LITHIUM

ENZYMATIC

Intended use

BIOANALYTIC Lithium Enzymatic Assay kit is for Reagent for quantitative in vitro determination of lithium in biological fluids.

Clinical Significance

Lithium is administered as lithium carbonate and used for the treatment of the manic phase of affective disorders, mania, and manic-depressive illness. Absorption of lithium from the gastrointestinal tract is complete, with peak plasma concentration reached 2 to 4 hours after an oral dose. Lithium has a half-life of 48 to 72 hours in serum and its clearance is predominantly a function of the kid-neys. Hence, reduced renal function causes prolonged clearance times. Lithium acts by enhancing reuptake of catecholamines, thereby reducing their concentration in the neuronal junction and producing a sedating effect on the central nervous system.

Serum lithium concentrations are monitored to ensure patient compliance and avoid intoxication. Early symptoms of intoxication include apathy, sluggishness, drowsiness, lethargy, speech difficulties, irregular tremors, myoclonic twitching, muscle weakness, and ataxia. A concentration in excess of 1.5 mM in a specimen drawn 12 hours after the dose indicates a significant risk for intoxication.

Test principle

Lithium reacts with a substituted porphyrin at an alkaline pH generating a complex which absorbs at 510 nm. The decrease in absorbance is directly proportional to the lithium concentration in the sample.

Reagent Composition

For in vitro diagnostic use only.

The components of the kit are stable until expiration date on the label.
Keep away from direct light sources.

Composition: sodium hydroxide > 0.3 M, subsituted por-phyrin > 10 mM, surfactant, preservative.

Standard: lithium 1 mmol/l - 5 ml

Reagent Stability and Storage

Store all components at 2-8°C.

Precautions

LIT R1: Warning. Causes serious eye irritation (H319). Causes skin irritation (H315). Wear protective gloves. Eye protection (P280). IF ON SKIN: Wash with plenty of water (P302+P352). IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Con-tinue rinsing (P305+P351+P338). If eye irritation persists: get medical advice (P337+P313).

Standard: It is not classified as hazardous.

Assay Procedure:

Wavelenght:	510 nm (allowed 505 ÷ 520 nm)		
Lightpath:	1 cm		
Temperature:	37°C		
dispense:	blank	standard	sample
reagent	1 ml	1 ml	1 ml
water	20 µl	-	-
standard	-	20 µl	-
sample	-	-	20 µl

Mix, incubate at 37°C for 3 minutes.
Read absorbances of standard (As) and samples (Ax) against reagent blank.

Results Calcution

Serum, plasma EDTA:

lithium mmol/l = Ax/As x standard value

Calibration

S1: 0.9% NaCl
S2: Lithium Calibrator #B11868

Quality Control

Lithium Control #B10868

Reference Range

Therapeutic concentration: 0.6 - 1.2 mmol/l

Toxic concentration: > 2 mmol/l

Each laboratory should establish appropriate reference intervals related to its population.

Limitations

1. The assay is designed for use with human serum samples only.
2. There is a possibility that technical or procedural errors as well as other substances or factors not listed may interfere with the test and cause false results.

Performance Characteristics

Linearity

The method is linear up to 4 mmol/l.
If the limit value is exceeded, it is suggested to dilute sample 1 + 4 with distilled water and to repeat the test, multiplying the result by 5.

Sensitivity/limit of detection (LOD)

The limit of detection is 0.04 mmol/l.

Methods comparison

A comparison between Chema and a commercially availa-ble product gave the following results:

Lithium Chema = x
Lithium competitor = y
n = 41

y = 0.9945x + 0.0336 mmol/l r2 = 0.9998

Interferences

No interference was observed by the presence of:

hemoglobin	≤ 1000 mg/dl
bilirubin	≤ 53 mg/dl
lipids	≤ 1800 mg/dl
ammonium	≤ 480 mg/dl
calcium	≤ 33 mg/dl
iron	≤ 1000 mg/dl
magnesium	≤ 8 mEq/l
potassium	≤ 18 mmol/l
copper	≤ 10000 mg/dl
sodium	≤ 290 mmol/l
zinc	≤ 10000 mg/dl

Precision

Intra-assay (n=10)	**mean (mmol/l)**	**SD (mmol/l)**	**CV%**
sample 1	0.87	0.01	0.81
sample 2	1.94	0.02	1.00
Inter-assay (n=20)	**mean (mmol/l)**	**SD (mmol/l)**	**CV%**
sample 1	0.86	0.01	1.48
sample 2	1.94	0.03	1.31

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SPECIMEN

Serum, plasma EDTA.
Serum or plasma samples are stable at 2-8°C for one week and at -20°C for one month.
It is recommended that a standardised 12-hour post dose serum lithium concentration be used to assess adequate therapy. Peak concentration is reached 2 to 4 hours after oral dose.
Samples should be diluted 1:10 before the analysis (1 part of sample and 9 parts of distilled water).

References:

1. LaGow B et al., eds. PDR Lab Advisor. A Comprehensive Point-of-Care Guide for Over 600 Lab Tests. First ed. Montvale, NJ: Thomson PDR; 2007.
2. Amdisen A. Clinical and serum-level monitoring in lithium therapy and lithium intoxication. J Anal Toxicol. 1978;2:193–202.

Order information (Cat No.) :

B21235	B25235	B30235	B33235	B36235	
B22235	B27235	B31235	B34235	B37235	
B24235	B28235	B32235	B35235	B80235	

Manufacturer

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SYMBOLS

IVD	for in vitro diagnostic use only
LOT	lot of manufacturing
REF	code number
	storage at temperature interval
	expiration date (year/month)
	warning, read enclosed documents
	Read the directions

ISO 9001:2015
ISO 13485:2016