Enzymatic creatinine assays have less interference than older Jaffe creatinine assays. Studies from leading clinical journals have shown that interference with Jaffe creatinine assays may lead to inaccuracies in estimated glomerular filtration rates that are clinically important, especially in children and neonates.1 Diazyme’s Enzymatic Creatinine is intended for the in vitro quantitative determination of creatinine in serum and urine. The assay is cost effective and provides outstanding reagent stability combined with the added convenience of instrument specific packing for several major instrument families.

**DIAZYME CREATININE ASSAY ADVANTAGES**

- Diazyme’s enzymatic methodology is a better clinical choice than the older Jaffé method for the accurate measurement of creatinine, especially for neonates, pediatrics, and hematology units.2
- Significantly reduced interference with no cuvette staining
- Wide range of instrument parameters available for facilitating and simplifying implementation
- Liquid stable reagent and controls requires no reagent preparation, saving time and reducing sample handling

**REGULATORY STATUS**

510(k) Cleared

**AVAILABLE INSTRUMENT SPECIFIC PACKAGING**

- Roche
  - Hitachi
- Beckman
  - AU Series
ASSAY SPECIFICATIONS

<table>
<thead>
<tr>
<th>Method</th>
<th>Enzymatic Assay</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sample Type &amp; Volume</td>
<td>• Serum</td>
</tr>
<tr>
<td></td>
<td>• Urine</td>
</tr>
<tr>
<td></td>
<td>Sample Volume 8 μL</td>
</tr>
</tbody>
</table>

Method Correlation

| Linear Range | Serum: 0.14 - 13.56 mg/dL (12 - 1200 μmol/L)  |
|             | Urine: 0.14 - 141.25 mg/dL (12 - 12500 μmol/L) |

LOD

12 μmol/L (0.14 mg/dL)

Calibration Levels

1-Point Calibration

Traceability

Standard traceable NIST's SRM 914a

Reagent On-Board Stability

Opened: 4 weeks when stored at 2-8°C

Creatinine Assay Procedure*

R1: 270 μL
Sample: 8 μL

R2: 90 μL

37°C

0 5 min 550 nm 10 min

A1 A2

*Analyzer Dependent

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

ASSAY PRECISION

The assay was evaluated according to Clinical Laboratory Standards Institute EP5-A guidelines. Four serum specimens were tested on a Hitachi 917 twice daily, in duplicates over 20 days.

<table>
<thead>
<tr>
<th>Serum Testing</th>
<th>Within-Run Precision (80 Data Points)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean mg/dL (μM)</td>
<td>0.74 (66.4)</td>
</tr>
<tr>
<td>SD mg/dL (μM)</td>
<td>0.015 (1.37)</td>
</tr>
<tr>
<td>CV%</td>
<td>1.1%</td>
</tr>
</tbody>
</table>

Total Precision (80 Data Points)

| Mean mg/dL (μM)             | 0.75 mg/dL (66.3 μM)                  |
| SD mg/dL (μM)               | 0.015 (1.37)                          |
| CV%                         | 1.1%                                  |

Urine Testing

Within-Run Precision (21 Data Points)

<table>
<thead>
<tr>
<th>Level 1</th>
<th>Level 2</th>
<th>Level 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean mg/dL (μM)</td>
<td>29.09 (2572)</td>
<td>87.1 (7711)</td>
</tr>
<tr>
<td>SD mg/dL (μM)</td>
<td>0.1 (8.84)</td>
<td>0.27 (23.60)</td>
</tr>
<tr>
<td>CV%</td>
<td>0.36%</td>
<td>0.31%</td>
</tr>
</tbody>
</table>

Total Precision (20 Data Points)

<table>
<thead>
<tr>
<th>Level 1</th>
<th>Level 2</th>
<th>Level 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean mg/dL (μM)</td>
<td>29.86 (2640)</td>
<td>87.7 (7765)</td>
</tr>
<tr>
<td>SD mg/dL (μM)</td>
<td>0.79 (69.8)</td>
<td>0.67 (59.2)</td>
</tr>
<tr>
<td>CV%</td>
<td>2.64%</td>
<td>0.76%</td>
</tr>
</tbody>
</table>

ASSAY INTERFERENCE

Interference for the Diazyme Creatinine Assay was evaluated on the Hitachi 917. The following substances normally present in serum produced less than 10% deviation at the listed concentrations:

- Triglyceride: up to 1000 mg/dL
- Ascorbic Acid: up to 10 mM
- Bilirubin (Conjugate): up to 30 mg/dL
- Hemoglobin: up to 500 mg/dL

The following substances normally present in urine produced less than 10% deviation at the listed concentrations:

- Triglyceride: up to 1000 mg/dL
- Ascorbic Acid: up to 10 mM
- Bilirubin (Conjugate): up to 40 mg/dL
- Hemoglobin: up to 1000 mg/dL

DIAZYMЕ LABORATORIES

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