Minimum standards - sample collection and sample transport policy

1. Scope. - (1) The Compliance to the minimum standards for sample collection and transport will be the responsibility of parent laboratory.

(2) **Patient preparation & sample collection**
Collection and labeling, preliminary preparation, storage and transport of human sample or specimens e.g. Blood, sputum, stool, swabs, urine, body fluids, biopsy sample, etc

(3) Sample transportation
Maintaining the integrity of the test sample at all the stages of collection, handling, transportation and storage, till it is received in the testing medical diagnostic laboratory.

(4) Sample receiving
Receiving of samples or specimen collected at home or hospitals or health Centre or clinics or field (provided the sample integrity is maintained). It is desirable that such samples shall be directly deposited in the medical diagnostic laboratories.

2. **Patient Information and Education, -**

(1) Communication system, such as telephone or mobile number or email or website for appointment and reports shall be there.

(2) A Directory of services providing list of investigation, sample type and rate or charge, factors known to significantly impact the examination results, timeline of report availability [Clear information about receipt of the report (time and place shall be mentioned]

(3) Cost (if any) or "free" investigations shall be mentioned

(4) Feedback or suggestion and complaint registration protocol

3. Human Resources,- (1) The Staff required shall be as per the workload and duration of the services

(2) there shall be atleast 1 Medical laboratory technologist or Phlebotomist and one Nursing staff or Doctor

(3) Periodic health checkup and vaccination for hepatitis B and tetanus for staff with records shall be maintained.

(4) Training and competency assessment (staff shall have training for first aid measures, basic life support, latest biomedical waste guidelines, standard precautions, spill management, post exposure prophylaxis)

(5) The records of anti HBs antibody titers shall be maintained as desired.

4. Devices or Instruments,-Material required for specimen collection: tourniquet, gloves, vacuumized blood collection tubes, syringes, needles, tubes, swabs, cotton, alcohol or spirit, appropriate container for special investigation-such as urine or stool or semen or fluids, additives if necessary.

Sharp Containers for safe disposal of sharps.

5. Requisition form,-The requisition forms shall be duly filled with

(1) Patient details including patient name, demographic details, contact details, registration number, relevant clinical details
(2) Sample details including type of sample, investigations or tests required, date and time of sample collection
(3) Name of the requester.

6. Primary sample collection and handling,-Patient Consent

(1) For most routine procedures like venipuncture, the consent is inferred
(2) Special procedures may need more detailed explanation and informed consent

7. Pre collection Activities,-(1) Preparation of patient

(2) Type and amount of primary sample shall be collected with descriptions of containers and any necessary additives

(3) Sample labelling with at least two identifiers for unequivocal identification of patient

(4) Signages for color coding of vacutainers for different investigations, for collection of samples with specific additives: charts for order of draw as per the recommended guidelines

8.Collection Activities,-(1) Verification of the identity of the patient from whom a primary sample is collected

(2) Verification and when relevant, recording that the patient meets pre-examination requirements [e.g. fasting status, medication status (time of last dose) sample collection at predetermined time or time intervals]

(3) Recording of the identity of the person collecting the primary sample
(4) Stabilization and proper storage conditions before collected samples are delivered to the laboratory
(5) Safe disposal of materials used in the collection process as per Bio-Medical Waste Management Rules 2016 (as amended from time to time) policy https://cpcb.nic.in/uploads/projects/bio-medical-waste/guidelines_healthcare_june_2018.pdf

9. Sample Transportation,-(1) WHO Bio-safety guidelines to be followed for transport of all biological specimens. [WHO Laboratory Biosafety Manual (LBM)] https://iris.who.int/bitstream/handle/10665/337956/9789240011311-eng.pdf?sequence=1

(2) Samples shall reach the laboratory within the specified period (usually samples for routine investigations shall be transported within 2 to 4 hours), For samples that require immediate transportation or special handling conditions, appropriate measures shall be taken to ensure timely and proper transport.

(3) The staff responsible for specimen transport shall be trained in sample transport and handling of emergencies

(4) If the integrity of a sample has been compromised and there is a health risk, the organization responsible for the transport of the sample shall be notified immediately and action to reduce the risk and to prevent recurrence.

(5) The parent laboratory shall establish and periodically evaluate adequacy of sample transportation systems.

10. Sample receipt procedure,-(1) The labelling on the sample shall match the details of the requisition form
(2) Criteria for rejection of samples.
- Incorrect patient or sample identification,
- Inappropriate container or inappropriate sample,
- Insufficient sample volume.
- Incorrect storage or handling temperature,
- Sample instability due to, for example, delay in transport

(3) Recording the date and time of receipt of the sample
(4) Recording the identity of the person receiving the sample
(5) Evaluation of received samples, by authorized personnel
(6) Instructions for samples specifically marked as urgent

When a compromised clinically critical or irreplaceable sample is accepted, after consideration of the risk to patient safety, the final report shall indicate the nature of the problem and where applicable, advising caution when interpreting results that can be affected.

The LIS (if available) shall be preferably in place with proper backup available and the software shall cater to the needs of the user and the laboratory and it shall be

regularly updated. The patients shall be able to download reports on their mobile phones or desktop

Any changes or updates made in standard guidelines from time to time by national bodies will be followed by parent laboratory, specimen collection and transport facility.