

Liquid Reagents – ready to use

LITHIUM ENZYMATIC

2 Reagents

Diagnostic reagent for quantitative in vitro determination of Lithium in human serum on photometric systems

REF

Cont.

910210 3 x 20 ml 2 x 20 ml Reagent 1
2 x 10 ml Reagent 2

Additionally offered:

910280 3 x 3 ml Lithium Standard Set (3 levels)
910290 2 x 3 ml Lithium Control Set (2 levels)

TEST PARAMETERS

Method: enzymatic, 2 Point Kinetic (fixed time)
Wavelength 550 nm
Temperature: 37°C
Sample: Serum
Measuring range: 0.19 – 3.0 mmol/L

REAGENT COMPOSITION

Reagent 1: Good's buffer
phosphatase substrate
4-AA
enzymes
stabilizers

Reagent 2: Good's buffer
enzymes
EHSPT
MgCl₂
stabilisers

REAGENT PREPARATION

The reagents are ready to use.

REAGENT STABILITY AND STORAGE

Conditions: protect from light
close immediately after use
do not freeze!

Storage: at 2 – 8°C
Stability: up to the expiration date

SPECIMEN COLLECTION AND HANDLING ^[2,3]

The assay is designed for use with human serum samples only.

For use with non-hemolysed serum.

No special handling or pretreatment is needed.

It is recommended that a standardised 12-hour post dose serum lithium concentration be used to assess adequate therapy.

Serum samples should be collected such that testing may be performed as soon as possible after the specimen collection.

INTERFERING SUBSTANCES

The assay is not interfered by the following substances at indicated concentrations:

Na ⁺	200 mM
K ⁺	10 mM
NH ₄ ⁺	0.5 mM
Ca ²⁺	4.0 mM
Mg ²⁺	2.0 mM
Ascorbic acid	5.0 mM
Zn ²⁺	0.25 mM
Fe ³⁺	0.25 mM
Cu ²⁺	0.25 mM
Triglycerides	1000 mg/dL
Conj. bilirubin	20 mg/dL
Unconj. bilirubin	15 mg/L

ASSAY PROCEDURE:

Wavelength: 550 nm

Second wavelength: 700 nm

→ Reagent 1: 180 µl

Sample: 5 µl

→ Incubation: 5 minutes

→ Reagent 2: 90 µl

→ 1st Reading: 3 minutes after adding R2

→ 2nd Reading: 5 minutes after adding R2
(time between the 2 readings: 2 minutes)

3-point calibration

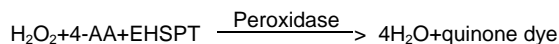
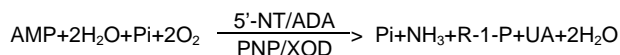
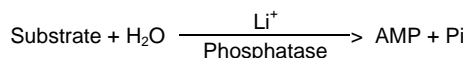
REFERENCE RANGE ^[2,3,4]

12 hour post dose:	1.0 – 1.2 mmol/L
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Levels higher than 1.5 mM, 12 hours after a dose, indicate a significant risk of intoxication.

Values indicated should be used only as a guide. It is recommended that each laboratory establishes or derives a reference interval for the population it serves.

TEST PRINCIPLE



Lithium is determined spectrophotometrically through a kinetic coupled enzyme assay system involving lithium sensitive phosphatase¹. Through enzymatic coupling, the phosphatase substrate is converted to hypoxanthine by a series of enzymatic reactions to generate uric acid and hydrogen peroxide (H₂O₂). H₂O₂ generated reacts with N-Ethyl-N-(2-hydroxy-3-sulfopropyl)-3-m-toluidine (EHSPT) and 4-aminoantipyrine (4-AA) in the presence of peroxidase (POD) to form a quinone dye which has maximal absorbance at 556 nm. The rate of the quinone dye formation is proportional to the concentration of lithium in serum samples.

ABBREVIATIONS

5'-NT: 5'-Nucleotidase
ADA: Adenosine Deaminase
PNP: Purine Nucleoside
XOD: Xanthine Oxidase
AMP: Adenosine-5'-phosphate
R-1-P: Ribose-1-phosphate

PERFORMANCE CHARACTERISTICS

All performance studies were conducted using the Hitachi 717 automated chemistry analyser.

LINEARITY, SENSITIVITY

The assay has a measuring range from 0.19 mmol/L – 3.0 mmol/L.

Samples with values greater than 3.0 mmol/L should be diluted with an equal part of 0.9% saline (1:1) and rerun. Multiply results by 2.

Limit of detection (LOD): 0.051 mmol/L

Limit of quantitation (LOQ): 0.19 mmol/L

ACCURACY

Comparison of the Dialab potassium test (y) with ISE (x) gave the following equation (N=62):

$$y = 1.03x - 0.04 \text{ mmol/L}; R^2 = 0.99$$

PRECISION (at 37°C)

Within run, n = 40	Mean [mmol/L]	SD [mmol/L]	CV [%]
Sample 1	0.97	0.042	4.3
Sample 2	2.50	0.030	1.2

Total, n = 40	Mean [mmol/L]	SD [mmol/L]	CV [%]
Sample 1	0.97	0.047	4.8
Sample 2	2.50	0.033	1.3

QUALITY CONTROL

We recommend that each laboratory uses Lithium controls to validate the performance of the Lithium assay.

We recommend:

REF

Cont.

910290 2 x 3 ml **Lithium Control Set (2 levels)**

CALIBRATION

A 3-point calibration using low, medium and high lithium calibrators is recommended every 2 weeks.

We recommend:

REF

Cont.

910280 3 x 3 ml **Lithium Standard Set (3 levels)**

AUTOMATION

Special adaptations for automated analyzers can be made on request.

WARNINGS AND PRECAUTIONS

1. Do not ingest. Avoid contact with skin and eyes.
2. Specimens should be handled as if potentially infectious, using safe laboratory procedures.
3. Take the necessary precautions for the use of laboratory reagents.

WASTE MANAGEMENT

Please refer to local legal requirements.

REFERENCES

1. J.R. Murguia, J.M. Belles and R. Serrano, A salt-sensitive 3'(2'),5'-bisphosphate nucleotidase involved in sulphate activation (1995), Science 267: 232-234.
2. T.P. Moyer and C.E. Pippenger, Therapeutic Drug Monitoring, Tietz Textbook of Clinical Chemistry. CA C.A. Burtis and E.R. Ashwood eds, (Second ed.) W.B. Saunders Company.
3. A. Amidsen, Serum Lithium Determinations for Clinical Use (1967), Scand. J. Clin. Lab Invest. 30:104-108
4. M.S. Wachtel et al., Creation and Verification of Reference Intervals (1955), Laboratory Medicine 26: 593-597.



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