15 to 8.0 µg/mL FEU
LOB LOD LOQ	0.06 µg/mL FEU 0.09 µg/mL FEU 0.15 µg/mL FEU
Calibration Levels	6-Point Calibration
Calibration Interval	14 days
Reagent On-Board Stability	30 days

D-Dimer Assay Procedure



ASSAY INTERFERENCE

The following substances do not interfere at the levels tested (< 10% bias):

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

ASSAY PRECISION

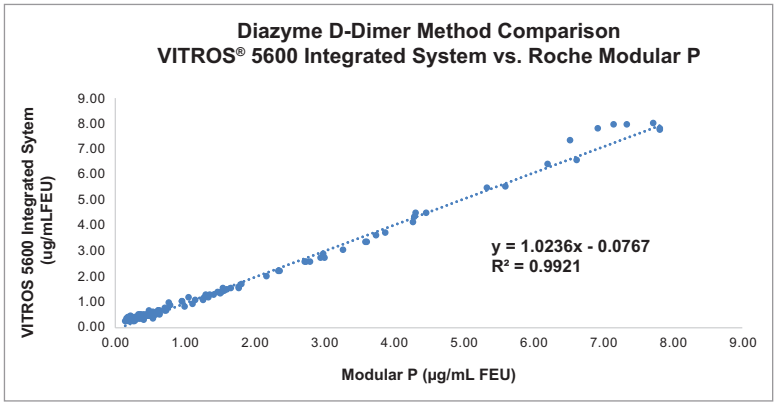
The precision of Diazyme's D-Dimer was evaluated according to CLSI protocol EP5-A2 guideline on the VITROS® 5600 Integrated System and VITROS® 4600 Chemistry System. In the study, 5 levels of patient samples (low, normal, abnormal, extended abnormal) were tested in 2 runs per day, 2 replicates per run, over 20 working days using at least 2 reagent lots.

VITROS® 5600 Integrated System									
Panel Members	Mean (mg/L) (N=80)	Within-Run		Between-Run		Between-Day		Total	
		SD (mg/L)	%CV	SD (mg/L)	%CV	SD (mg/L)	%CV	SD (mg/L)	%CV
Patient 1	0.287	0.035	12.4	0.000	0.0	0.013	4.6	0.038	13.2
Patient 2	0.989	0.025	2.5	0.002	0.2	0.026	2.6	0.036	3.7
Patient 3	1.891	0.034	1.8	0.026	1.4	0.053	2.8	0.068	3.6
Patient 4	3.261	0.065	2.0	0.000	0.0	0.052	1.6	0.083	2.5
Patient 5	6.097	0.220	3.6	0.000	0.0	0.188	3.1	0.289	4.7

METHOD COMPARISON

A method comparison study evaluated the performance of Diazyme's D-Dimer assay on VITROS® 5600 Integrated System and VITROS® 4600 Chemistry System was tested with a total of 128 individual serum samples and were compared to values obtained on the Roche Modular P according to CLSI EP9-A2 as a guideline.

Below is representative data from the VITROS® 5600 Integrated System.



ORDERING AND TECHNICAL SUPPORT INFORMATION

Please place your order with Ortho Clinical Diagnostics. Ordering and Technical Support contact information available on www.orthoclinicaldiagnostics.com.

Reagent	Reference No.	Packaging
D-Dimer - 86t/kit	DZ179AK	R1: 1 x 20 mL R2: 1 x 8 mL
D-Dimer Cal	DZ179ACAL	5 levels (6 levels total) 1 set (5 x 1 mL/each) *Level 0 – DI water, not included*
D-Dimer Control	DZ179ACON	1 set (2 x 1 mL/each)

Each kit contains enough reagents to fill 2 Ortho UDA packs (sold separately).

Ortho Clinical Diagnostics

Distributed by
Ortho Clinical Diagnostics