DXC (LI) LITHIUM

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PURPOSE

To provide instruction for the quantitative determination of lithium on the DXC 600/800.

PRINCIPLE

LI reagent, when used in conjunction with UniCel® DxC 600/800 System(s), is intended for the quantitative determination of Lithium concentrations in human serum and plasma activity.

BACKGROUND

Clinical Significance

Lithium is widely used in the treatment of manic depressive psychosis. Administered as Lithium Carbonate, it is completely absorbed by the gastrointestinal 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 concentration is used in monitoring the presence of Lithium to ensure appropriate therapy. 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

The Lithium assay is a spectrophotometric method which has been adapted to run on the UniCel® DxC 600/800 System(s). Lithium present in the sample reacts with a substituted porphyrin compound at an alkaline pH, resulting in a change of absorbance which is directly proportional to the concentration of Lithium in the sample.

RELATED DOCUMENTS

R-PO-CH0810	Quality Control Program General Laboratory
R-PO-CH0809	Quality Control Westgard Rules Statistics
R-PR-AD0540	Specimen Rejection/Cancellation Protocol
J-F-CH0820	DXC 800 Controls
M-F-CH0820	Chemistry Controls
J-F-CH0826	DXC 800 Calibrators
M-F-CH0826	Chemistry Calibrators
M-F-CH1940	DXC 600 (AMR) Analytical Measurement Range
J-F-CH1940	DXC 800 (AMR) Analytical Measurement Range

SPECIMEN

Type of Specimen

Serum: **Non-hemolyzed, freshly drawn serum is the preferred sample.**

Plasma: Sample collected in Lithium heparin (Green Top) are unacceptable.

Whole blood / urine: Not recommended for use as a sample.

Specimen Storage and Stability

1. Tubes of blood are to be kept closed at all times and in a vertical position. It is recommended that the serum or plasma be physically separated from contact with cells within four hours from the time of collection.

2. Separated serum or plasma should not remain at room temperature longer than 8 hours. If assays are not completed within 8 hours, serum or plasma should be stored at +2°C to +8°C. If assays are not completed within 1 week, or the separated sample is to be stored beyond 1 week, samples should be frozen at -20°C. Frozen samples are stable for 6 months at -20°C and should be thawed only once. Analyte deterioration may occur in samples that are repeatedly frozen and thawed.

Sample Type	Volume	Sample Stability
Serum	0.5ml	• 8 hours at 18-26°C • 48 hours at 2-8°C • After 48 hours, freeze at -15 to -20°C

Criteria for Unacceptable Specimens

See Specimen Rejection/Cancellation Protocol

Sample Preparation

Sample preparation is not required.

Sample Volume

A filled 0.5 mL sample cup is the optimum volume. For optimum primary sample tube volumes in primary tube samples and minimum volumes, refer to the Primary Tube Sample Template for your system.

REAGENTS

Contents

Each kit contains the following items:
Two Reagent Cartridges (2 x 65 tests)
Lithium Calibrator, 2.0 mmol/L

Volume per Test	
Sample Volume	10 µL
Ordac Sample Volume	4 µL
Total Reagent Volume	480 µL
Cartridge Volumes	A 280 µL B 200 µL C – –

Reactive Ingredients	
Sodium Hydroxide	0.5 mol/L
EDTA	50 µmol/L
Substituted Porphyrin	15 µmol/L

Also non-reactive chemicals necessary for optimal system performance.

Reagent Preparation

Reagent is supplied ready to use. Transfer entire contents of reagent to Compartment B of the Synchron cartridge.

Acceptable Reagent Performance

The acceptability of a reagent is determined by ensuring that quality control results are within your facility`s acceptance criteria.

Reagent Storage and Stability

LI reagent when stored unopened at +2°C to +8°C, will obtain the shelf-life indicated on the cartridge label. Once opened, the reagent is stable for 14 days at +2°C to +8°C on Synchron Systems. Do not use beyond the manufacturer's expiration date.

CALIBRATION

Calibrator Required

LI is calibrated using a two point calibration with deionized water (low calibrator) and 2.0 mmol/LThermo Lithium Calibrator.

Calibrator Preparation

No preparation is required.

Calibrator Storage and Stability

Calibrator is stable until package expiration.

Calibration Information

1. Under typical operating conditions the LITHIUM reagent cartridge must be calibrated every 5 days and also with certain parts replacements or maintenance procedures, as defined in the UniCel DxC 600/800 System *Instructions For Use* (IFU) manual. This assay has within-lot calibration available. Refer to the UniCel DxC 600/800 System *Instructions For Use* (IFU) manual for information on this feature.

2. For detailed calibration instructions, refer to the UniCel DxC 600/800 System *Instructions For Use* (IFU) manual.

3. The system will automatically perform checks on the calibration and produce data at the end of calibration. In the event of a failed calibration, the data will be printed with error codes and the system will alert the operator of the failure. For information on error codes, refer to the UniCel DxC 600/800 System *Instructions For Use* (IFU) manual.

Traceability

This measurand (analyte) is traceable to the manufacturer's selected Measurement Procedure as described in the Methodology section. The Thermo Lithium Calibrator is traceable to NIST SRM 3129.

QUALITY CONTROL

See Related Documents J-F-CH0820 DXC 800 Controls & M-F-CH0820 Chemistry Controls

STEPS

1. If necessary, load the reagent onto the system.

2. After reagent load is completed, calibration may be required.

3. Program controls for analysis.

4. After loading controls onto the system, follow the protocols for system operations. For detailed testing procedures, refer to the UniCel DxC 600/800 System *Instructions For Use* (IFU) manual.

CALCULATIONS

The SYNCHRON® System(s) performs all calculations internally to produce the final reported result. The system will calculate the final result for sample dilutions made by the operator when the dilution factor is entered into the system during sample programming

PERFORMANCE CHARACTERISTICS

Reference Range

Therapeutic	0.5 -1.5 mmol/L
Critical	>1.5 mmol/L

Analytic Range

The SYNCHRON® System(s) method for the determination of Lithium provides the following analytical range, which has been confirmed as the reportable range.

Sample Type	Conventional Units
Serum or Plasma	0.1 – 3.0 mmol/L

Reporting results outside of analytical range

Lower limit of detection	0.1 mmol/L	Results below 0.1, report as <0.1 mmol/L
Upper limit of detection	3.0 mmol/L	Results >3.0 mmol/L should be diluted with saline, reanalyzed and dilution factor applied. The maximum allowable dilution is x2. Results >6.0 should be reported as >6.0 mmol/L.

Sensitivity

Sensitivity is defined as the lowest measurable concentration which can be distinguished from zero with 95% confidence. Sensitivity for LI determination is 0.06 mmol/L, which rounds up to 0.1 mmol/L .

LIMITATIONS

The reagent is light sensitive and will absorb atmospheric carbon dioxide. Avoid hemolysis.

Interferences

1. The following substances were tested for interference with this methodology:

Substance	Source	Level Tested	Observed Effect
Bilirubin (unconjugated/conjugated)	Serum	45 mg/dL INDEX of 20	NSI (<10% deviation)
Hemoglobin	RBC hemolysate	200 mg/dL INDEX of 5	<5% deviation
Lipemia	Triglycerides	2000 mg/dL INDEX of 10	NSI (<10% deviation)
Sodium	Serum	Up to 200 mmol/L	NSI (<5% deviation)
Potassium	Serum	Up to 8.00 mmol/L	NSI (<5% deviation)
Calcium	Serum	Up to 16 mg/dL	NSI (<5% deviation)
Magnesium	Serum	Up to4.86 mg/dL	NSI (<5% deviation)
Iron	Serum	Up to1117 µg/dL	NSI (<5% deviation)
Zinc	Serum	Up to 1625 µg/dL	NSI (<5% deviation)
Copper	Serum	Up to 1588 µg/dL	NSI (<5% deviation)

ADDITIONAL INFORMATION

For more detailed information on UniCel DxC Systems, refer to the appropriate system manual.

REFERENCES

Infinity Lithium (Li) Reagent for Beckman Coulter Synchron Systems package insert, Thermo Fisher Scientific Inc., 2008

Lithium (LI) , Therapeutic Drug Monitoring Bulletin 9282 (tdm6a), Beckman Coulter, Inc for UniCel DXC and SYNCHRON LX Clinical Systems, 2005.

DOCUMENT APPROVAL Purpose of Document / Reason for Change:			
Updated formatting, added maximum allowable dilution, added Index to interfering substances, removed references to EDTA (we don't use).			
Committee Approval Date	☒ Date: 7/2/15 ☐ NA – revision of department-specific document which is used at only one facility	**Medical Director Approval** *(Electronic Signature)*	Katie Wilkinson, MD 7/30/15