DIAZYME



# CREATININE ASSAY

## Dual Vial Liquid Stable

**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 then 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

CE

## AVAILABLE INSTRUMENT SPECIFIC PACKAGING

- **Roche**
  - Hitachi
- **Beckman**
  - AU Series


# CREATININE ASSAY

**Dual Vial Liquid Stable**

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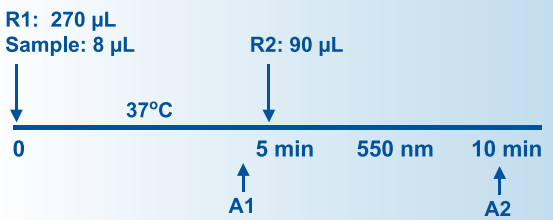
## ASSAY SPECIFICATIONS

| | |
|---|---|
| ***Method*** | Enzymatic Assay |
| ***Sample Type & Volume*** | • Serum<br>• Urine<br>Sample Volume 8 µL |
| ***Method Correlation*** | Serum:<br>N = 55<br>y-intercept = 0.0643<br>Slope = 0.9467<br>$R^2$ = 0.9981<br>Urine:<br>N = 51<br>y-intercept = -0.0518<br>Slope = 1.0002<br>$R^2$ = 0.9968 |
| ***Linear Range*** | Serum:<br>0.14 - 13.56 mg/dL<br>(12 - 1200 µmol/L)<br>Urine:<br>0.14 - 141.25 mg/dL<br>(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:<br>4 weeks when stored at 2-8°C |

### *Creatinine Assay Procedure**




***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*


*1. Cobbaert, C. M., H. Baadenhuijsen, and C. W. Weykamp. "Prime Time for Enzymatic Creatinine Methods in Pediatrics." Clinical Chemistry 55.3 (2009): 549-58. Web.*

*2. Badiou S, Dupuy AM, Descomps B, Cristolead, JP. Comparison between the enzymatic vitros assay for creatinine determination and three other methods adapted on the Olympus analyzer, Journal of Clinical Laboratory Analysis 2003:17, 235 – 240*


## 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.*

| ***Serum Testing*** | **Within-Run Precision (80 Data Points)** | | | |
|---|---|---|---|---|
| | 0.75 mg/dL (66.3 µM) | 1.41 mg/dL (125 µM) | 4.11 mg/dL (346 µM) | 10.28 mg/dL (908.7 µM) |
| ***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% |
| ***Serum Testing*** | **Total Precision (80 Data Points)** | | | |
| | 0.75 mg/dL (66.3 µM) | 1.41 mg/dL (125 µM) | 4.11 mg/dL (346 µM) | 10.28 mg/dL (908.7 µM) |
| ***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.*

| ***Urine Testing*** | **Within-Run Precision (21 Data Points)** | | |
|---|---|---|---|
| | **Level 1** | **Level 2** | **Level 3** |
| ***Mean mg/dL (µM)*** | 29.09 (2572) | 87.1 (7711) | 196.7 (17407) |
| ***SD mg/dL (µM)*** | 0.1 (8.84) | 0.27 (23.60) | 0.90 (79.71) |
| ***CV%*** | 0.36% | 0.31% | 0.46% |
| ***Urine Testing*** | **Total Precision (20 Data Points)** | | |
| | **Level 1** | **Level 2** | **Level 3** |
| ***Mean mg/dL (µM)*** | 29.86 (2640) | 87.7 (7765) | 195 (17265) |
| ***SD mg/dL (µM)*** | 0.79 (69.8) | 0.67 (59.2) | 1.19 (105.2) |
| ***CV%*** | 2.64% | 0.76% | 0.60% |

## 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 | | |


### DIAZYME LABORATORIES

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