LITHIUM

REFERENCE	PACKAGE CONTENTS	VIAL(S)
40043	2x20 ml 1x4 ml	2xR1 1x4 Cal.

INTENDED USE

In vitro diagnostic reagent for the quantitative determination of lithium in serum and EDTA plasma on automated clinical chemistry analysers.

TEST SUMMARY[1,3]

Lithium has been widely used as a therapeutic drug for the treatment of patients suffering from bipolar disorder, mania, manic depression and other psychiatric illnesses.

It has been found that lithium in the form of lithium carbonate acts on the neurotransmitters resulting on a sedative effect on the central nervous system. It is important for physicians to monitor lithium ion blood concentration within the therapeutic concentration range of 0.5 to 1.0 mmol/L to avoid toxicity.

To make sure that the patients are compliant with their treatment, and avoiding toxicity, it is crucial that lithium levels in biological samples are monitored frequently.

METHOD

Methods such as atomic absorption spectrophotometry, flame emission photometry and ion-selective electrode (ISE) has been widely used for determining lithium in biological fluids, but these methods require specific instrumentation, experienced laboratory staff and is often very costly. These methods alone are open to interferences caused by other ions and proteins from the sample.

In this method, lithium present in the sample reacts with a highly specific ionophore and as a result absorbance of the sample changes significantly; which is directly proportional to the concentration of lithium in the sample.

CONTENTS

Ionophore……40 µmol/L

Hydroxides……..≥ %1 (m/v)

Preservatives

Stabilisers

Surfactants

SPECIMEN[1,3]

Collect the samples after a 12 hour period post dose. Peak concentrations occur 2 to 4 hours after oral dose.

For serum samples do not use lithium heparin, avoid haemolysed serum samples.

For plasma samples use only EDTA plasma samples.

Lithium is stable for a week when is kept under 2-8°C. If samples are kept under -20°C, lithium is stable about a year.

STABILITY AND STORAGE

Unopened reagent vials are stable up to its stated expiry date on label, when stored at 2°C-8°C.

Opened reagent vials are stable up to a month on board.

Do not use turbit reagents or expired reagents. Discard the reagent if the color is turning purple. Do not use the reagent if there's a failure to recover control values within assigned ranges.

CALIBRATON

Use National Institute of Standards and Technology (NIST) traceable methods for serum/plasma calibrator and control materials.

A standard calibrator of 1 mmol/L is included in the reagent kit.

Also use ***Bio Aktif Kimya's*** 40047 reference numbered calibrator pack when the calibrator is insufficient. On most automated analysers, the calibration frequency is expected to be 1 week.

However, please perform calibration if the following errors occur:

i) the lot number of the reagent is changed or the reagent vial has been changed

ii) preventive maintenance is performed or a critical component such as cuvettes, reagent and sample probes, lamps, syringes, tubings, mixers, washing unit components, photometer components or washing wells are changed.

iii) control values shift, or out of range and a new vial of control does not change the results.

To ensure adequate quality control, follow good laboratory practices, use at least one normal and one abnormal levels of control serums or analytical standards.

QUALITY CONTROL

Perform QC each day, or a new bottle of reagent is used, preventive maintanance has been done, or the reagent is newly calibrated.

If QC samples are falling out of range, follow these guidelines:

i) make sure that the calibrator and control values with acceptable ranges are assigned correctly.

ii) repeat the same controls.

iii) check that the carry-over preventive solutions are not deteriorating or there is not enough volume.

iv) make sure that preventive maintenance washing cycles has been performed weekly.

v) if results are still out of control, recalibrate with fresh calibrator standards then repeat the test.

vi) if results are still out of control, prepare fresh control materials.

vii) if results are still out of control, perform a calibration with a fresh reagent then repeat the test.

viii) if results are still out of control, contact technical services.

Use serum or analyte based QC materials or ***Bio Aktif Kimya's*** 40048 reference numbered QC pack.

INTERFERENCES[2,6*]

1. This reagent is highly light sensitive and will absorb atmospheric carbon dioxide. Please store the reagent capped and in a dark container when it is not used for prolonged periods of time.

2. Studies show that some analytes and serum components interfere up to %5 of assigned lithium values when:

Calcium:	above	15 mg/dl
Potassium:	above	7.0 mmol/L
Sodium:	above	180 mmol/L
Iron:	above	800 µg/dl
Zinc:	above	500 µg/dl
Magnesium:	above	4 mg/dl
Copper:	above	600 µg/dl
Conjugated bilirubin:	above	15 mg/dl
Triglycerides:	above	600 mg/dl
Hemoglobin:	above	2 g/L

For drug interferences refer to "*Effects of Drugs on Clinical Laboratory Tests" by Young.*

REFERENCE INTERVALS[1,3*]

Lithium is toxic at concentrations above 1.5 mmol/L.

Therapeutic interval for lithium is 1.00-1.20 mmol/L.

Minimum effective concentration is 0.6 mmol/L.

PERFORMANCE STUDIES[4,5*]

The following data was gathered from a Mindray BS800M clinical chemistry analyser.

Imprecision

These studies have been performed with using commercially available quality control serums following the CLSI EP05-A3 protocol.

Table 1. Within-run

Mean	SD	CV%	n
1.00 mmol/L	0.019	1.90	80
2.5 mmol/L	0.055	2.20	80
0.8 mmol/L	0.018	1.87	80

Table 2. Day to day run

Mean	SD	CV%	n
1.00 mmol/L	0.023	2.30	80
2.5 mmol/L	0.071	2.84	80
0.8 mmol/L	0.021	2.62	80

Assay Comparision

The Bio Aktif Kimya Lithium reagent (y) was designed to have a correlation coefficient of > 0.97 and a slope of 1.00±0.1. Assay comparisons were performed by using CLSI EP09-A3 protocol against a lithium ISE analyser and the following results were obtained:

Sample interval:	0.15-2.90 mmol/L
Mean of ISE results:	0.95 mmol/L
Mean of Bio Aktif Kimya lithium:	0.90 mmol/L
Slope:	0.95
Correlation coefficient:	0.98

Linearity

Linear from 0.05 to 3.00 mmol/L.

Limit of detection

When run as recommended the lowest detection limit is 0.045 mmol/L.

NOTES

1. Dilute samples with more than 3.00 mmol/L lithium with 1:2 de-ionised water, re-run the sample and multiply the result with 2 when reporting.

2. Please add the necessary carry-over parameters before performing automated analysis. For more info contact our e-mail found in the REFERENCES section of this leaflet.

GHS HAZARD CLASSIFICATIONS

H314 Causes severe skin burns and eye damage.

IF INHALED: Do not breathe or inhale the reagent, consult your physician.

IF IN EYES: Rinse with water for several minutes, remove contact lenses immediately consult your physician.

IF ON SKIN: Rinse with water for several minutes. If irritation occurs consult your physician.

IF INGESTED/SWALLOWED: Rinse mouth, do not induce vomiting. Immediately consult a physician.

REFERENCES*

1. Tietz., Fundamentals of Clinical Chemistry, Sixth Edition, Elsevier, 2008.
2. Young DS., Effects of Preanalytical Variables on Clinical Laboratory Tests, Second Edition.
3. Amdisen A., Serum Lithium determinations for Clinical use., Scand. Clin. Lab. Invest., 1967.
4. Clinical and Laboratory Standards Institute, Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline, Third Edition, Wayne, 2014.
5. Clinical and Laboratory Standards Institute, Measurement Procedure Comparison and Bias Estimation Using Patient Samples; Approved Guideline, Third Edition, Wayne, 2013.
6. Young DS., Effects of Drugs on Clinical Laboratory Tests, Fifth Edition.

BİO AKTİF KİMYA İTHALAT İHRACAT İMALAT SANAYİ VE TİCARET LİMİTED ŞİRKETİ

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SYMBOLS

MANUFACTURER

PACKAGE INSERT/INFORMATION SHEET

IVD IN-VITRO DIAGNOSTICS

LOT LOT NUMBER

REF REFERENCE NUMBER

EXPIRATION DATE

TEMPERATURE LIMIT