Diazyme’s NAG Assay is a cost effective test that uses a “highly sophisticated and powerful colorimetric substrate” that is not affected by urine color. Each kit is supplied with a calibrator set for added convenience and controls are available separately. The test offers a wide range of instrument parameters for facilitating and simplifying implementation in the laboratory. Increased NAG levels in urine are usually an early indication of renal disease and can serve as a valuable renal monitoring test in disorders such as nephritic syndrome, glomerulonephritis, drug abuse associated nephrotoxicity, diabetes-associated nephropathy, hypertension and urinary tract infections.

**Diazyme NAG Assay Advantages**

- Fast test results (under 5.5 minutes) 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) Exempt

**Available Instrument Specific Packaging**

- Roche
- Hitachi
**ASSAY PRECISION**

In the study, two levels of NAG controls and one NAG urine sample containing 40.9 U/L, 124.0 U/L and 9.64 U/L NAG respectively were tested on a Hitachi 917 in one run with 20 in replicates.

**Within-Run Precision:**

<table>
<thead>
<tr>
<th></th>
<th>Sample 1</th>
<th>Sample 2</th>
<th>Sample 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>20</td>
<td>20</td>
<td>20</td>
</tr>
<tr>
<td>Mean</td>
<td>38.99</td>
<td>119.71</td>
<td>9.68</td>
</tr>
<tr>
<td>Std. Dev.</td>
<td>0.39</td>
<td>1.16</td>
<td>0.41</td>
</tr>
<tr>
<td>CV %</td>
<td>0.99%</td>
<td>0.97%</td>
<td>4.23%</td>
</tr>
</tbody>
</table>

**ASSAY INTERFERENCE**

The common urine interfering substances triglyceride, ascorbic acid, free bilirubin, and conjugated bilirubin showed no significant interference (≥10%) up to the concentrations summarized below.

- Triglyceride: 1000 mg/dL
- Ascorbic Acid: 0.500 mg/dL
- Bilirubin: 5 mg/dL
- Bilirubin Conjugated: 5 mg/dL