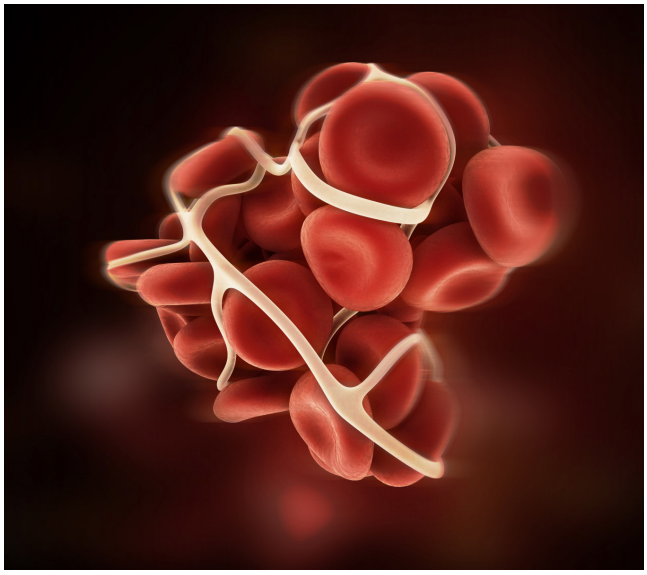

D-DIMER TEST KIT

LIQUID STABLE ASSAY FOR CLINICAL CHEMISTRY ANALYZERS

For Research Use Only in USA.

PRECISE QUANTITATIVE RESULTS

Published literature states that D-Dimer is a very sensitive marker for the activation of coagulation. When D-Dimer values below the cutoff are obtained, deep venous thrombosis (DVT) of the lower limb and pulmonary embolism (PE) can be excluded with high sensitivity, when used in conjunction with a non-high clinical probability assessment.

ADAPTABLE TO HIGH SPEED AUTOMATED CHEMISTRY ANALYZERS

Diazyme's Latex enhanced immunoturbidimetric D-Dimer method has been designed to work on most modern high throughput clinical chemistry analyzers. This means faster reporting and improved workflow for research laboratories testing D-Dimer as well as a lower reagent cost per test.

RELIABLE AND PRECISE TEST RESULTS

In addition to improving test speed and research laboratory workflow Diazyme's Latex enhanced immunoturbidimetric D-Dimer offers a highly precise result with excellent correlations to existing commercial D-Dimer assays.

BACKGROUND

D-Dimer is a product of the degradation of fibrin clots caused by the action of enzymes in the coagulation cascade. D-Dimer levels rise in the presence of an active clot, so a negative or normal test suggests that either deep venous thrombosis (DVT) of the lower limb and pulmonary embolism (PE) are unlikely. D-Dimers primary value is as a test to rule out these conditions because it can be elevated in other conditions such as cancer, stroke, infection, liver or renal disease among others.

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DIAZYME

D-DIMER TEST KIT

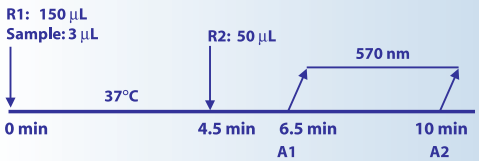
LIQUID STABLE ASSAY FOR CLINICAL CHEMISTRY ANALYZERS

D-Dimer

Method	Latex enhanced immunoturbidimetric assay
Correlation	N = 60 r^2 = 0.9964 X = 1.08 - y 0.0173 Samples ranged from 0.14-7.33 µg/mL FEU in comparison with an existing commercial D-dimer assay method.
Calibration Interval	Four weeks
On-Board Stability	Four weeks
Calibration	Six Point Calibration*
Sample Type	Sodium Citrate Plasma
Sample Volume	3 µL
Linearity	0.23 to 8.0 µg/mL FEU

Test Scheme for Chemistry Analyzer

A five point D-Dimer calibrator (DZ179A-Cal) is provided separately. Assay calibration frequency is dependent on instrument used.



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

CONVENIENT

- Stable liquid stable format requires no reagent preparation
- Lyophilized calibration set available separately
- High and low controls available separately

ANALYTICAL CHARACTERISTICS

- Excellent precision
- Extended linearity to 600 ng/mL

EXCELLENT REAGENT STABILITY

- 18-month kit stability

FLEXIBILITY

- Requires as little as 3 µL sample
- Automated parameters available for a wide range of clinical instrumentation

PRECISION

- The precision of the Diazyme D-Dimer Assay was evaluated according to Clinical Laboratory Standards Institute (formerly NCCLS) EP5-A guideline. In the study, three samples containing D-Dimer were tested on Hitachi 917 2 runs per day in duplicates over 20 working days

Within-Run Precision

	Patient Sample: 0.5 mg/mL	Level 1: 1.5 mg/mL	Level 2: 5.6 mg/mL
N	80	80	80
Mean	0.52	1.46	5.60
SD	0.03	0.03	0.06
CV%	6.7%	2.1%	1.1%

Within-Laboratory Precision

	Patient Sample: 0.5 mg/mL	Level 1: 1.5 mg/mL	Level 2: 5.6 mg/mL
N	80	80	80
Mean	0.52	1.46	5.60
SD	0.04	0.04	0.11
CV%	8.1%	2.9%	1.9%

Conclusion: The results listed in the table above demonstrated that the reagents were stable for about 14 days at 37°C, for 2 months at 25°C. According to our Arrhenius equation, the real time stability of the reagents and calibrators at 4°C is at least 18 months.

The real time stabiliy at 2-8°C is still on-going.

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