

Category : Patient Care
Title : Procedure for collection of blood sample for Therapeutic Drug Monitoring (TDM).
SOP No. and Version: TDM 02/02
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 technique for performing a venipuncture to obtain a blood sample for therapeutic drug monitoring for drugs like Phenytoin (PBT), Phenobarbitone (PHT), Carbamazepine (CBZ), Lamotrigine (LTG), Sodium Valproate (VAL), Levetiracetam (LEV), Primaquine (PQ) & Carboxyprimaquine (CPQ), Vancomycin (VAN) etc.

2. Scope:

This SOP is limited to the procedure of blood collection for Therapeutic Drug Monitoring (TDM).

3. Responsibilities:

The Head of the department is responsible for the medical care and welfare of all patients pertaining to TDM. The task of performing veni-punctures 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.02/02: Estimation of PBT, PHT and CBZ
- SOP No. 03/02: Estimation of VAL
- SOP No. 06/02: Estimation of LTG
- SOP No. 07/02: Estimation of Li
- SOP No. 08/02: Estimation of LEV
- SOP No. 09/01: Estimation of PQ & CPQ
- SOP No. 10/01: Estimation of VAN

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6. Detailed instructions

1. Care must be taken to maintain patients' comfort and integrity of patient's veins. Good aseptic techniques (**universal precautions**) should be followed to minimize the risk of infection during blood collection.
2. Prepare the blood collection kit, as follows:
 - i. Vacutainers containing Heparin or plain bulbs for plasma and serum.
 - ii. 10ml or 5 ml. syringes.
 - iii. Needle (22 G. or 23G.)
 - iv. Tourniquet
 - v. Cotton swabs
 - vi. Spirit or 70% ethanol
 - vii. Gloves
 - viii. Sticking plaster
 - ix. Thrombophob ointment
3. The vacutainer tubes should be labeled with patient name, TDM No. & date and time of collection.
4. Ensure that the patient has been informed about the blood collection procedure and the purpose of the same.
5. The patient must be allowed to rest for at least 5 minutes prior to the blood collection.
6. Escort patient to the site where the blood will be drawn.
7. Precautions to be taken by the technician before the blood collection:
 - Apply **sterilium** thoroughly on both the hands.
 - For personal protection use equipments which include gloves and laboratory coats

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8. Ask the patient to be seated and place his/her arm out, palm up on a flat surface, arm extended all the way out and to make a fist. Place a tourniquet around one of the participant's arms (**slightly above the elbow area**). When wrapping the tourniquet, instead of tying it completely, only pull one end part of the way through as to create a loop. This will allow for quick one hand release of the tourniquet.
9. Locate a vein by pressing the area over the elbow. If necessary, repeat on another arm. You will be able to judge that you are in the right area by the firm, bouncy, spongy feeling of the vein.
10. Apply spirit or **70%** ethanol swabs on the site of blood collection and allow to air-dry, to make the area aseptic.
11. The appropriate needle is attached to the syringe. The cover of needle must not be removed until the technician is ready to draw the blood. When ready for use, examine the needle especially the tip and check for any blockage by pressing the piston (The piston will not move freely if needle is blocked).
12. Syringe with the needle is held in the hand in such a way that nozzle is opposed against patient's skin.
13. Skin is punctured **about 0.5cm** below the point where the vein is to be punctured and along the same line of the vein. Then the needle is pushed along the line of the vein to puncture it. When the vein is punctured the blood appears in the syringe.
14. Required amount of blood (**5ml**) is drawn by pulling the piston back.
15. A piece of sterile cotton swab is pressed firmly at the puncture.
16. Then slowly the syringe is removed by holding it in by little and ring fingers. The index finger put on the edge of the needle and the syringe is withdrawn.
17. Remove the tourniquet and tell the patient to open the fist.
18. Immediately after removing the syringe, transfer blood in heparinised tube by inverting the syringe into the tube and slowly pushing down the piston.

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19. Shake the tubes properly so that blood is completely mixed with the anticoagulant but do not shake vigorously so as to avoid hemolysis.
20. Ask patient if he/she feels lightheadedness during the procedure, and if so, place patient in supine, or near supine position.
21. Ensure that the oozing of blood has stopped and apply sticking plaster
22. In case of **hematoma (swelling / bruising)** apply thrombophob ointment
23. In case of needle stick injury/ spillage/ leakage of blood on an intact or broken skin refer to **NACO guidelines Appendix (I)**.
24. Syringe, gloves and needle are then disposed off as per Department of Clinical Pharmacology **SOP for biomedical waste management (SOP No. 24 /02)**
25. Centrifuge the tube at **2,500 rpm** for **15 min** and separate plasma in another clean glass tube with labelling, keep it in **refrigerator (2-8°C)** for pending analysis.

7. Appendix

Post Exposure Prophylaxis, NACO Guidelines

http://www.nacoonline.org/National_AIDS_Control_Program/PEP_full/