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 in vitro quantitative determination of Cardiac Troponin I in serum and plasma.

**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

**REGULATORY STATUS**

EU: CE [IVD];
USA: For Research Use Only
ASSAY SPECIFICATIONS

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

Cardiac Troponin I Assay Procedure*

Parameter questions for Cardiac Troponin I Assay should be addressed to Diazyme technical support. Please call 858.455.4768 or email support@diazyme.com

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

DIAZYME LABORATORIES, INC.
12889 Gregg Court, Poway, CA 92064 USA
PO Box 85608, San Diego, CA 92186 USA
Tel: +1-858-455-4768 +1-888-DIAZYME
www.diazyme.com sales@diazyme.com

DIAZYME EUROPE GMBH
Zum Windkanal 21, 01109 Dresden, Germany
Tel: +49-351-886-3300 Fax: +49-351-886-3366
sales@diazyme.de

DIAZYME SHANGHAI CO., LTD.
Room 201,1011 Halei Road, Zhangjiang Hi-tech Park
Shanghai, 201203, People’s Republic of China
Tel: +86-21-51320668 Fax: +86-21-51320663
www.lanyuanbio.com service@lanyuanbio.com