

Lithium (porphyrin-like colorimetric method)

This kit is used for in vitro quantitative determination of lithium content in human serum.

REF: BS.1/LI02.025.0050

CLINICAL SIGNIFICANCE

Lithium is widely used in the treatment of mania. It is typically administered as lithium carbonate, which is fully absorbed through the gastrointestinal tract: serum lithium levels peak 2-4 hours after oral administration, with a half-life of 48-72 hours; this period may be prolonged in patients with renal insufficiency. Lithium salts significantly inhibit the release of norepinephrine and dopamine from the central nervous system and increase neuronal reuptake, thereby exerting an antimanic effect. In psychiatry, lithium carbonate is used as a mood stabilizer to treat mania and is considered a potent drug for bipolar disorder, also having preventive effects on both mania and depression. Additionally, lithium carbonate is used to treat schizoaffective disorder, schizophrenia, and psychiatric disorders caused by epilepsy, and to control impulsive aggressive behavior in patients. The measurement of serum lithium concentration is primarily for controlling drug levels while avoiding toxicity. Early symptoms of poisoning mainly include apathy, sluggishness, drowsiness, stupor, speech disorders, irregular tremors, muscle spasms, muscle weakness, and ataxia.

METHOD PRINCIPLE

This reagent is a porphyrin-like colorimetric method. Under strong alkaline conditions, lithium in the sample reacts with porphyrin-like compounds to produce a change in absorbance, which is positively correlated with the concentration of lithium in the sample.

REAGENT COMPOSITION

Reagent 1: caustic soda complexon II	1.0 mol/L 0.05 mmol/L
Reagent 2: caustic soda class porphyrin compounds	1 mol/L 0.06 mmol/L
Calibration sample (liquid): 4-Hydroxyethylpipera zine ethanesulfonic acid bovine serum albumin lithium	10mmol/L 1 5% Level 1: 0.00 mmol/L Level 2: 0.50 mmol/L Level 3: 1.00 mmol/L Level 4: 2.00 mmol/L Level 5: 3.50 mmol/L
Quality control samples (liquid): 4-Hydroxyethylpipera zine ethanesulfonic acid bovine serum albumin lithium	10mmol/L 1 5% Level 1: 0.40-1.20 mmol/L level 2: 1.50-3.00 mmol/L

PRECAUTIONS AND WARNINGS

Reagent to be handled by entitled and professionally educated person.

Good Laboratories practices using appropriate precautions should be followed in:

- Wearing personnel protective equipment (overall, gloves, glasses,).
- Do not pipette by mouth.
- In case of contact with eyes or skin; rinse immediately with plenty of soap and water. In case of severe injuries; seek medical advice immediately.
- Respect country requirement for waste disposal.
S56: dispose of this material and its container at hazardous or special waste collection point.
S57: use appropriate container to avoid environmental contamination.
S61: avoid release in environment.

For further information, refer to the Lithium reagent material safety data sheet.

REAGENT PREPARATION, STORAGE AND STABILITY

BioScien Lithium reagents are supplied ready-to-use. All reagents are stable until expiration date stated on label when stored at 2 - 8°C.

Deterioration

The **BioScien** Lithium reagent is normally clear, do not use reagent if it is turbid.

SPECIMEN COLLECTION AND PRESERVATION

Serum samples

It can be stored for 7 days at 2°C~8°C and 6 months at -20°C

SYSTEM PARAMETERS

Wavelength	505 nm
Optical path	1 cm
Assay type	Endpoint
Direction	Decrease
Sample Reagent Ratio	4:1
Incubation Time	3 min
Temperature	37°C
Zero adjustment	Reagent blank

EQUIPMENT REQUIRED NOT PROVIDED

- Sterile Syringe
- Analytical tubes, automatic pipet
- Centrifuge and spectrophotometer

ASSAY PROCEDURE

	Standard	Specimen	Blank
Reagent 1	150 µl	150 µl	150 µl
Standard	3 µl	-	-
Specimen	-	3 µl	-
Mix, incubate 37°C for 3 minutes, read A1, incubate for another 2 minutes, and add			

Reagent 2 (R2)	50µL	50µL	50µL
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After mixing, read the absorbance A2 immediately after incubation at 37°C and calculate the change of absorbance ($\Delta A = A2 - A1$).

CALCULATION

Lithium concentration (mg/dl) = $\frac{\Delta A(T) \text{ specimen}}{\Delta A(S) \text{ standard}} \times \text{standard concentration}$

QUALITY CONTROL

To ensure adequate quality control, it is recommended that normal and abnormal commercial control serum of known concentrations included in each run. If control values are found outside the defined range, check the instrument calibration, and reagent for problems. If control still out of range please contact **BioScien** technical support.

PERFORMANCE CHARACTERISTICS

Accuracy

For the national standard 360018, the deviation should not exceed $\pm 10\%$.

Sensitivity

When the sample concentration is 1.00 mmol/L, the absorbance change should not be less than 0.2000.

linearity

In the range of [0.05 - 3.50] mmol/L, the linear correlation coefficient $r \geq 0.99$, in the range of [0.05, 0.60] mmol/L, the absolute deviation measured should not exceed ± 0.06 mmol/L, and in the range of (0.60 - 3.50) mmol/L, the relative deviation measured should not exceed $\pm 10\%$.

precision of measurement

Repetition

The coefficient of variation (CV%) of the measured values should not be greater than 10% when the samples with different high and low concentrations were measured 20 times.

Batch difference

The relative batch difference (R) of the three batches of kits randomly selected should not be greater than 10%.

Validation of the effectiveness of quality control samples

The results obtained by using the quality control samples should be within the quality control range.

Limitations

1. The reagent contains sodium azide. If it enters the eyes, mouth or skin, rinse thoroughly with water immediately and seek medical attention if necessary.
2. The reagent contains sodium azide, which can react strongly with copper, lead and other metals to form metal azide. Therefore, when discarded, please fully dilute the waste liquid and flush the drain pipe to avoid residual in the drain pipe.
3. The reagent is strongly alkaline. Do not contact skin or clothing directly. When discarded, dilute the waste liquid and flush the drain pipe thoroughly to avoid residual in the drain pipe.

EXPECTED VALUES

12 hour post dose trough concentration: 1.0 - 1.2 mmol/L . Minimum effective concentration: 0.6 mmol/L Values > 1.5 mmol/L 12 hours after dose indicates a significant risk of intoxication.

DYNAMIC RANGE

0.05 - 3.5 mmol/L.

REFERENCES

1. Balazs et al. Lithium detection in liquid biological samples and reagents therefor [J]. United States. US 7241623 B2. 20070610.
2. Zhang Jihua et al. Research progress on detection methods of lithium drug concentration [J]. Continuing Medical Education, December 2013, Vol 27, No. 12, 48-49.
3. Land and sea first class. Concentration of lithium salt drugs and clinical application progress [J]. Journal of Nanjing Military Medical College, 2001, 3(1): 33-35.
4. Yu Aiping. Clinical application of serum lithium concentration monitoring [J]. Management of Rural Health Service in China, 2011, 31(12): 1306.
5. Rosalie A. Richards, Kelly Hammons, Melanie Joe, and Gordon M. Miskelly. Observation of a Stable Water-Soluble Lithium Porphyrin [J]. Inorg. Chem. 1996, 35, 1940-1944

SYMBOLS IN PRODUCT LABELLING			
	For in-vitro diagnostic use		Number of <n> test in the pack
	Batch Code/Lot number		Caution
	Catalogue Number		Do not use if package is damaged
	Temperature Limitation		Consult Instruction for use
	Expiration Date		
	Manufactured by		



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