LITHIUM

LT F030 CH 2 x 15 ml

INTENDED USE

Reagent for quantitative in vitro determination of lithium in biological fluids.

SUMMARY OF TEST

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 kidneys. 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.

PRINCIPLE OF THE METHOD

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.

KIT COMPONENTS

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.

LIT R1 F030: 2 x 15 ml (liquid) blue cap

Composition: sodium hydroxide > 0.3 M, subsituted porphyrin > 10 µM, surfactant, preservative.

Standard: lithium 1 mmol/l - 5 ml

Store all components at 2-8°C.

MATERIALS REQUIRED BUT NOT SUPPLIED

Current laboratory instrumentation. Spectrophotometer UV/VIS with thermostatic cuvette holder. Automatic micropipettes. Glass or high quality polystyrene cuvettes. Saline solution.

REAGENT PREPARATION

Reagent R1: ready to use.
Stability of unopened vials: up to expiration date on labels at 2-8°C.
Stability since first opening of vials: preferably within 60 days 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. Continue rinsing (P305+P351+P338). If eye irritation persists: get medical advice (P337+P313).

Standard: It is not classified as hazardous.

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).

TEST 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 CALCULATION

Serum, plasma EDTA:

lithium mmol/l = Ax/As x standard value

EXPECTED VALUES

Therapeutic concentration: 0.6 - 1.2 mmol/l

Toxic concentration: > 2 mmol/l

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

QUALITY CONTROL AND CALIBRATION

It is suggested to perform an internal quality control. For this purpose the following human based control sera are available:
QUANTINORM CHEMA
with normal or close to normal control values,
QUANTIPATH CHEMA
with pathological control values.

If required, a multiparametric, human based calibrator is available:
AUTOCAL H

Please contact Customer Care for further information.

TEST PERFORMANCE

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.

Interferences
No interference was observed by the presence of:

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

Methods comparison
A comparison between Chema and a commercially available product gave the following results:

Lithium Chema = x
Lithium competitor = y
n = 41

y = 0.9945x + 0.0336 mmol/l r^2 = 0.9998

WASTE DISPOSAL

This product is made to be used in professional laboratories.
P501: Dispose of contents according to national/international regulations.

REFERENCES

B. Rumbelow, M. Peake - Ann. Clin. Biochem. 38, 684-686 (2001).
Tietz Textbook of Clinical Chemistry, Fourth Edition, Burtis-Ashwood-Bruns (2006).

MANUFACTURER

Chema Diagnostica
Via Campania 2/4
60030 Monsano (AN) - ITALY - EU
phone +39 0731 605064
fax +39 0731 605672
e-mail: mail@chema.com
website: http://www.chema.com

SYMBOLS

IVD	*in vitro* diagnostic medical device
LOT	batch code
REF	catalogue number
	temperature limit
	use by date
	caution
	consult instructions for use

CE