**PRODUCT SUMMARY**

<table>
<thead>
<tr>
<th>Stability</th>
<th>Until Expiry at 2-8°C</th>
</tr>
</thead>
<tbody>
<tr>
<td>Linear Range</td>
<td>Up to 7.0 mmol/L</td>
</tr>
<tr>
<td>Specimen Type</td>
<td>Serum/EDTA Plasma</td>
</tr>
<tr>
<td>Method</td>
<td>Endpoint</td>
</tr>
<tr>
<td>Reagent Preparation</td>
<td>Supplied ready to use.</td>
</tr>
</tbody>
</table>

**STABILITY AND STORAGE**

The unopened reagents are stable until the expiration date when stored at 2-8°C. When stored on SYNCHRON Systems, the reagent is stable for 14 days.

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

**SPECIMEN COLLECTION AND HANDLING**

Collection: It is recommended that a standardized 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.

Storage: Samples are stable for 1 week at 2-8°C or >1 year at -20°C.

**STORAGE**

Samples are stable for 1 week at 2-8°C or >1 year at -20°C. Plasma: Use EDTA plasma only.

**INDICATIONS OF REAGENT DETERIORATION**

- If results are still out of control, contact Technical Services or the local distributor.
- If results are still out of control, recalibrate with fresh calibrator, then repeat the test.
- Repeat the same controls.
- Preventative maintenance is performed or a critical component is replaced.
- Control values have shifted or are out of range and a new vial of control does not rectify the problem.
- The lot number of reagent changes.

**TESTING PROCEDURES**

All samples, calibrators and controls are diluted on-line.

- Sample Size 5µL (1:29 dilution: 10 µL neat sample plus 280 µL diluent)
- ORDAC sample size 5 µL (1:71 dilution: 4 µL neat sample plus 280 µL diluent)

**MATERIALS PROVIDED**

- Thermo Lithium reagent for Beckman Coulter SYNCHRON Systems.
- Thermo Lithium Calibrator, 2.0 mmol/L.
- Beckman Coulter SYNCHRON Cartridge with Diluent.

**ADDITIONAL EQUIPMENT REQUIRED BUT NOT PROVIDED**

- Beckman Coulter SYNCHRON chemistry analyzer.
- Beckman Coulter sample cups.
- Assayed Normal and Abnormal Controls.
- Deionized water (low calibrator).

**CALIBRATION**

- The system must have a valid calibration curve in memory before control or patient samples can be run. Under typical operating conditions the Lithium reagent cartridge must be calibrated every 5 days.
- SYNCHRON Systems are calibrated using a two point calibration with deionized water (low calibrator) and Thermo Lithium Calibrator. However, if during this period any one of the following events occurs, recalibration is recommended:-
  - The lot number of reagent changes.
  - Preventative maintenance is performed or a critical component is replaced.
  - Control values have shifted or are out of range and a new vial of control does not rectify the problem.

**TRACEABILITY**

The Thermo Lithium Calibrator is traceable to NIST SRM 3129.

**RESULTS**

Results are calculated, automatically by the instrument.

**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.
- With every calibration.

Control results falling outside the upper or lower limits of the established ranges indicate that the assay may be out of control. The following corrective actions are recommended in such situations:-
- Repeat the same controls.
- If repeated control results are outside the limits, prepare fresh control serum and repeat the test.
- If results are still out of control, recalibrate with fresh calibrator, then repeat the test.
- If results are still out of control, perform a calibration with fresh reagent, then repeat the test.
- If results are still out of control, contact Technical Services or the local distributor.

**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 (eg. overnight).
2. Studies to determine the level of interference from other cations normally present in...
were determined and LDL was calculated using the formula:

$$LDL = \overline{x} + (2 \times s)$$

Where: $\overline{x}$ = mean value of replicates
$s$ = standard deviation of replicates (n - 1).

When run as recommended the lowest detection limit is 0.06 mmol/L.

**PRECISION**

A properly operating SYNCHRON System should exhibit precision values less than or equal to the following:

<table>
<thead>
<tr>
<th>TYPE OF PRECISION</th>
<th>SAMPLE TYPE</th>
<th>1 SD</th>
<th>CHANGEOVER VALUE*</th>
<th>% CV</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>mmol/L</td>
<td>mmol/L</td>
<td></td>
</tr>
<tr>
<td><strong>WITHIN RUN</strong></td>
<td>Serum/Plasma</td>
<td>0.03</td>
<td>1.0</td>
<td>3.0</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(Values ≤ 3.0)</td>
<td>(Values &gt; 3.0)</td>
<td></td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td>Serum/Plasma</td>
<td>0.045</td>
<td>1.0</td>
<td>4.5</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(Values ≤ 3.0)</td>
<td>(Values &gt; 3.0)</td>
<td></td>
</tr>
</tbody>
</table>

* When the mean of the test precision data is less than or equal to the changeover value, compare the test SD to the SD guideline given above to determine acceptability. When the mean of the test precision data is greater than the changeover value, compare the test %CV to the %CV guideline given above to determine acceptability. Changeover value = (SD guideline × CV guideline) × 100.

**REFERENCES**

3. Young DS. “Effects of Preanalytical Variables on Clinical Laboratory Test” 2nd Ed. pg 3-36.

**Hazard Symbol:** Corrosion

**Signal Word:** Danger

**Hazard Statements**

Causes severe skin burns and eye damage

Precautionary Statements - Prevention

Do not breathe dust/fume/gas/mist/vapors/spray
Wear protective gloves/protective clothing/eye protection/face protection

Precautionary Statements - Response

Immediately call a POISON CENTER or doctor/physician
Specific treatment (see supplemental first aid instructions on this label)

Precautionary Statements - Storage

Dispose of contents/container to an approved waste disposal plant

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