DZ072B

CREATININE LIQUID REAGENT ASSAY

Renal and Pancreatic Marker

Enzymatic creatinine assays have less interference than older Jaffe creatinine assays. A study from leading clinical journal shows 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 Creatinine Liquid Reagent assay 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 LIQUID REAGENT 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

DIAZYME
Innovations in Clinical Diagnostics

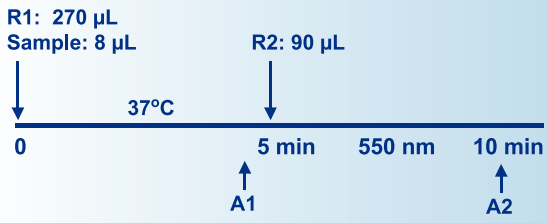
CREATININE LIQUID REAGENT ASSAY

Dual Vial
Liquid Stable

ASSAY SPECIFICATIONS

Method	Enzymatic Assay
Sample Type & Volume	• Serum • Urine Sample Volume 8 µL
Method Correlation	Serum: N = 55 y-intercept = 0.0643 Slope = 0.9467 R^2 = 0.9981 Urine: N = 51 y-intercept = -0.0518 Slope = 1.0002 R^2 = 0.9968
Linearity	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**



***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.

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 producedless 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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