

## Updated Draft of Minimum Standards for Collection Center

<b>Template for Minimum Standards for Collection Center</b>	
<b>The Compliance to the minimum standards for collection centre will be the responsibility of parent laboratory.</b>	
<b>Definition</b>	<b>Collection Centre for Pathology/Microbiology/Biochemistry Laboratories</b>
<b>Scope of Services</b>	<p>Patient preparation</p> <p>Collection and labeling, preliminary preparation (if applicable), storage and transport of human sample/specimens e.g. Blood, sputum, stool, swabs, urine etc.</p> <p>Maintaining the integrity of the test sample at all the stages of collection, labeling handling, storage and transportation till it is received in the testing medical diagnostic laboratory.</p> <p>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.</p>
<b>Infrastructure</b>	<b>1. Location: Easily accessible and as per State</b>
	<b>2. Signage</b>
	<b>2a. Informative Signage – A signage within or outside the facility should be made available containing the following information</b>
	a) Name of the collection center (if applicable)

	<p>b) Name of the person in-charge of Collection center with qualification and registration number if applicable.</p> <p>c) Name of the associated parent laboratory (ies).</p> <p>d) Accreditation with any agency/organization (if applicable)</p>
	<p>e) Entry / patient waiting area</p> <p>f) Reception and registration area</p>
	<p>g) Specimen/sample collection area</p>
	<p>h) Specimen/sample receiving and sorting area (if patient is bringing the sample from home etc)</p>
	<p>i) Timings of the facility and collection of report.</p>
	<p>j) Internet facility (Website/email) or Telephone and mobile number for appointment.</p>
	<p><b>2b. Safety Signage's (wherever applicable)</b></p> <ul style="list-style-type: none"> <li>• Safety hazard and caution signs</li> <li>• Biomedical waste segregated in colored bins and bags as per Biomedical Waste Management Rules, 2016 including radioactive materials, toxic chemicals, microbial agents, infected biological material.</li> </ul>
	<ul style="list-style-type: none"> <li>• Appropriate fire safety provisions like Fire exit ,available water, minimum one fire extinguisher etc as per applicable State/ local laws</li> </ul>
	<ul style="list-style-type: none"> <li>• Emergency shower and eye flushing facilities; drainage to a</li> </ul>

	separate holding area (desirable)
	<b>3.Space Requirement</b> - sample collection area must be secure with restricted access to dedicated staff only
	<p>a) Reception, Registration (computerized desirable), billing and report handover and patient waiting area, Public Utilities, Safe drinking water etc.</p> <p>b) Disabled friendly entry(desirable)</p>
	c) Sample collection area including patient toilets ( this area may also be located remotely in Ambulatory Care areas); the collection area shall have a workbench, comfortable chair with arm rest for patient seating and hand washing facilities (wash basin)
	d) adequate diffuse and spot lighting(desirable)
	e) Separate toilet for male and female. (desirable)
	f) Staff room -Male and female different where 24 hours services are being provided(desirable if applicable)
	g) Washing area (for laboratory use)
	h) Area for Preservation of the specimens and slides
	i) Electrical facilities with 24hrs

	back up. (if applicable)
	j) Ambient temperature control for specialized equipment ex. Refrigerators, autoclave for sterilization etc.(If applicable)
	k) FNAC room with bed and chair etc for sample collection(if applicable)
	l) Couch or Couch like bed for management of Vasovagal Syncope or hypoglycemic attacks.
	m) Counseling room/ separate area for HIV counseling etc
	<b>4. Furniture &amp; Fixtures</b> – as per the scope of services
	<b>5. Communication system</b> –Telephone / mobile number/ email/ website for appointment etc
	<b>6. Wash basins-</b> (number as per scope of services)
	<b>7. Patient Information and Education-</b> A directory of services provided including list of type of investigation sample type and rate/charges i.e., Special and routine tests
<b>Human Resource</b>	Lab technician with qualification as per minimum standards of laboratories (minimum 1)
	Support staff like Lab assistant /Lab attendant/ Phlebotomist, and housekeeping staff etc (as per scope of services)
	Periodic health checkup and vaccination for hepatitis B and tetanus for staff with records to be maintained.
<b>Equipment / Instruments / Drugs</b>	List of minimum Equipment with

	number.(as per scope)
	List of minimum inventory needed for Sample/Specimen Collection.(as per scope)
	List of reagents and Consumables required.(as per scope)
<b>Legal/ Statutory Requirements</b>	Legal / statutory requirements such as registration with State Pollution Control board with registration number and date of expiry (if applicable). Site, Space, Location and building and fire safety requirements to be as per State/local bye law
	Bio-medical waste(BMW) collaboration certificate with any agency/local authority etc(if applicable)
	NOC for Fire Safety (if applicable)
	Collection Center agreement /MOU with medical diagnostic laboratories.
	Compliance under Water (Prevention & Control of Pollution) Act 1974(if applicable)
	Compliance under Air (Prevention & Control of Pollution) Act 1981(if applicable)
	Hg free environment (no mercury instruments) (if applicable)
<b>Record Maintenance (with appropriate access control)</b>	Daily logs for refrigerator, centrifuge, room temperature and humidity etc.
	Reports of patients date wise and specialty wise for ex Histopathology, Cytology, Hematology and Laboratory Medicine etc. including electronic records to be maintained.(if applicable)
	Medico legal records if applicable
	Annual Maintenance records for

	equipment/instruments.
	Record of technicians/Phlebotomist etc working in collection center indicating their details of qualification training and others. Degree/ diploma certificate of lab technicians working in collection
	Instruments' and equipment calibration records/certificates as applicable
	Availability of reference SOPs in hard or soft copy (desirable)
<b>Standards on Basic Processes (SOPs)</b>	Compliance to infection Control practices
	Compliance to BMW management as per latest Bio Medical Waste Management Rules.  BMW disposal collaboration certificate with any agency/local authority etc.(if applicable)
	Document of specific instructions for proper collection and handling of primary samples e.g. order of draw of samples including duration of preservation of record
	Proper labeling- it desirable to have barcoding of samples to maintain sample identification and avoid mixing up  Packaging of sample/specimen and proper transportation including compliance to temperature maintenance requirement and transit time as per SOPs of samples/ specimen
	Safety considerations-Fire safety, First aid measures to be taken and use of disposable needles, syringes, vacutainer etc.
	Management of Vasovagal Syncope : as per SOP (Couch or Couch like bed is required)

	Spillage : Management of blood / mercury spills etc. as per SOP
	Occupational Safety: Needle stick injury and the action taken as per SOP and report to be maintained.
	Patient Information and Education including the list of affiliated Labs to which it sends samples with their details regarding NABL accreditation /Lab in charge/addresses etc
	Process of calibration of equipment and instruments. (desirable)
	Grievance Registration and Disposal mechanism