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 ENZYMATIC ASSAY ADVANTAGES**

- Accurate measurement of creatinine with enzymatic method
- Reduced interferences and no cuvette staining as seen in Jaffe method
- Assay is traceable to NIST material (IDMS)
- Measuring range: Serum: 0.14-13.56 mg/dL  
  Urine: 0.14-141.25 mg/dL
- Liquid stable reagent, calibrator and controls requires no reagent preparation
- Wide range of instrument parameters available for simplifying implementation

**REGULATORY STATUS**

510(k) Cleared; EU: [CE IVD]
### ASSAY SPECIFICATIONS

<table>
<thead>
<tr>
<th>Method</th>
<th>Enzymatic Assay</th>
</tr>
</thead>
</table>
| **Sample Type & Volume** | • Serum  
• Urine  
Sample Volume 8 μL |
| **Method Correlation** | Serum:  
N = 55  
y-intercept = 0.0643  
Slope = 0.9467  
R² = 0.9981  

Urine:  
N = 51  
y-intercept = -0.0518  
Slope = 1.0002  
R² = 0.9968 |
| **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

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### 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>
</table>
| Mean mg/dL (μM) | 0.74 (65.4)  
1.38 (122.3)  
4.04 (357.5)  
10.28 (908.7) |
| SD mg/dL (μM) | 0.015 (1.3)  
0.015 (1.37)  
0.029 (2.54)  
0.015 (1.3) |
| CV% | 2.1%  
1.1%  
0.7%  
0.1% |

<table>
<thead>
<tr>
<th>Serum Testing</th>
<th>Total Precision (80 Data Points)</th>
</tr>
</thead>
</table>
| Mean mg/dL (μM) | 0.74 (65.4)  
1.38 (122.3)  
4.04 (357.5)  
10.28 (908.7) |
| SD mg/dL (μM) | 0.022 (1.9)  
0.026 (2.29)  
0.058 (5.11)  
0.014 (12.4) |
| CV% | 3.0%  
1.9%  
1.4%  
1.4% |

The assay precision was evaluated with urine samples with a modified EP10 protocol. Within-run precision; 21 replicates of commercial urine controls were tested. Total precision; 2 runs of each commercial urine control were performed consecutively for 5 days.

<table>
<thead>
<tr>
<th>Urine Testing</th>
<th>Within-Run Precision (21 Data Points)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level 1</td>
<td>Mean mg/dL (μM)</td>
</tr>
<tr>
<td>SD mg/dL (μM)</td>
<td>0.1 (8.84)</td>
</tr>
<tr>
<td>CV%</td>
<td>0.36%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Urine Testing</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Level 1</td>
<td>Mean mg/dL (μM)</td>
</tr>
<tr>
<td>SD mg/dL (μM)</td>
<td>0.79 (69.8)</td>
</tr>
<tr>
<td>CV%</td>
<td>2.64%</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  
- Bilirubin: up to 40 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  
- Bilirubin: up to 40 mg/dL  
- Hemoglobin: up to 1000 mg/dL

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