Standard No.CEA/Laboratory- 026

Clinical Establishment Act Standard for Medical (Clinical) Laboratory

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Introduction

In 2010 Clinical Establishments (Registration and Regulation) Act, 2010 has been 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 has notified the "National Council for Clinical Establishments" and 'The Clinical Establishments (Central Government) Rules, 2012" under this Act vide Gazette. *This Act is applicable to all kinds of clinical establishments from the public and private sectors, of all recognized systems of medicine including single doctor clinics. The only exception will be establishments run by the Armed forces.*

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Medical or Clinical Laboratory Collection Centres

1. Definition

The medical or clinical laboratory is the place where materials of human origin and/or human healthcare environment are collected, stored, processed and/or analyzed and reported for the purpose of screening, diagnosis, prognosis, treatment or prevention of diseases and for clinical research.

Note: Facilities which only collect or prepare specimen, or act as a mailing or distribution centre, are not considered to be medical or clinical laboratory, although they may be part of a larger laboratory network or system

2. Scope

a) Clinical Biochemistry

b) Pathology

c) Microbiology and Serology

d) Genetics

e) Nuclear Medicine (in-vitro tests only) – requirement as laid down by Atomic Energy Regulatory Board (AERB).

3. Infrastructure

3.1 The laboratory shall be developed and maintained to provide safe, clean and hygienic environment for patients, their families, staff and visitors.

3.2 The facility shall be well illuminated and ventilated and shall have adequate water supply and electricity through regular or alternate sources.

3.3 Total area requirements can be broadly classified in two categories, viz., common area and laboratory area. The former includes facilities such as reception, waiting, sample collection, reporting, dispatch, and hand washing. Clean toilet facility shall be available in the vicinity of the laboratory facility.

3.4 The laboratory area for activities including test analysis, washing, biomedical waste storage and ancillary services like Storage of records, reagents, consumables, stationary etc eating area for staff. In view of wide variation of

tests and equipments involved in the laboratory processes, indicative list for facility infrastructure requirement is detailed in Annexure 1.

3.5 Common area can be shared between the different divisions/sections of the laboratory/HCO. Within the laboratory various work benches/sections can also share the resources and space however not compromising the quality of work.

3.6 **Auxiliary area** for reception, waiting, toilet etc shall be adequate as per the requirement and workload of the laboratory.

3.7 **Ancillary area**for storage of records, reagents, consumables, stationary etc eating area for staff shall be as per requirement and workload of the laboratory.

3.8 The area shall be well lighted, ventilated with continuous water supply.

3.9 **Following basic signage shall be available:**

a) Name of the service provider e.g. (XYZ Diagnostic/clinic/Hospital)
b) Timings of services e.g. (24hrs/8am to 8pm)
c) Scope of services e.g.(Biochemistry/Haematology/microbiology/Histopathology including services outsourced)

Others

a) Fire exit route
b) Safety instructions e.g BMW
c) Rate list of the test shall be available on request.
d) Laboratory shall identify the outsourced tests and patient must be informed regarding the same

3.10 **Furniture & Fixtures:**Furniture and fixtures shall be available in accordance with the activities and workload of the laboratory.The furniture and fixtures shall be functional all the time. Indicative list of items is as per Annexure 1

4. Equipment/instruments requirements

4.1 Each laboratory shall prepare an exhaustive list of equipment and consumables required and available for general functioning of the laboratory and specialized equipment for special tests.

4.2 Laboratory shall have adequate equipment to meet work load requirement. For indicative list refer to Annexure 2.

4.3 Equipment shall be suitably located in the laboratory so as to allow accessibility and sequential utilization thus minimizing the need for frequent movement of specimens or reagents.

4.4 All equipment shall be in good working condition at all times. Periodic inspection, cleaning, maintenance of equipment should be done. An equipment log book should be maintained for all major equipment. Laboratories should maintain necessary instructions for operation and maintenance of equipment in the form of Standard Operating Procedures (SOPs). A copy of SOP shall be readily available.

4.5 The laboratory shall have record of maintenance contracts including warranty cards and telephone numbers of staffto be contacted in case of equipment malfunction. User manual shall be available readily for reference. The staff shall be aware of trouble shooting measures to be adopted for preventing equipment malfunction.

4.6 The laboratory shall have provision of calibration and validation of all the new equipment before routine use.

4.7 Periodic performance check/calibration check for all equipment shall be done using reference standard/reference material. The frequency of performance check shall be based on the day-to-day performance of the equipment.

4.8 Equipment performance shall be verified from Internal Quality Control results and External Quality Assessment results. Outlier parameter trend analysis record shall be maintained in respect of its effect on the equipment

5. Human Resource

5.1 The laboratory shall have qualified staff as per the scope of service provided. Please refer to Annexure 3.

5.2 The laboratory shall have services of a qualified Pathologist/Biochemist /Microbiologist or Registered Medical Practitioner competent for interpretation and reporting. Please refer to Annexure 3.

5.3 The laboratory shall have the services of qualified technologist to process the sample and operation of equipment. Please refer to Annexure 3.

5.4 The test reports can be processed and generated by the BSc MLT, DMLT, MSc MLT, MSc Medical Biochemist and MSc Medical Microbiologist.

5.5 The person signing and interpreting the report shall be registered with Medical Council of India / State Medical Council In case of location of laboratory in the peripheral area where qualified personnel for interpretation and reporting is not available a Registered Medical Practitioner MBBS/MD/MS in other specialization can release and interpret the routine reports as per local law &regualtion. .

6. Legal/Statutory Requirements

6.1 Every application shall be accompanied with the documents conforming compliance with local/regional regulations and laws. For indicative list refer to Annexure 4.

7. Record Maintenance and reporting

7.1 The minimum medical records to be maintained and nature of information to be provided by the Hospitals shall be as prescribed in CEA rules.

7.2 Medical Records may be maintained in physical or digital format.

7.3 Confidentiality, security and integrity of records shall be ensured at all times.

8. Basic processes

8.1 **Registration / help desk and billing:** The laboratory shall register all patients who visit the lab except if the required services are not available in the facility, in which case the patient is guided to the appropriate nearest facility.

8.2 Once registered, depending on the clinical need, patient is guided to appropriate service area.

8.3 Patient shall be guided and informed regarding Patients' rights & responsibilities, cost estimates, third party services (e.g. Insurance) etc.

8.4 The billing shall be as per the lab tariff list, which shall be available to patients in a suitable format

8.5 **Infection Control**: Hand HygieneStandard precautions like practicing hand hygiene, use of personal protection equipment, etc to reduce the risk of healthcare associated infections shall be followed.

a. Adequate and proper spacing in the patient care area shall be provided so as to prevent transmission of infections.

b. Regular cleaning of all areas with disinfectant shall be done as per prescribed & documented procedure.

c. All biomedical waste management shall be done as per the applicable regional laws.

8.6 **Quality Control:**The system of Internal Quality Control and External Quality Assessment Scheme shall be established and followed.

Annexure 1

I. The space requirement for Auxiliary and Ancillary area which shall have reception/dispatch, waiting area, toilet sample collection area, reporting area etc as per the scope of service provided and workload:3.6 for reception, waiting, toilet etc shall be adequate as per the requirement and workload of the laboratory.

3.7 Ancillary area for etc eating area for staff shall be as per requirement and workload of the laboratory

Area		**Requirement**
Auxiliary area	Reception/Dispatch Area, Waiting Area, Sample Collection Area, Toilet Area/Change Room etc.	As perWorkload
Ancillary Area	Storage of records, reagents, consumables, stationary etc.	As perWorkload

II. The minimum space requirement for the operation of lab equipments shall include analysis, washing and storage area:

	Lab Area (approx)			
	Column II			
Branch of Medical Clinical Laboratory	Sub Laboratory	Analysis area	Washing area and BMW	Ancillary area/space
Clinical Biochemistry		40 sq ft	36 sqft + 10 sq ft (BMW)	10% of total area of the lab
Pathology				
	Clinical Pathology	30 sq ft and washing area		
	Cytopathology			
	Haematology			
	Histopathology	100 sq ft+ 100 sq ft for block and gross storage including		

		Grossing and washing area		
Microbiology and Serology				
	Bacteriology	60 sq ft		
	Parasitology			
	Mycology	30 sq ft		
	Mycobacteriology	75 sq ft		
	Virology (Culture based)	100 sq ft		
	Immunoserology	30 sq ft		
	Molecular Biology	100 sq ft with all preventive measures to avoid cross contamination		
Genetics		150 sq ft		
	Cytogenetics			
Nuclear Medicine (in-vitro tests only)	AERB			

Annexure 2

Essential Furniture and fixture in a lab:(This list is indicative and not exhaustive)

S. No.	Articles
1.	Table
2.	Chairs
3.	Blood Collection Chairs/Couch
4.	Lab working bench with sink with elbow tap
5.	Storage Cabinet for records
6.	BMW storage area

Annexure 3

Minimum essential equipment requirement in a laboratory:

Medical Clinical Laboratory	Sub Laboratory	Essential Equipments
Clinical Biochemistry		1. Microscope 2. Stopwatch 3. Spirit lamp/gas 4. Glass slide/coverslip/ mounting media 5. Staining solution/reagents/powder for Romanowsky stains 6. Normal saline 7. Pipette 8. Cedarwood oil 9. Distiled water 10. Hypochlorite solution 11. Tissue paper/Filter paper/cotton 12. Centrifuge 13. Incubator 14. Refrigerator 15. Tube racks/slide racks 16. Buffer 17. Modified Neubaurs chamber 18. Semiautoanalyzer/Test reagents 19. Simple Balance
Pathology	Clinical Pathology	1. Microscope 2. Stopwatch 3. Spirit lamp/gas 4. Glass slide/coverslip/ mounting media 5. Staining solution /reagents / powder for Romanowsky stains/iodine stains 6. Normal saline 7. Pipette 8. Cedarwood oil 9. Distiled water 10. Hypochlorite solution 11. Tissue paper/Filter paper/cotton 12. Centrifuge 13. Incubator 14. Refrigerator 15. Tube racks/slide racks 16. Buffer

		17. Modified Neubaurs chamber 18. Urine testing strips 19. Occult blood strips
	Haematology	1. Microscope 2. Stopwatch 3. Spirit lamp/gas 4. Glass slide/coverslip/mounting media 5. Staining solution/reagents/powder for Romanowsky stains/reticulocyte stain 6. Pipette 7. Normal saline 8. Cedarwood oil 9. Distiled water 10. Hypochlorite solution 11. Tissue paper/Filter paper/cotton 12. Centrifuge 13. Glass tubes 14. Incubator 15. Refrigerator 16. Tube racks/slide racks 17. Buffer 18. Westergren tube 19. Wintrobes tube 20. Sahli'sHemoglobinometer 21. Modified Neubaurs chamber 22. Thoma WBC pipette 23. RBC Pipette 24. Diluting fluids 25. Semiauto coagulation analyser/ Coagulation reagents 26. Blotting paper for BT 27. Capillary tube for CT 28. Rapid MP kits
	Histopathology and Cytopathology	1. Microscope 2. Stopwatch 3. Spirit lamp/gas /hot air oven 4. Glass slide/coverslip/ mounting media 5. Staining solution/reagents/powder for hematoxylinesoin stains/ special stains 6. Normal saline 7. Pipette 8. Cedarwood oil 9. Distiled water

		10. Hypochlorite solution 11. Tissue paper/Filter paper/cotton 12. Centrifuge 13. Incubator 14. Refrigerator 15. Tube racks/slide racks 16. Buffer 17. Grossing equipment like surgical blade/ knife/cassettes etc. 18. Tissue processor(Optional) according to the workload 19. L- mould/ embedding staion 20. Microtome 21. Cytocentrifuge(Optional) 22. Waterbath 23. Hotplate 24. clearing and dehydrating solutions 25. Staining moulds/staing jars/slide trays
Microbiology and Serology	Bacteriology	1. Microscope 2. Stopwatch 3. Biosafety cabinet Class II 4. Autoclave 5. Spirit lamp/gas 6. Glass slide/coverslip 7. Pipette 8. Sample container/swab stick/syringe needle 9. Staining solution/reagents/powder for Grams stain/AFB stain/KOH stains 10. Normal saline 11. cedarwood oil 12. Distiled water 13. Hypochlorite solution 14. Sterile loops/forceps 15. Tissue paper/Filter paper/cotton 16. Centrifuge 17. Petridish / glass tubes 18. Incubator 19. Refrigerator 20. Antiobiotic disc 21. Culture Media 22. Reagents for Biochemical tests 23. Rapid test kits Malaria,Dengue,HIV, HCV, Syphilis, scrub typhus, typhoid,pregnancy test 24. Tube racks/slide racks
	Parasitology	

	Mycology	As a supplementary lab to bacteriology they should also have 1. Microscope-1 2. Refrigerator-1 3. Cooling Incubator
	Mycobacteriology	1. Refrigerator-2 2. Microscope-1 3. Autoclave-1 4. Hot air oven 5. Incubator 6. Gas Burner with cylinder 7. Bio safety cabinetII B
	Virology (Culture based)	1. Refrigerator-3 2. Inverted Microscope-1 3. Autoclave-1 4. Hot air oven 5. Incubator 6. Gas Burner with cylinder 7. Bio safety Cabinet III
	Immunoserology	1. Shaker 2. Centrifuge 3. Microwell plate reader-1 4. Refrigerator-2 5. Incubator
	Molecular Biology	1. Refrigerator-2 2. Autoclave-1 3. Hot air oven-1 4. PCR Machine 5. Centrifuge 6. Micro centrfuge-1 7. Bio safety cabinet II 8. PCR Cabinet 9. Electrophoresis 10. UV Torch/ 11. transilluminator 12. Hot plate/ micro plate 13. Gas Burner with cylinder 14. Deep freezer
Genetics		1. Refrigerator-3 2. Inverted Microscope-1 3. Autoclave-1 4. Hot air oven 5. Incubator

		6. Autoclave-1 7. PCR Machine 8. Centrifuge 9. Micro centrfuge-1 10. Bio safety cabinet 11. PCR Cabinet 12. Electrophoresis 13. Hot plate/ micro plate 14. Gas Burner with cylinder 15. Deep freezer 16. UV Torch/Trans illuminator
	Cytogenetics	As above
Nuclear Medicine (in-vitro tests only)	AERB	As per AERB requirement

Annexure 4

Minimum human resource requirement shall be as follows:

	Column I	**Column II**		
Medical (Clinical) Laboratory		For processing of samples and operation of equipment	For interpretation signing and reporting	Administrative staff
Clinical Biochemistry	Qualified	MSc MLT, BSc MLT, DMLT and vocational and/or certificate course in technology	M.B.B.S. with post graduate diploma/ degree in Biochemistry/ Pathology/Microbiology/Lab medicine or equivalent recognized by MCI or NBE or as applicable and registered medical practioner with Medical Council of India/ State Medical Council	As per requirements
	Trained	MSc Medical Biochemistry/ Medical Microbiology/ Biotechnology/ BSc Medical Biochemistry/ Medical Microbiology/ Biotechnology/Metric with 5 yrs of experience in clinical laboratory under qualified authorised signatory refer to next column	MBBS with work experience in a clinical laboratory registered with Medical Council of India/ State Medical Council	
Pathology including Clinical Pathology, Cytopathology, Haematology, Histopathology	Qualified	MSc MLT, BSc MLT, DMLT and vocational and/or certificate course in technology	M.B.B.S. with post graduate diploma/ degree in Pathology /or equivalent recognized by MCI or NBE or as applicable and registered with Medical Council of India/ State Medical Council.	

			M.B.B.S. with post graduate diploma/ degree in Microbiology for reporting histopathology of infectious diseases	
	Trained	MSc Medical Biochemistry/ Medical Microbiology/ Biotechnology/ BSc Medical Biochemistry/ Medical Microbiology/ Biotechnology/Metric with 5 yrs of experience in clinical laboratory under qualified authorised signatory refer to next column	-	
Microbiology and Serology including Bacteriology, Parasitology, Mycology, Mycobacteriology, Virology (Culture based)	Qualified	MSc MLT, BSc MLT, DMLT and vocational and/or certificate course in technology	M.B.B.S. with post graduate diploma/ degree in Microbiology /Lab medicine or equivalent recognized by MCI or NBE or as applicable and registered medical practioner with Medical Council of India/ State Medical Council	
	Trained	MSc Medical Biochemistry/ Medical Microbiology/ Biotechnology/ BSc Medical Biochemistry/ Medical Microbiology/ Biotechnology/Metric with 5 yrs of experience in clinical laboratory under qualified authorised signatory refer to		

		next column		
Immunoserology	Qualified	MSc MLT, BSc MLT, DMLT and vocational and/or certificate course in technology	M.B.B.S. with post graduate diploma/ degree in Biochemistry/ Pathology/Microbiology/Lab medicine or equivalent recognized by MCI or NBE or as applicable and registered with Medical Council of India/ State Medical Council	
	Trained	MSc Medical Biochemistry/ Medical Microbiology/ Biotechnology/ BSc Medical Biochemistry/ Medical Microbiology/ Biotechnology/Metric with 5 yrs of experience in clinical laboratory under qualified authorised signatory refer to next column	MBBS with work experience in a clinical laboratory and registered with Medical Council of India/ State Medical Council	