OXALATE ENZYMATIC ASSAY

Renal and Pancreatic Marker

The Oxalate is a common component in urine originating from liver metabolism and dietary sources. The formation of calcium oxalate salt in the urinary tract is the main factor in urolithiasis. Urine oxalate testing provides valuable information related to hyperoxaluria and stone formation risk.

Diazyme's Oxalate Enzymatic Assay is a cost-effective, reliable method for quantitative determination of oxalate in human urine samples. The assay utilizes industry-standard enzymatic chemistry with oxalate oxidase to generate hydrogen peroxide, which undergoes oxidative condensation with TOPS and 4-aminoantipyrine in the presence of peroxidase, producing a compound with maximum absorption at 550 nm.

DIAZYME OXALATE ENZYMATIC ASSAY ADVANTAGES

- Enzymatic assay for accurate determination of oxalate in urine samples
- Fast test results for rapid turnaround time
- Liquid stable reagent, calibrator, and controls offered separately for added convenience
- Wide analytic measuringrange (0.011 - 4.0 mmol/L of 0.099 - 36.0 mg/dL)
- Excellent precision with total CV% ranging from 2.7% to 6.6%

REGULATORY STATUS

510(k) Exempt

OXALATE ENZYMATIC ASSAY

Dual Vial
Liquid Stable

ASSAY SPECIFICATIONS

Method	Enzymatic
Sample Type & Volume	• 24-Hour Urine Sample Volume: acidified & diluted urine 100 µL
Method Correlation to Predicate	N = 41 y-intercept = 0.0625 Slope = 1.087 R^2 = 0.9991
Traceability	Lot-specific calibrator values provided on Certificate of Analysis
Calibration Levels	1-Point Calibration
Linearity	4.0 mmol/L (36.0 mg/dL)
Analytical Measuring Range	0.011 - 4.0 mmol/L (0.099 - 36.0mg/dL)
LOB ***LOD*** ***LOQ***	0.003 mmol/L (0.027 mg/L) 0.006 mmol/L (0.054 mg/L) 0.011 mmol/L (0.099 mg/L)
Reagent On-Board Stability	Opened: 4 weeks when kept stored at 2-8°C

ASSAY PRECISION

Precision studies were conducted using four urine samples and two levels of oxalate controls. Four urine samples and two control levels were tested in duplicate per run, 2 runs per day for 12 days using two lots of the reagents (N=96):

	Mean (mmol/L)	Within-Run SD (CV%)	Between-Run SD (CV%)	Between-Day SD (CV%)	Between-Lot SD (CV%)	Total SD (CV%)
Urine Sample 1	0.093	0.0035 3.8%	0.0043 4.7%	0.0026 2.8%	0.0061 6.6%	0.0061 6.6%
Urine Sample 2	0.244	0.0065 2.7%	0.0046 1.9%	0.0039 4.0%	0.0127 5.2%	0.0127 5.2%
Urine Sample 3	1.230	0.0117 1.0%	0.0154 1.3%	0.0356 2.9%	0.0406 3.3%	0.0406 3.3%
Urine Sample 4	3.166	0.0242 0.8%	0.0514 1.6%	0.0650 2.1%	0.0863 2.7%	0.0863 2.7%
Control 1	0.318	0.0053 1.7%	0.0040 1.3%	0.0129 4.1%	0.0129 4.1%	0.0129 4.1%
Control 2	1.608	0.0158 1.0%	0.0246 1.5%	0.0729 4.5%	0.0729 4.5%	0.0729 4.5%

ASSAY INTERFERENCE

The common urine interfering substances showed no significant interference (≤10%) up to the concentrations summarized below:

Ascorbic Acid:	16 mmol/L
Hemoglobin:	5 mg/dL
Bilirubin:	10 mg/dL
Conjugated Bilirubin:	10 mg/dL
Uric Acid:	15 mM

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

SHANGHAI DIAZYME CO., LTD.
Building 8, 3879 Dongchuan Road
Minhang District, Shanghai, 200245
Tel: +86-21-54843802 Fax: +86-21-51320663
www.lanyuanbio.com service@lanyuanbio.com