Published literature states that serum levels of cardiac enzymes and isoenzymes are essential to the diagnosis or exclusion of myocardial damage and that Cardiac Troponin I (cTnI) is specific for cardiac tissue and is detected in the serum only if myocardial injury has occurred.\(^1\)\(^-\)\(^6\)

Diazyme’s Cardiac Troponin I Assay is a cost effective dual vial liquid stable reagent system intended for the \textit{in vitro} quantitative determination of Cardiac Troponin I in serum and plasma.

\textbf{DIAZYME CARDIAC TROPONIN I ASSAY ADVANTAGES}

- Latex enhanced immunoturbidimetric methodology offers excellent analytical performance
- Liquid stable reagent, calibrator and controls are offered separately for added convenience
- Fast test results (10 minutes) for a rapid turnaround time
- Liquid stable format requires no reagent preparation
- Wide range of instrument parameters available for simplifying implementation

\textbf{REGULATORY STATUS}

EU: ☻ \(\text{ IVD}\);

USA: For Research Use Only
ASSAY SPECIFICATIONS

<table>
<thead>
<tr>
<th>Method</th>
<th>Latex Enhanced Immunoturbidimetric</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sample Type &amp; Volume</td>
<td>• Serum&lt;br&gt;• Plasma - Li-heparin</td>
</tr>
<tr>
<td>Sample Volume</td>
<td>25 μL</td>
</tr>
<tr>
<td>Method Correlation</td>
<td>N = 38&lt;br&gt;y-intercept = 0.0232&lt;br&gt;Slope = 0.9971&lt;br&gt;R² = 0.992</td>
</tr>
<tr>
<td>Linearity</td>
<td>Up to 10 ng/mL</td>
</tr>
<tr>
<td>LOD</td>
<td>0.28 ng/mL</td>
</tr>
<tr>
<td>Calibration Levels</td>
<td>6-Point Calibration</td>
</tr>
<tr>
<td>Reagent On-Board</td>
<td>Opened: Four weeks when stored at 2-8°C</td>
</tr>
</tbody>
</table>

Cardiac Troponin I Assay Procedure*


ASSAY PRECISION

In the study, two levels of controls containing 2.59 and 5.77 ng/mL troponin I and one serum sample were tested with Diazyme Troponin I Assay in replicates of 20 on an Olympus AU 400 analyzer. Precision is listed in the table below:

<table>
<thead>
<tr>
<th>Expected Value (ng/mL)</th>
<th>Control 1 (2.59±0.39)</th>
<th>Control 2 (5.77±0.87)</th>
<th>Serum Sample (0.80)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Average (ng/mL)</td>
<td>2.38</td>
<td>5.62</td>
<td>0.83</td>
</tr>
<tr>
<td>SD (ng/mL)</td>
<td>0.092</td>
<td>0.175</td>
<td>0.074</td>
</tr>
<tr>
<td>CV (%)</td>
<td>3.9%</td>
<td>3.1%</td>
<td>8.9%</td>
</tr>
</tbody>
</table>

ASSAY INTERFERENCE

The common serum interfering substances triglyceride, ascorbic acid, bilirubin, hemoglobin, and rheumatoid factor showed less than 10% interference up to the concentrations summarized below:

- Triglyceride: 500 mg/dL
- Ascorbic Acid: 10 mM
- Bilirubin: 10 mg/dL
- Bilirubin Conjugated: 20 mg/dL
- Hemoglobin: 200 mg/dL
- Rheumatoid Factor: 150 IU/mL

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