Urinary excretion of the lysosomal enzyme N-Acetyl-\(\beta\)-D-Glucosaminidase (NAG) has been proposed as a biomarker of impaired renal tubular function and damage. Studies in literature show that determination of urinary NAG activity provides a very sensitive and reliable indicator of renal damage, such as injury or dysfunction due to diabetes mellitus, nephrotic syndrome, inflammation, hypertension, heavy metals poisoning and treatment with nephrotoxic drugs. NAG activity can serve as a valuable renal monitoring test in disorders such as nephrotic syndrome, glomerulonephritis, drug abuse associated nephrotoxicity, diabetes-associated nephropathy, hypertension and urinary tract infections.\(^1\) There is also increasing evidence that it has a predictive value on functional outcome and response to therapy.\(^2\)

Diazyme’s NAG Assay is a cost effective test used for the determination of NAG in urine samples.

### DIAZYME NAG ASSAY ADVANTAGES

- Liquid stable reagent, calibrator and controls are offered separately for added convenience
- Fast test results (under 5.5 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>Colorimetric (Enzymatic cleavage of a colorimetric substrate)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sample Type &amp; Volume</td>
<td>Urine, Sample Volume 10 μL</td>
</tr>
<tr>
<td>Linearity</td>
<td>Up to 200 U/L</td>
</tr>
<tr>
<td>LOQ</td>
<td>1.64 U/L</td>
</tr>
<tr>
<td>Calibration Levels</td>
<td>1-Point Calibration</td>
</tr>
<tr>
<td>Reagent On-Board Stability</td>
<td>Opened: 1 month when stored at 2-8°C</td>
</tr>
</tbody>
</table>

**NAG Assay Procedure***

- **R1 + R2 Mix:** 150 μL of Sample 10 μL
- **R3:** 50 μL
- **A1:** 37°C
- **A2:** 5 min
- **5.3 min**

*Analyzer Dependent

Parameter questions for NAG 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 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><strong>N</strong></td>
<td>20</td>
<td>20</td>
<td>20</td>
</tr>
<tr>
<td><strong>Mean (U/L)</strong></td>
<td>38.99</td>
<td>119.71</td>
<td>9.68</td>
</tr>
<tr>
<td><strong>SD (U/L)</strong></td>
<td>0.39</td>
<td>1.16</td>
<td>0.41</td>
</tr>
<tr>
<td><strong>CV (%)</strong></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

---

**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