Diazyme’s Myoglobin Assay is an excellent cost effective cardiovascular test that is used to aid in the early detection of myocardial damage. The latex enhanced immunoturbidimetric methodology is highly precise with excellent correlations to existing commercial myoglobin tests and is designed to work on most modern high throughput clinical chemistry analyzers. The Myoglobin assay offers liquid stable reagent, calibrator, high and low end controls separately for added convenience.

**DIAZYME MYOGLOBIN ASSAY ADVANTAGES**

- Fast test results for a rapid turnaround time
- Liquid stable reagent, calibrator and controls are offered separately for added convenience
- 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

**AVAILABLE INSTRUMENT SPECIFIC PACKAGING**

- Roche
  - Hitachi
ASSAY PRECISION

The precision of the Diazyme Myoglobin Assay was evaluated according to CLSI EP5-A guideline. In the study, three levels of serum based controls containing approximately 66, 170, and 335 ng/mL of myoglobin, and three serum sample containing approximately 35, 150, and 414 ng/mL of myoglobin, respectively, were tested with 2 runs per day in duplicates over 20 working days. Results were calculated using the EP Evaluator software precision statistic template and summarized in the following tables:

<table>
<thead>
<tr>
<th>Control Level</th>
<th>Control Level 2</th>
<th>Control Level 3</th>
<th>Serum Level 1</th>
<th>Serum Level 2</th>
<th>Serum Level 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>80</td>
<td>80</td>
<td>80</td>
<td>80</td>
<td>80</td>
</tr>
<tr>
<td>Mean</td>
<td>65.97</td>
<td>175.8</td>
<td>337.0</td>
<td>37.78</td>
<td>148.6</td>
</tr>
<tr>
<td>SD</td>
<td>2.45</td>
<td>6.69</td>
<td>11.9</td>
<td>1.77</td>
<td>3.53</td>
</tr>
<tr>
<td>CV%</td>
<td>3.71%</td>
<td>3.87%</td>
<td>3.54%</td>
<td>4.69%</td>
<td>2.37%</td>
</tr>
</tbody>
</table>

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<td>148.6</td>
</tr>
<tr>
<td>SD</td>
<td>3.37</td>
<td>7.37</td>
<td>14.9</td>
<td>1.97</td>
<td>5.32</td>
</tr>
<tr>
<td>CV%</td>
<td>5.10%</td>
<td>4.30%</td>
<td>4.40%</td>
<td>5.20%</td>
<td>3.58%</td>
</tr>
</tbody>
</table>

ASSAY INTERFERENCE

The following substances do not interfere with this assay at the levels tested (less than 10% bias):

- Ampicillin: up to 152 μM
- Carbamazepine: up to 0.13 mM
- Na2+-Cefoxitin: up to 1549 μM
- Ibuprofen: up to 2425 μM
- Cyclosporin: up to 0.125 μM
- Methyldopa: up to 71 μM
- Levodopa: up to 701 μM
- Metronidazole: up to 701 μM
- Rifampicin: up to 78.1 μM
- Theophylline: up to 222 μM
- Valproic Acid, Sodium Salt: up to 3.5 mM
- Hemoglobin: up to 1000 mg/dL
- Bilirubin: up to 40 mg/dL
- Conjugated Bilirubin: up to 40 mg/dL
- Triglycerides: up to 1000 mg/dL
- Intralipid: up to 125 mg/dL
- Ascorbic acid: up to 176 mg/dL
- Rheumatoid factor: up to 100 IU/mL
- Heparin: up to 1.5 IU/mL
- N-acetylcysteine: up to 11.04 mM
- Acetylsalicylic acid: up to 2.78 mM

**Myoglobin Assay Procedure**

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

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DZ053 (06/2016)