

CURRENT

Category: Patient Care

Title: Procedure for estimation of Lithium in human serum by Electrolyte Analyzer.

SOP No. and version: TDM07/02

Date first effective: 1st January 2025

Review date: 31st December 2025

Department of Clinical Pharmacology, 1st Floor, New MS Building, Seth GS Medical College & KEM Hospital, Parel, Mumbai 400012.

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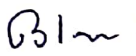
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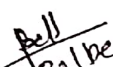

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Confidential

Page 1 of 5



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1. Table of Contents

No.	Contents	Page No.
1	Purpose	3
2	Scope	3
3	Responsibility	3
4	Applicable rules/guidelines	3
5	Reference to other applicable SOPs	3
6	Detailed instructions	4
7	Abbreviations	5

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1. Purpose:

This SOP describes the technique for the qualitative and quantitative estimation of Lithium in human serum by Electrolyte Analyzer.

2. Scope:

This SOP is limited estimation of lithium in $\mu\text{g/ml}$ in human serum by electrolyte analyzer.

3. Responsibilities:

The Head of the department is responsible for the medical care and welfare of all patients pertaining to TDM of lithium. The task of performing estimation of serum lithium will be delegated to trained personnel who will perform this function.

4. Applicable rules, regulations and guidelines

ICMR Good Clinical Laboratory Practices Guidelines 2021
(<http://icmr.nic.in/guidelines/GCLP.pdf>)

5. Reference to other applicable SOPs

- SOP No. 24/02: Biomedical waste management.
- SOP No. TDM 01/02: Collection and separation plasma for TDM

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6. Detailed instructions

1. Patients are referred for serum lithium estimation to TDM OPD (OPD: 201) Department of Clinical Pharmacology, 1st floor, New building KEM Hospital.
2. Blood sample must be collected at least 12 hours after the last dose of lithium.
3. Four ml of blood sample must be collected for serum lithium estimation in plain bulb (red/yellow vacutainer without anticoagulant).
4. Blood sample should be labelled with patient's identification number with name, age, and date & time of collection.
5. Details must be entered in the Lithium TDM ledger mentioning the lithium intake dose, frequency, time of last dose.
6. The sample is kept for **30 minutes** at room temperature to allow the clot formation prior to centrifugation.
7. The blood sample is then centrifuged at 2500 rpm for 10 minutes.
8. The serum that gets separated in the tube is used for analysis.
9. Prior to performing the first lithium sample analysis, automatic calibration process on electrolyte analyzer should be done that runs for **2 minutes** (During this process, the analyzer is conducting measurement operations to ensure the accuracy of the instrument).
10. Separated serum sample is run for **3 minutes** in analyzer that provides serum lithium level.
11. Stored separated sample has to be analyzed within **30 minutes** up to maximum of 2 hours.
12. An automated serum lithium report will be obtained from the machine and given to the medical officer for reporting within 1 hour.
13. Serum Lithium results are entered in a sample entry ledger and excel database for departmental records.

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7. Abbreviations:

1. TDM: Therapeutic drug monitoring
2. OPD: Out Patient Department