

MINIMUM STANDARDS FOR MEDICAL LABORATORIES IN THE STATE

According to the facilities available in the medical laboratories , labs are broadly classified into three levels- Level I , Level II and Level III (Level III being the highest category , facility wise).

General Standards Applicable to All Levels of Laboratories

1. Basic Amenities- All levels of laboratories should have
 - Proper Waiting area, Seating Facility, Drinking water facility, Toilet facility, Proper Lighting
2. Adequate space with designated areas for Registration area, sample collection, pre analytical , analytical and post analytical areas

MINIMUM STANDARDS FOR MEDICAL LABORATORY

Level I

Space

- 500 sq Feet for Pathology Microbiology and Biochemistry together

HR

- Minimum one Diploma MLT Qualified Lab Technician, Lab Attender

Bio safety

- Sterile Blood Collection , Disposable Needles, Syringes, Gloves, Needle Destroyer

Bio Medical Waste

- Segregation and Disposal of Waste as per IMAGE/ National Norms

PATHOLOGY

Category	Tests	HR*		Equipment Automated/ manual	EQAS IQA
		Medical	Non Medical		
Level I	Basic Clinical Pathology / Basic Haematology - Blood Routine Examination- Hb, TC, DC, ESR, PCV, Urine Routine Examination – Albumin, Sugar, Deposit, CSF- Routine Examination, Body Fluids - Routine Examination, Stool Routine Examination, Occult Blood	NA	Lab Technician (Diploma MLT)	Binocular Microscope, Colorimeter/Haematology Analyser 3 Part	Sample Repeatability

MICROBIOLOGY

Category	Bacteriology	Mycobacteriology	Serology/ Immunology	Parasitology	Mycology	Equipment	Other requirements
Level I	a. Routine Microscopy using Binocular Microscope b. Staining facilities 1. Gram staining 2. Ziehl- Neelsen 3. Methylene blue c. Rapid detection of bacterial antigen in body fluids – [CSF] - Latex agglutination test	a) Microscopic examination - Ziehl- Neelsen	a. Serological test for diagnosis a. Widal b. RPR b. CRP, ASO, RA, Agglutination test etc.	a) Direct microscopic examination for Parasitic ova/cyst/parasite b) Staining 1. Lugol's iodine 2. Modified Ziehl- Neelsen	a) Microscopic examination 1. India ink preparation 2. KOH mount Skin, hair, nail, Tissue etc.	Binocular Microscope, Small Vertical Autoclave	<ul style="list-style-type: none"> Bio safety measures in the lab must be as per the norms. Fire safety as per norms. Bio medical waste management as per the norms.

BIOCHEMISTRY

Category	Tests	Equipment automated/ Manual	Bio - safety	EQAS/ IQA
Level I	Sugar (FBS/PPBS/RBS) Pl. Urea S. Creatinine S. Cholesterol	Semi auto Analyzer.	All bio safety and fire safety measures should be made available.	Internal Quality Control

MINIMUM STANDARDS FOR A MEDICAL LABORATORY

Level II

Space

- 1500 sq Feet for Pathology Microbiology and Biochemistry together

Bio safety

- Sterile Blood Collection , Disposable Needles, Syringes, Gloves, Needle Destroyer

Bio Medical Waste

- Segregation and Disposal of Waste as per IMAGE/ National Norms

PATHOLOGY

Category	Tests	HR*		Equipment Automated/ manual	EQAS IQA
		Medical	Non Medical		
Level II	Level I + Special Haematology , Peripheral Smear, Bone Marrow, Osmotic Fragility , LE Cells, Special Stains for Luekemia Cytology – FNAC + PAP Smear, Fluid Cytology , Sputum	MD Pathology	Lab Technician Diploma MLT, Lab Assistant , Cleaner	Binocular Microscope, , Automated Haematology Analyser	IQC and EQAS

MICROBIOLOGY

Category	Bacteriology	Mycobacteriology	Serology/ Immunology	Parasitology	Mycology	Equipments	HR*		Other requirements
							Medical	Non Medical	
Level II	a. Routine Microscopy using Binocular Microscope b. Staining facilities 1. Gram staining 2. Ziehl- Neelsen 3. Methylene blue 4. Leishman 5. Albert's 6. Modified Ziehl-Neelsen c. Routine Culture, Identification and sensitivity testing of all samples (Blood, CSF, Urine, Sputum, Exudates, aspirates, stool etc.) 1. conventional method d. Automated blood culture system. e. Rapid detection of bacterial antigen in body fluids –[CSF] - Latex agglutination test f. ANTISERA for Cholera, Salmonella, Shigella etc g. Stock cultures	a) Microscopic examination - Ziehl-Neelsen b) Culture, identification by Conventional method only.	a. serological test for diagnosis of bacterial/ viral, Rickettsial &/ Chlamydial infections 1. ELISA 2. Rapid test b. ANA, CRP, ASO, RA, Cold agglutination test etc.	a) Direct microscopic examination for Parasitic ova/cyst/ parasite b) Staining 1. Lugol's iodine 2. Modified Ziehl-Neelsen	a) Microscopic examination 1. India ink preparation 2. KOH mount Skin, hair, nail, Tissue etc. b. Staining 1. LCB c. Culture identification	Binocular Microscope, Biosafety Cabinet, Autoclave, Incubator, Hot Air Oven, etc	MD Microbiology	Scientific Officer (MSc MLT/ Msc Microbiology), Lab Technician Diploma MLT Lab Assistant, Cleaner	<ul style="list-style-type: none"> • 24 hr laboratory service • Computerised • Reporting system must be prompt and adhere to the turn around time. • Active participation in EQA as well as IQA. • Regular and periodic standardization of all equipments by an approved agency. • Bio safety measures in the lab must be as per the norms. • Fire safety as per norms. • Bio medical waste management as per the norms. • Lab manuals should be prepared as

	of standard strains (Esch.coli, Staph aureus, Psuedo. aeromonas, Salmonella, Enterococci)									per the CLSI guidelines and must be followed in all laboratory procedures.
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MINIMUM STANDARDS FOR A MEDICAL LABORATORY

Level III

Space

- 2000 sq Feet for Pathology Microbiology and Biochemistry together

Bio safety

- Sterile Blood Collection , Disposable Needles, Syringes, Gloves, Needle Destroyer

Bio Medical Waste

- Segregation and Disposal of Waste as per IMAGE/ National Norms

PATHOLOGY

Category	Tests	HR*		Equipment Automated/ manual	EQAS IQA
		M	NM		
Level III	Level II+Histopathology, Immuno histochemistry, Frozen Section Coagulation Studies	MD Pathology with training	Scientific Officer M.Sc MLT/ BSc MLT Lab Technician B.Sc MLT/ DMLT With training Lab Assistant, Cleaner	Automated Tissue Processor Microtome	IQC and EQAS

MICROBIOLOGY

Category	Bacteriology	Mycobacteriology	Serology/ Immunology	Parasitology	Mycology	Equipment	HR*		Other requirements
Level III	<p>a. Routine Microscopy using Binocular Microscope .</p> <p>c. Staining facilities</p> <ol style="list-style-type: none"> 1. Gram staining 2. Ziehl- Neelsen 3. Methylene blue 4. PAS, Giemsa 5. Leishman 6. Albert's Staining 7. Modified Ziehl- Neelsen <p>d. Routine Culture, Identification and sensitivity testing of all samples (Blood, CSF, Urine, Sputum, Exudates , aspirates, stool etc.)</p> <ol style="list-style-type: none"> 1. conventi 	<p>a) Microscopic examination</p> <ol style="list-style-type: none"> 1. Ziehl-Neelsen 2. Fluorescent staining <p>b) Automated system for culture, identification and antibiotic sensitivity testing.</p>	<p>a. serological test for diagnosis of bacterial/ viral, Rickettsial&/ Chlamydial infections</p> <ol style="list-style-type: none"> 1. ELISA (Automated) 2. Rapid test <p>b) VDRL/RPR, TPHA</p> <p>c) ANA, CRP, ASO, RA, Cold agglutination test etc.</p>	<p>a) Direct microscopic examination for Parasitic ova/cyst/parasite</p> <p>b) Staining</p> <ol style="list-style-type: none"> 1. Lugol's iodine 2. Cold Kinyoun <p>Iron Hematoxylen e--</p>	<p>a) Microscopic examination</p> <ol style="list-style-type: none"> 1. India ink preparation 2. KOH mount Skin, hair, nail, Tissue etc. <p>b. Staining</p> <ol style="list-style-type: none"> 1. LCB 2. PAS <p>c. Culture identification and sensitivity testing of fungi</p>	<p>Automated Blood Culture System, Automated Identification System, Biosafety Cabinet, Autoclave, etc</p>	<p>Medical</p> <p>MD Microbiology</p>	<p>Non Medical</p> <p>Scientific Officer (MSc MLT/ Msc Microbiology), Lab Technician Diploma MLT Lab Assistant , Cleaner</p>	<ul style="list-style-type: none"> • 24 hr laboratory service • Computerised • Reporting system must be prompt and adhere to the turn around time. • Active participation in EQA as well as IQA. • Regular and periodic standardization of all equipments by an approved agency. • Bio safety measures in the lab must be as per the norms. • Fire safety as per norms. • Bio medical waste management as per National /IMAGE Norms • Lab manuals should be prepared as per the CLSI

	<p>onal method and 2. fully Automated system</p> <p>e. Anaerobes - Anaerobic workstation</p> <p>f. Automated blood culture system.</p> <p>g. Rapid detection of bacterial antigen in body fluids – [CSF] - Latex agglutination test</p> <p>h. Antisera - for serotype level identification of salmonella sps. Shigella sps, Vibrio sps.</p> <p>i. Stock</p>								<p>guidelines and must be followed in all laboratory procedures.</p>
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	cultures of standard strains (Esch.col i, Staph aureus, Psuedo. aeromonas, Salmonella, Enterococci)								
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BIOCHEMISTRY

Category	Tests	HR*	Equipment automated/ Manual	EQAS/ IQA
Level III	Level II + Blood gas analysis (Hospital Attached Lab) S. Copper S. Ceruloplasmin Vitamin B12 Vitamin D3 S. Ferritin Etc	1) MD Biochemistry 2)Scientific officer MSc MLT 3) Lab Technician BSc MLT/ DMLT 4)Junior Lab Assistants 5)Cleaners.	Chemiluminescence ABG Analyzer (Hospital Attached Lab) Fully Automated Analyzer. Electrolyte Analyzer.	As per norms

* Number of Manpower depends upon the volume of workload

Other Conditions

Test facilities and turnaround time should be displayed. Name and Designation of Specialist working in the Lab should also be displayed
 Accreditation Status ,if available, should be displayed