

Category : Patient Care
Title : Procedure for registration and follow-up in TDM OPD
SOP No. and version: TDM 01/02
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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1. Purpose:

This SOP describes the procedure for registration and follow-up in TDM OPD

2. Scope:

This SOP is limited for blood test of Therapeutic drug monitoring (TDM) in patient care.

3. Responsibilities:

The Head of the department is responsible for the medical care and welfare of all patients pertaining to TDM.

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. TDM01/02: Collection and separation of blood plasma for TDM
- SOP No. TDM05/02: Operation of High-Performance Liquid Chromatography

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6. Detailed instructions:

- i. Patients must obtain the OPD case paper from registration counter no. 15 of KEM hospital.
- ii. All documents regarding the treatment and investigations done till date, must be carried by the patient or his/her relative.
- iii. Patients should visit TDM OPD No. 201, 1st floor, New building on Fridays and Saturdays only, between 8.30 am to 12 pm.
- iv. Patients visiting the TDM OPD for the first time should provide their personal details and history of illness, which will be recorded on TDM card by the medical officer.
- v. Patients whether visiting the TDM OPD for the first time or for the follow up visits should skip the morning dose of the TDM medication on the day of collection of blood sample.
- vi. Patients must ensure a gap of at least 12 hrs. between the last dose and blood collection time for TDM valproate, phenytoin, phenobarbitone, carbamazepine, lamotrigine, Levetiracetam, lithium, voriconazole and vancomycin.
- vii. In case of patients who are recently prescribed above medications, TDM will be done only after 2 weeks of starting of treatment.
- viii. If blood sample has been collected elsewhere as in hospitalized patients, ensure that the sample has been stored appropriately in cool temperature and avoid exposure to sunlight. The sample must be centrifuged prior to accepting a sample from outside.
- ix. Patients coming for follow-up visits must collect their TDM card by giving file no. at TDM OPD counter and they will be directed to the medical officer who will record the medical history with details.
- x. Patients will be instructed to go to the blood collection room for withdrawal of blood.
- xi. A nominal amount will be charged depending on the drug being investigated.
Rs. 50 /- each for TDM valproate, lamotrigine, levetiracetam, Phenytoin, phenobarbitone, carbamazepine and lithium.
Rs.50/- for TDM of Phenytoin, phenobarbitone and carbamazepine in combination.
Rs. 500/- each for voriconazole and vancomycin
- xii. The reports for TDM Valproate, phenytoin, phenobarbitone, carbamazepine, lamotrigine, Levetiracetam, Voriconazole and vancomycin will be available 1 week after sample collection.

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- xiii. The report for TDM Lithium will be available 60 minutes after the sample has been drawn.
- xiv. On the day of report collection, patient has to report at the TDM counter where they will be provided with their TDM OPD card.
- xv. The patient will be directed to a medical officer who will then hand over the report.

7. Abbreviations:

TDM: Therapeutic drug monitoring

OPD: Out-patient department