CE IVD DIALAB

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 $MgCl_2$ 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

Levels higher than 1.5 mM, 12 hours after a dose, indicate a significant risk of intoxication.

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

TEST PRINCIPLE

$$\text{Substrate} + H_2O \xrightarrow[\text{Phosphatase}]{Li^+} \text{AMP} + \text{Pi}$$

$$\text{AMP} + 2H_2O + \text{Pi} + 2O_2 \xrightarrow[\text{PNP/XOD}]{\text{5'-NT/ADA}} \text{Pi} + NH_3 + \text{R-1-P} + \text{UA} + 2H_2O$$

$$H_2O_2 + \text{4-AA} + \text{EHSPT} \xrightarrow{\text{Peroxidase}} 4H_2O + \text{quinone dye}$$

Lithium is determined spectrophotometrically through a kinetic coupled enzyme assay system involving lithium sensitive phosphatase[1]. Through enzymatic coupling, the phosphatise substrate is converted to hypoxanthine by a series of enzymatic reactions to generate uric acid and hydrogen peroxide (H_2O_2). H_2O_2 generated reacts with N-Ethyl-N-(2-hydroxy-3-sulfopropyl)-3-m-toluidine (EHSPT) and 4-aminoantipyrine (4-AA) in the presence of peroxidise (POD) to form a quinine dye which has maximal absorbance at 556 nm. The rate of the quinine 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 CHARACTERISITICS

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

LINEARITY, SENSITIVITY

The assay has a measuring range fro 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):
$y = 1.03\ x - 0.04$ 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.

2°C 8°C IVD

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