**Reagent Preparation**

Supplied ready to use.

**Method**

Endpoint

**Specimen Type**

Serum/EDTA plasma

**Measuring Range**

0.04 - 3.00 mmol/L

**Stability**

Until Expiry at 2-8°C

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**INTENDED USE**

This reagent is intended for the in vitro quantitative determination of Lithium (Li) in human serum or EDTA plasma.

**CLINICAL SIGNIFICANCE**

Lithium is widely used in the treatment of manic depressive psychosis. Administered as Lithium Carbonate, it is completely absorbed by the gastro-intestinal tract, peak serum levels occur 2 to 4 hours after an oral dose. The half life in serum is 48 to 72 hours and it is cleared through the kidneys (excretion parallels that of sodium). Reduced renal function can prolong clearance time. Lithium acts by enhancing the uptake of neurotransmitters which produces a sedative effect on the central nervous system. Serum Lithium concentrations are carried out essentially to ensure compliance and to avoid toxicity. Early symptoms of intoxication include apathy, sluggishness, drowsiness, lethargy, speech difficulties, irregular tremors, myoclonic twitchings, muscle weakness and ataxia. Levels higher than 1.5 mmol/L (12 hours after a dose) indicate a significant risk of intoxication.

**METHODOLOGY**

Lithium can be determined by atomic absorption spectrophotometry, flame emission photometry or ion- selective electrode. These methods require specific and often dedicated instrumentation.

This Lithium reagent is a spectrophotometric method which can be readily adapted to automated clinical chemistry analysers. Lithium present in the sample reacts with a substituted porphyrin compound at an alkaline pH, resulting in a change in absorbance which is directly proportional to the concentration of Lithium in the sample.

**REAGENT COMPOSITION**

**Active ingredients**

- Sodium hydroxide 0.5 mol/L
- EDTA 50 µmol/L
- Substituted Porphyrin 15 µmol/L
- Preservative surfactant

**Concentration**

**Calculation**

For determination of lithium concentration, the absorbance of unknown sample is compared with that of the standard by the following equation:

\[
\text{Lithium concentration (mmol/L)} = \frac{\text{Abs of Unknown} - \text{Abs of Calibrator}}{\text{Sample: Reagent Ratio}} \times \text{Calibrator Value}
\]

**System Parameters**

- **Temperature**: 37°C
- **Primary Wavelength**: 510 nm (505-520nm)
- **Secondary Wavelength**: 480 nm (450-480nm)
- **Assay Type**: Endpoint
- **Direction**: Decrease
- **Reagent Blank**: Yes

**Sample Preparation**

For analysers which do not have automatic dilution, samples, controls and calibrators should be prediluted 1:10 with distilled or deionized water.

**Calculation**

Results are calculated, automatically by the instrument, as follows:

\[
\text{Lithium (mmol/L)} = \frac{\Delta \text{Abs of Unknown}}{\Delta \text{Abs of Calibrator}} \times \text{Calibrator Value}
\]

**Example (at 505, 480nm):**

- Absorbance of calibrator = 0.116
- Absorbance of unknown = 0.095

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**Symbols in Product Labelling**

- **EC REP**
  - Authorized Representative
- **LVD LOT REF**
  - Batch code/Lot number
  - Catalogue number
  - Consult instructions for use

**Precautionary Statements - Disposal**

Dispose of contents/container to an approved waste disposal plant.

Refer to the product Safety Data Sheet for additional information.

**Reagent Preparation**

Reagent is supplied ready to use.

**Stability and Storage**

Once opened the reagent is stable in the opaque bottle until the expiry date stated, provided that it is capped when not in use and stored at 2-8°C. When stored on board a Hitachi 911® automated analyser, the reagent will remain stable for 1 month. Refer to calibration section for expected calibration frequency.

**Indications of Reagent Deterioration:**

- Turbidity:
  - Failure to recover control values within the assigned range; and/or
  - Color of reagent is light purple.

**Collection and Handling**

Collection: 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. Serum or EDTA plasma should be separated from cells if storage of more than 4 hours is anticipated.

Serum: The best specimen is non-haemolysed serum.

Plasma: Use EDTA plasma only.

**Sample Preparation**

For analysers which do not have automatic dilution, samples, controls and calibrators should be prediluted 1:10 with distilled or deionized water.

**Technical Support Group**

For further information or technical support, please contact the Technical Support Group.
If results are still out of control, contact Technical Services or your local distributor.

Quality Control
To ensure adequate quality control, normal and abnormal control with assayed values should be run as unknown samples:-

• At least once per day or as established by the laboratory.

• When a new bottle of reagent is used.

• After preventative maintenance is performed or a critical component is replaced.

• When a new bottle of reagent is used.

• At least once per day or as established by the laboratory.

No significant interference (<5% deviation from assigned Lithium concentration) from:

- Sodium: Up to 200 mmol/L
- Potassium: Up to 8.00 mmol/L
- Calcium: Up to 4.00 mmol/L (16 mg/dL)
- Magnesium: Up to 2.00 mmol/L (8.66 mg/dL)
- Iron: Up to 200 µmol/L (117 µg/dL)
- Zink: Up to 250 µmol/L (1625 µg/dL)

The quoted values should serve as a guide only. It is recommended that each laboratory verify this range or derives a reference interval for the population it serves.

Performance Data
The following was obtained using the Infinity Lithium Liquid Stable Reagent on a well maintained automated clinical chemistry analyser (Hitachi 911). Users should establish product performance on their specific analyser used.

IMPROVEMENT
Imprecision was evaluated using two levels of commercially available quality control serum following the NCCLS EP5 procedure.

Limitations
1. The reagent is light sensitive and will absorb atmospheric carbon dioxide. It is recommended that the reagent be stored capped and in a dark container when not in use for prolonged periods of time (e.g., overnight).

2. Studies to determine the level of interference from other cations normally present in serum were carried out in the presence of a lithium concentration of approximately 1 mmol/L and the following results were obtained:

   No significant interference (<5% deviation from assigned Lithium concentration) from:

   - Conjugated Bilirubin: No significant difference from conjugated bilirubin (<10% deviation) up to 769 µmol/L (45 mg/dL)
   - Free Bilirubin: No significant difference from free bilirubin (<10% deviation) up to 769 µmol/L (45 mg/dL)
   - Lipase: No significant difference from lipase (<10% deviation) measured as triglycerides, up to 22.6 mmol/L (2000 mg/dL)
   - Haemoglobin: No interference from haemoglobin (<5% deviation) up to 2g/L

   Interference (≥10% deviation from 1 mmol/L Lithium concentration) was observed with this method for concentrations of bilirubin and lypaeina greater than those stated above.

   EXPECTED VALUES:

   12 hour post dose trough concentration: 1.0 - 1.2 mmol/L

   Minimum effective concentration: 0.5 mmol/L

   Values > 1.5 mmol/L 12 hours after dose indicates a significant risk of intoxication.

   The quoted values should serve as a guide only. It is recommended that each laboratory verify this range or derives a reference interval for the population it serves.

References
3. Young DS. “Effects of Preanalytical Variables on Clinical Laboratory Test” 2nd Ed. pg 868.

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Reorder Information

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