

 TATA MEDICAL CENTER	Standard Operating Procedure Sample collection, processing and shipment for Asparaginase activity assay and Sampling Schedule	
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Standard Operating Procedure

Sample collection , processing and shipment for Asparaginase Activity Assay

Version: 1.0

Date: 16/06/2026

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1. Purpose

To standardize the collection, labelling, storage, shipment, receipt, and processing of whole blood/plasma samples for asparaginase activity testing from participating centers to the central laboratory at TTCRC (Tata Translational Cancer Research Centre, Tata Medical Center, Kolkata).

2. Scope

Applies to all clinical sites collecting samples and to the central laboratory receiving and processing them for patients enrolled in the study.

3. Responsibilities

- Site clinical team: patient verification, timing coordination, sample collection, sample processing, labelling, storage, packaging, shipment, and data entry in the study database.
- Courier/logistics: maintain -80°C cold chain and deliver within 3 months of plasma storage.
- Central laboratory: verify receipt conditions, accession, integrity assessment, activity assay within 15-30 days of receipt, documentation, and reporting.

4. Safety and Compliance

- Handle human blood under BSL-2 precautions. Wear appropriate lab coat.
- Plasma obtained from blood should be stored at -80°C till shipped.
- Package and ship according to applicable regulations for Biological Substance, Category B (UN 3373).
- Follow institutional biosafety and waste disposal procedures and Bio-Medical Waste Management.

5. Materials and Supplies (Site)

- Phlebotomy supplies (needles, vacutainer system or syringes).
- EDTA tubes (capacity for ~2 mL whole blood).
- Centrifuge tubes for plasma separation.
- Table top Centrifuge equipment.
- Freezer for sample storage (-80°C).

6. Patient Eligibility and Timing

- Confirm patient enrolment and unique/study ID before sampling.
- Prespecified time points:
 - PEG-asparaginase: Collect on day 14 $\pm$ 2 days after the first PEG-asparaginase dose in each treatment phase as per the sampling schedule (given along with document).
- Unscheduled samples may be collected per protocol (e.g., suspected hypersensitivity); document rationale.

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7. Sample Collection Procedure (Site)

1. *Prelabel the EDTA tube with:
 - Unique/Study ID
 - Phase and dose number (e.g., Induction dose 1/Consolidation dose 2/Delayed Intensification dose 1)
 - Collection date and time
2. Perform venipuncture using aseptic technique.
3. Collect approximately 2 mL whole blood into EDTA tube; gently invert 8–10 times to mix.
4. Inspect for clots or visible hemolysis; recollect if feasible when compromised.
5. Store the tube at room temperature 25-27°C until processed. Do not centrifuge or aliquot at site. Do not freeze.
6. **Plasma processing:**
 - Process the plasma strictly within 48 hours of collection.
 - Centrifuge at 200 rcf/4000RPM for 10 minutes at 4°C ±2°C using a table top centrifuge instrument.
 - Once the plasma is separated from the blood cells, carefully pipette out the plasma and dispense in separate micro-centrifuge tubes.
 - Equally distribute the plasma into 2 separate micro-centrifuge tubes and label them accordingly.
 - Store the vials at -80°C until shipped to the central laboratory.

8. Post-Collection Handling and Temporary Storage (Site)

- Maintain samples at -80°C until shipment.
- Shipment should be done as a batch within a stipulated time frame of 3 months.

9. Packaging and Shipment (Site)

- Complete requisition/manifest with unique/study ID, phase and dose number, drug administered (Brand of PEG-Asparaginase), date & time of collection, site contact, and any deviations.
- Pack within an insulated shipper with dry ice packs to maintain -80°C.
- Follow instructions provided by the courier service
- Notify the central laboratory with tracking number and expected arrival via the agreed channel.

10. Data Management (Site)

- Enter all relevant data in the separate study database promptly, including: unique/study ID; patient demographics; drug administered (Brand), manufacturer/batch/lot (if available), dose and route, administration date/time; phase and dose number; sample collection date/time; premedications; adverse reactions; deviations; shipping/tracking details; temperature excursion notes if any.

11. Receipt and Processing (Central Laboratory)

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- On receipt, record date/time; inspect packaging and note temperature indicator status and any visible leaks/damage.
- Verify label completeness and reconcile with requisition/database.
- Assess integrity (hemolysis, clots, volume). Document any issues.
- Store at -80°C until testing and process within 15-30 days of receipt.
- If activity assay cannot occur within 30 days, document deviation and potential impact. Total time from receipt of shipment to initial processing must not exceed 60 days.

12. Acceptance and Rejection Criteria

- Acceptable:
 - Correctly labelled and matched to requisition.
 - Volume of plasma in microfuge tubes ≥ 0.5 - 1.0 mL.
 - Cold chain maintained at -80°C.
 - Received within stipulated time of collection.
 - No gross hemolysis or clotting.
- Conditional accept (with comment/flag):
 - Minor resolvable labelling discrepancy.
 - Slight hemolysis not expected to impact assay per lab validation.
 - Slight delay supported by validated stability data.
- Reject:
 - Unlabelled/mismatched ID or unreadable label.
 - Temperature excursion above -20°C.
 - Severe hemolysis or clotting.
 - Insufficient volume (< 0.1 mL).
 - Document all decisions and notify the site for recollection if required.

13. Result Reporting

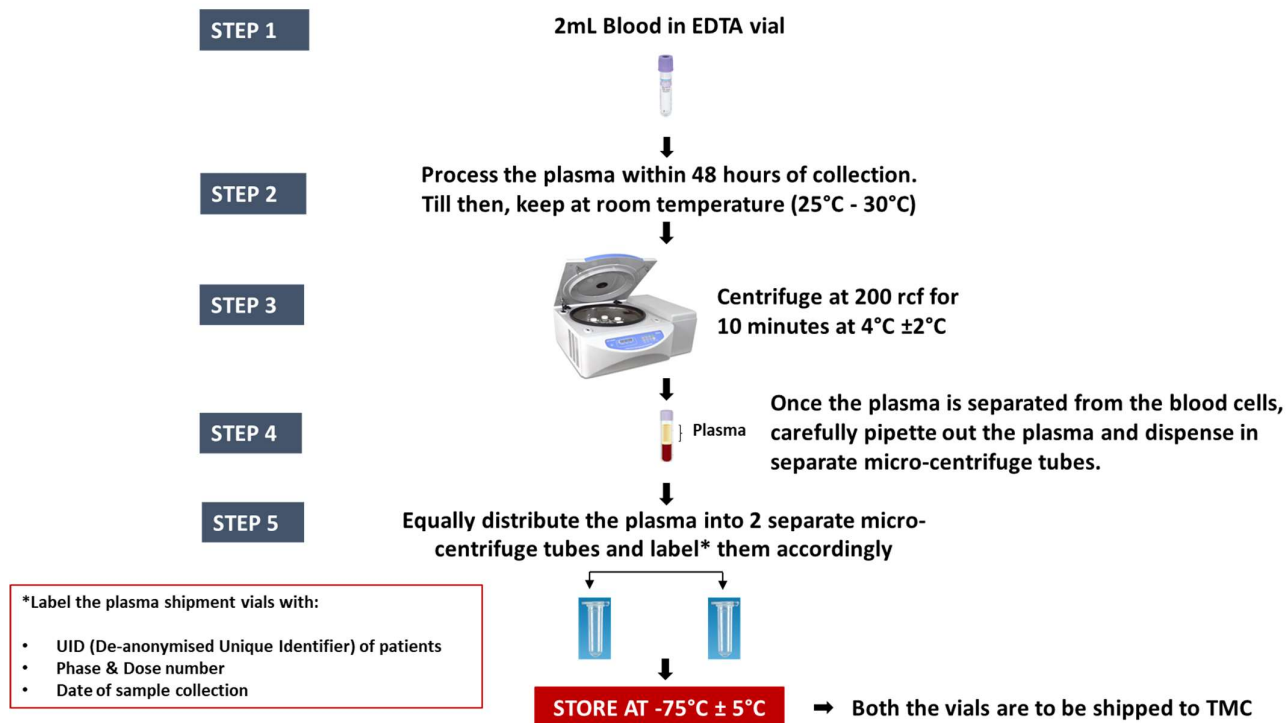
- Report asparaginase activity per laboratory standards, including units, assay method, and interpretive thresholds as defined by the study.
- Communicate results to the designated study contacts via the agreed channel within agreed turnaround times.

14. Operational Details

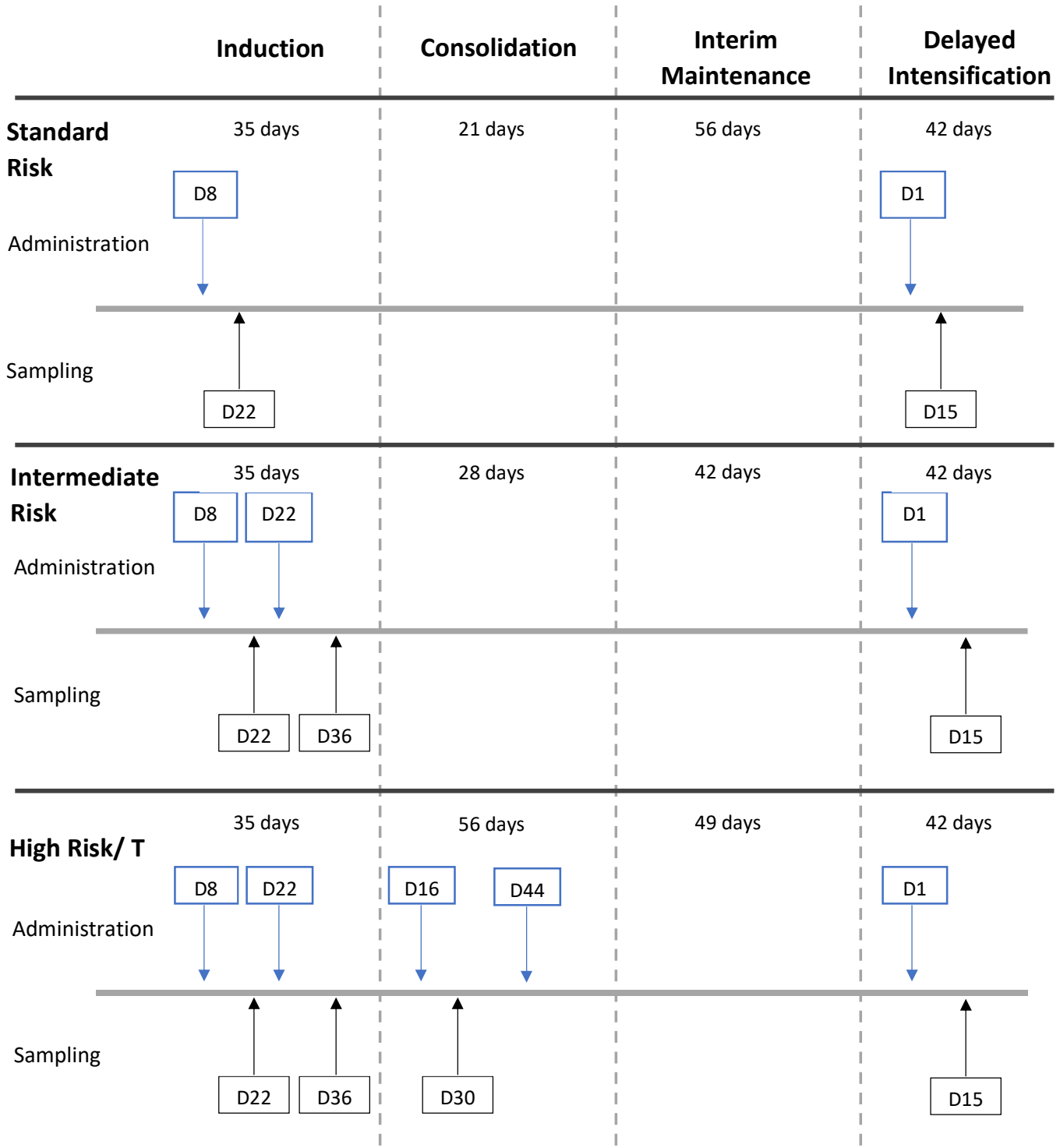
- Holiday/service disruptions: Sites should check the laboratory operating calendar before scheduling shipment close to holidays and use alternate plans where needed.
- Labelling convention example: "Unique/StudyID-Phase-Dose#-Date(DDMMYY)-Time(HHMM)".
- Contingency for missed windows: if a sample is outside the timing window, collect per clinician/PI instruction, annotate "Deviation—Timing," and consult whether recollection is necessary.

Figure:1. Sample processing workflow

SAMPLE PROCESSING: PLASMA



Protocol: ICiCle-ALL-14



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Protocol: ICiCle-ALL-24

