Measurement of myoglobin is used as an aid in the diagnosis of acute myocardial infarction. The rapid increase in the concentration of myoglobin after muscular trauma makes it an important diagnostic indicator of cardiac stress and muscle damage, and provides early detection of necrosis in cardiac and skeletal muscle. Myoglobin determination can be useful in exclusion diagnosis for myocardial infarction if the myoglobin level has not increased after serial determination.1-6

Diazyme’s Myoglobin Assay is an excellent cost effective cardiovascular test used for the quantitative determination of myoglobin in human serum and plasma. Diazyme’s Myoglobin Assay is highly precise with excellent correlations to existing commercial myoglobin tests.

**DIAZYME MYOGLOBIN ASSAY ADVANTAGES**

- The Myoglobin Assay is designed to work on most clinical chemistry analyzers
- Latex enhanced immunoturbidimetric method
- 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**

510(k) Cleared; EU: ³ IVD
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 1</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 (ng/mL)</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 (ng/mL)</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>

<table>
<thead>
<tr>
<th>Control Level 1</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 (ng/mL)</td>
<td>65.97</td>
<td>172.8</td>
<td>337.0</td>
<td>37.78</td>
<td>148.6</td>
</tr>
<tr>
<td>SD (ng/mL)</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
- Levodopa: up to 30.4 mM
- Methyldopa: up to 71 μM
- Metronidazole: up to 701 μM
- Rifampicin: up to 78.1 μM
- Theophylline: up to 222 μM
- Phenytoin: up to 650 μM
- Valproic Acid, Sodium Salt: up to 3.5 mM