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

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**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**
0.06 μg/mL FEU

**LOD**
0.09 μg/mL FEU

**LOQ**
0.15 μg/mL FEU

**Calibration Levels**
6-Point Calibration

**Calibration Interval**
14 days

**Reagent On-Board Stability**
30 days

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**D-Dimer Assay Procedure**

R1: 180 μL
D-dimer: 8.3 μL

R2: 60 μL

800 nm

0

37°C

5 min

6 min

A1

9 min

A2

---

**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

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**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.

**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.

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**ORDERING AND TECHNICAL SUPPORT INFORMATION**

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

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

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