DIAZYME

COAGULATION MARKER

# 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

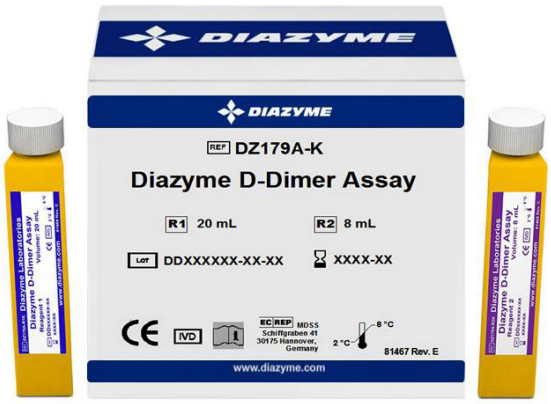
## REGULATORY STATUS

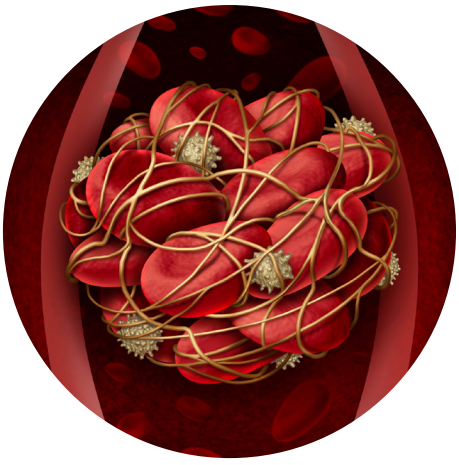
510(k) Cleared

CE

## AVAILABLE INSTRUMENT SPECIFIC PACKAGING

- **Roche**
  - Hitachi



# D-DIMER ASSAY
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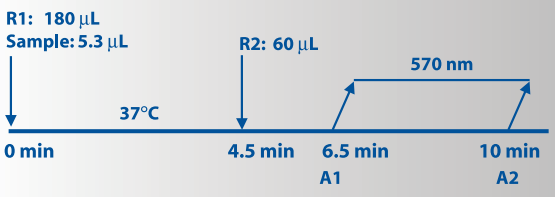
## ASSAY SPECIFICATIONS

| | |
|---|---|
| ***Method*** | Latex Enhanced Immunoturbidimetric |
| ***Sample Type & Volume*** | • Human Plasma<br>Sample Volume 5.3 µL |
| ***Method Correlation*** | N = 128<br>y-intercept = 0.106<br>Slope = 0.979<br>$R^2$ = 0.939<br>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<br>LOD<br>LOQ*** | 0.06 µg/mL FEU<br>0.09 µg/mL FEU<br>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 7.47µg/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<br>0.60 µg/mL FEU | Level 2<br>2.41 µg/mL FEU | Level 3<br>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<br>0.60 µg/mL FEU | Level 2<br>2.41 µg/mL FEU | Level 3<br>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<br>0.97 µg/mL FEU | Level 2<br>2.99 µg/mL FEU | Level 3<br>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<br>0.97 µg/mL FEU | Level 2<br>2.99 µg/mL FEU | Level 3<br>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 |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