Clinical Establishment Act Standards for Sample Collection And Sample Transport policy

Introduction

In 2010, 'The Clinical Establishments (Registration and Regulation) Act, 2010' (hereinafter referred as 'the Act' or 'CEA') was enacted by the Central Government to provide for registration and regulation of all Clinical establishments in the country with a view to prescribe the minimum standards of facilities and services provided by them.

The Ministry of Health & Family Welfare notified the "National Council for Clinical Establishments" and 'The Clinical Establishments (Central Government) Rules, 2012" under the Act *vide* Gazette Notification. *The Act is applicable to all kinds of clinical establishments from the public and private sectors, of all recognized systems of medicine including single doctors. The only exception will be establishments run by the Armed forces*.

Minimum standards - Sample collection and sample transport policy

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

Scope of services	**Patient preparation & sample collection** Collection and labeling, preliminary preparation, storage and transport of human sample/specimens e.g. Blood, sputum, stool, swabs, urine, body fluids, biopsy sample, etc **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. **Sample receiving** Receiving of samples/specimen collected at home/hospitals/health Centre/clinics/field (provided the sample integrity is maintained). It is desirable that such samples should be directly deposited in the medical diagnostic laboratories.
Communication system:	Telephone/mobile number/email/website for appointment and reports
Patient Information and Education-	A Directory of services providing list of investigation, sample type and rate/charge, factors known to significantly impact the examination results, timeline of report availability [Clear information about receipt of the report (time and place should be mentioned] Cost (if any) or "free" investigations to be mentioned Feedback/suggestion and complaint registration protocol
Human Resources (Staff required should be as per the workload and duration of the services)	• Medical laboratory technologist/Phlebotomist • Nursing staff/ Doctors (if applicable) Periodic health checkup and vaccination for hepatitis B and tetanus for staff with records to be maintained. Maintenance of records of anti HBs antibody titers (Desirable) Training and competency assessment (staff should have training for first aid measures, basic life support, latest biomedical waste guidelines, standard precautions, spill management, post exposure prophylaxis)
Devices/Instruments	Material required for specimen collection: tourniquet, gloves, vacuumized blood collection tubes, syringes, needles, tubes, swabs, cotton, alcohol/spirit, appropriate container for special

	investigation-like urine/stool/semen/fluids, additives if necessary. Sharp Containers for safe disposal of sharps.
Requisition form	Requisition forms should 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/tests required, date and time of sample collection 3. Name of the requester.
Primary sample collection and handling	Patient Consent • For most routine procedures like venipuncture, the consent is inferred • Special procedures may need more detailed explanation and informed consent **Pre collection Activities** • Preparation of patient • Type and amount of primary sample to be collected with descriptions of containers and any necessary additives • Sample labelling with at least two identifiers for unequivocal identification of patient 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 **Collection Activities** a) Verification of the identity of the patient from whom a primary sample is collected b) 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] c) Recording of the identity of the person collecting the primary sample d) Chemical disinfection of site in case of spillage of sample shall be done e) Stabilization and proper storage conditions before collected samples are delivered to the laboratory f) 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 **Sample Transportation** 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

Samples should reach the laboratory within the specified period (usually samples for routine investigations should 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.

The staff responsible for specimen transport should be trained in sample transport and handling of emergencies

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.

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

Sample receipt procedure

a) The labelling on the sample should match the details of the requisition form
b) Criteria for rejection of samples.
    - Incorrect patient or sample identification,
    - Inappropriate container/inappropriate sample,
    - Insufficient sample volume.
    - Incorrect storage or handling temperature,
    - Sample instability due to, for example, delay in transport
c) Recording the date and time of receipt of the sample
d) Recording the identity of the person receiving the sample
e) Evaluation of received samples, by authorized personnel
f) 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 should cater to the needs of the user and the laboratory and it should be regularly updated. The patients should be able to download reports on their mobile phones/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.