Version 18-11/24

User's Manual

Lithium Assay Kit

REF **DEIA-NS2408-5**

Σ **96T**

RUO

This product is for research use only and is not intended for diagnostic use.

For illustrative purposes only. To perform the assay the instructions for use provided with the kit have to be used.

Creative Diagnostics

Address: 45-1 Ramsey Road, Shirley, NY 11967, USA

Tel: 1-631-624-4882 (USA) 44-161-818-6441 (Europe) **Fax: 1-631-938-8221**

Email: info@creative-diagnostics.com **Web: www.creative-diagnostics.com**

PRODUCT INFORMATION

Intended Use

The Lithium Kit is for the quantitative determination of lithium in serum. Please read the complete kit insert before performing this assay. The kit is for RESEARCH USE ONLY. It is not intended for use in diagnostic procedures.

General Description

Lithium is an effective agent for the treatment of patients suffering from bipolar disorder. Recently, studies have also shown that lithium holds promise against Alzheimer' s disease. However, lithium has many side effects. Over dosage of lithium can cause acute Li+ intoxication, which occurs quite often due to its narrow therapeutic index. Therefore, the timely and accurate monitoring of serum levels of lithium is critical.

Principles of Testing

The Lithium Assay is based on a kinetic coupling assay system using proprietary phosphatase that is sensitive to lithium. The phosphatase substrate is converted to hypoxanthine to generate uric acid and hydrogen peroxide. Hydrogen peroxide then reacts with EHSPT and 4-AA to form a quinine dye which has a maximal absorbance around 550 nm. The rate of the quinine dye formation is inversely proportional to the concentration of lithium in serum samples.

Reagents And Materials Provided

1. Reagent CC1 (liquid) 1 × 20 mL
2. Reagent CC2 (liquid) 1 × 10 mL
3. Calibrator 1 (liquid) 1 × 3 mL
4. Calibrator 2 (liquid) 1 × 3 mL
5. Calibrator 3 (liquid) 1 × 3 mL

Materials Required But Not Supplied

1. Micropipettes and disposable tips
2. Clean glass tubes and test tube racks
3. Incubator (37°C)
4. Distilled water
5. Spectrophotometer (should read A550 values)
6. 0.9% saline

Storage

1. Upon receipt of the Lithium Kit, store it at 2-8°C (do not freeze the kit or hold it at temperatures above 25°C).
2. The kit should not be used after the expiration date.

Specimen Collection And Preparation

The Lithium Assay is formulated for use with non-hemolysed serum samples. No special handling or pretreatment is required. Serum samples should be collected such that testing is performed as soon as possible after the specimen collection.

Reagent Preparation

1. Preparation of reagents

All reagents are provided ready-to-use and should be brought to room temperature for at least 30 minutes prior to use. Reagents should be stored at 2-8°C immediately after use. Before use, mix the reagents thoroughly by gentle agitation or swirling

2. Preparation of samples, calibrators, and controls

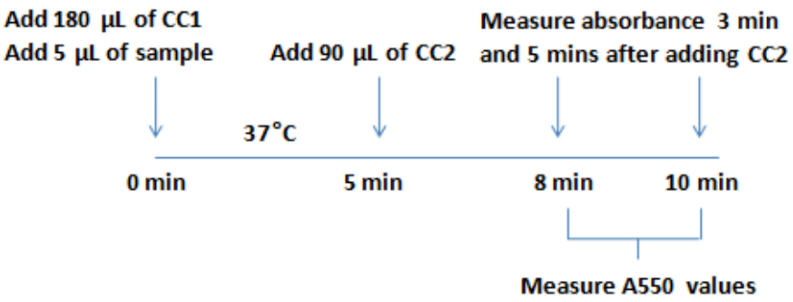
Bring all samples, calibrators, and controls to room temperature.

Assay Procedure

The procedure below reflects a manual procedure performed using a glass tube with a spectrophotometer. The assay can also be adopted to work on various automated analyzers.

1. Add 180 µL of Reagent CC1 and 5 µL of sample, calibrator, or control into a clean glass tube and mix well by repeated pipetting.
2. Place glass tube in incubator (37°C) and allow microplate to equilibrate to 37°C over 5 minutes.
3. Pipette 90 µL of Reagent CC2 into the glass tube and mix well by repeated pipetting. Start timer immediately upon addition of Reagent CC2. **Note:** The accuracy of the assay is based on measuring the change in absorbance at 3 min and 5 mins after the addition of Reagent CC2. Slight variations in the timing of the readings (ie. 2.5 mins and 5.5 mins) should not affect the results as long as the timing of the readings is consistent for both the calibrators and samples. Said another way, it is important that CC2 be added to the calibrators and samples at the same time and readings for both calibrators and samples be taken at the same time to obtain comparable absorbance readings.
4. Measure absorbance using a spectrophotometer (measure A550 values) 3 mins and 5 mins after the addition of Reagent CC2.

Summary of assay procedure



Calculation

1. Calculate the change in absorbance ΔA (5 mins ~ 3 min)

   ΔA = (OD550nm, 5 mins) - (OD550nm, 3 mins)

2. Using linear graph paper, construct the Lithium calibration curve by plotting the mean change in absorbance value for each calibrator on the Y axis versus the corresponding lithium concentration on the X axis. **Note:** Calibrator values vary per lot and should be obtained from the calibrator labels. A calibration curve should be plotted every time the assay is performed.
3. Lithium concentrations in the samples are interpolated using the calibration curve and mean absorbance values for each sample. The Lithium concentration is expressed as mmol/L. **Note:** Samples with a high Lithium concentration (3.0 mmol/L or higher) should be diluted with 0.9% saline (1:1) and rerun.

Precision

The assay has a within-run and total precision of CV < 10%.

Detection Range

The Lithium assay has a linear range from 0.19 - 3.0 mmol/L

Precautions

1. Only appropriately-trained personnel should use the kit. Laboratory personnel should wear suitable protective clothing. All chemicals and reagents should be considered potentially hazardous. Avoid ingestion and contact with skin and eyes.
2. Some assay components contain human sourced materials. Accordingly, all assay components should be handled as if potentially infectious using safe laboratory procedures.
3. Do not use the reagents after the expiration date.

Maximizing Kit Performance

1. Given the small sample volumes required (5 µL), pipetting should be done as carefully as possible. A high quality 10 µL or better precision pipette should be used for such volumes. Drops of liquid adhering to the outside of the pipette tips should be removed by wiping to ensure the highest degree of accuracy.
2. In order to prevent the glass tubes from drying out and to get the best results, samples and reagents should be dispensed quickly into the tubes.
3. Each calibrator and sample should be assayed in duplicate.
4. The same sequence of pipetting and other operations should be maintained in all procedures.
5. Do not mix reagents that have different lot numbers.