CARDIAC BIOMARKERS

CARDIAC TROTONIN I ASSAY
LIQUID STABLE ASSAY

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EARLY DETECTION OF MYOCARDIAL DAMAGE
Literature reports state that Cardiac Troponin I is specific for cardiac tissue and is detected in the serum only if myocardial injury has occurred. Reports state that Troponin I determination allows early identification and stratification of research subjects with chest pain suggestive of ischemia, allows identification of research subjects that present 48 hours to 6 days after infarction, and identifies samples with false positive elevations in CK-MB.

EASILY ADAPTABLE TO HIGH SPEED AUTOMATED CHEMISTRY ANALYZERS
Diazyme's Latex enhanced immunoturbidimetric Cardiac Troponin I method has been designed to work on most modern high throughput chemistry analyzers. This means faster reporting and improved workflow for research laboratories testing Cardiac Troponin I 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 Troponin I offers a highly precise assay with simple precision CV's under 6%.

BACKGROUND
Human troponin I is presented in three isoforms, two isoforms are expressed in skeletal muscle tissue and one isoform is expressed in cardiac muscle tissue. cTnI is expressed in cardiac muscle tissue by a single isoform with molecular weight 23876 Da and it consists of 209 amino acid residues. For more than 15 years cTnI has been known in the literature as a reliable marker of cardiac muscle tissue injury.
**CARDIAC TROPONIN I ASSAY**

**LIQUID STABLE ASSAY**

**Method**
- Latex enhanced immunoturbidimetric assay

**On-Board Stability**
- Six weeks

**Calibration Interval**
- Four weeks

**Calibration**
- Six Point Calibration

**Sample Type**
- Serum or Lithium Heparin Plasma

**Sample Volume**
- 25 μL

**Assay Range**
- 0.4 - 10 ng/mL

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

**ANALYTICAL CHARACTERISTICS**
- Excellent precision
- Linearity to 10 ng/mL

**EXCELLENT REAGENT STABILITY**
- 18-month kit stability

**FLEXIBILITY**
- Requires as little as 25 μL sample
- Automated parameters available for a wide range of clinical instrumentation

**PRECISION**
- In the study, three samples containing Cardiac Troponin I were tested on Hitachi 917 in one run with 20 replicates. Within-Run Precision is listed in the table below.

### Analytical Characteristics
**Within-Run Precision**

<table>
<thead>
<tr>
<th>Sample: 0.69 mg/mL</th>
<th>Level 1: 2.85 mg/mL</th>
<th>Level 2: 7.30 mg/mL</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>20</td>
<td>20</td>
</tr>
<tr>
<td>Mean</td>
<td>0.69</td>
<td>2.85</td>
</tr>
<tr>
<td>SD</td>
<td>0.0360</td>
<td>0.0799</td>
</tr>
<tr>
<td>CV%</td>
<td>5.2</td>
<td>2.8</td>
</tr>
</tbody>
</table>

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**General Test Scheme for Chemistry Analyzer**

- R1: 200 μL Sample: 25 μL
- R2: 50 μL
- 37°C
- 0 5 6 600 nm 10 min

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