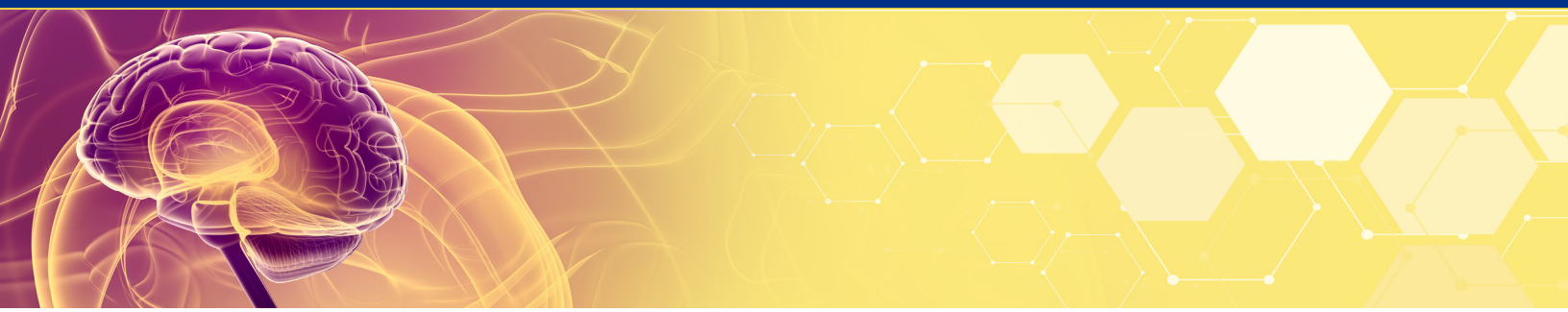
ENZYMATIC LITHIUM ASSAY



Therapeutic Drug Monitoring

DIAZYME ENZYMATIC LITHIUM ASSAY ADVANTAGES

- Highly stable enzymatic method for accurate and precise test results
- Low sample volume vs. ISE methods
- Convenient liquid stable reagent set
- Traceable to NIST standards
- Not light sensitive
- Low cost per test
- Robust performance with excellent on-board reagent stability and calibration curve stability
- Neutral pH, not corrosive to instruments, and not hazardous to ship
- Wide range of instrument parameters available for simplifying implementation
- Excellent within run precision (≤ 4.3 CV%)

REGULATORY STATUS

510(k) Cleared; EU: CE IVD;
Health Canada Registered

DIAZYME
Innovations in Clinical Diagnostics

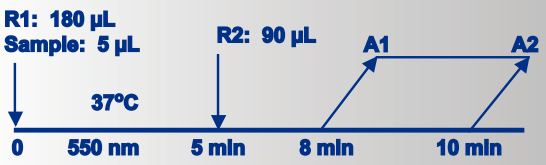
ENZYMATIC LITHIUM ASSAY

Dual Vial
Liquid Stable

ASSAY SPECIFICATIONS

Method	Enzymatic - A lithium sensitive phosphatase catalyzes the conversion of adenosine biphosphate (PAP) to hypoxanthine and hydrogen peroxide which is then quantified by a Trinder reaction
Sample Type & Volume	• Serum Sample Volume 5 µL
Method Correlation to Predicate	R^2 = 0.99 regression y = 1.03x - 0.04
Traceability	Traceable to NIST SRM 956 standard
Calibrator	Liquid stable calibrator set
Linearity	0.19 - 3.0 mmol/L
Reagent On-Board Stability*	8 weeks when stored at 2-8°C

*Assay Procedure**



***Analyzer Dependent**

Parameter questions for Lithium assay should be addressed to Diazyme technical support. Please call 858.455.4768 or email support@diazyme.com

ASSAY PRECISION

Diazyme's Liquid Stable Enzymatic Lithium Assay precision was evaluated according to NCCLS EP5-A guideline. Performance studies were conducted using the Hitachi 717 automated chemistry analyzer.

Within Run Precision		
	1.0 mM Li+ (10 days, n=4)	**2.5 mM Li+** (10 days, n=4)
Mean (mM)	0.97	2.50
CV (%)	4.3	1.2

Total		
	1.0 mM Li+ (10 days, n=4)	**2.5 mM Li+** (10 days, n=4)
Mean (mM)	0.97	2.50
CV (%)	4.8	1.3

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