NQAS Assessor's Guide for Integrated Public Health Laboratory (IPHL)

Version Number: NQAS/IPHL-2024/00

Name of the Laboratory		Date of Assessment	
Name of the Assessor		Name of Assessee	
Type of Assessment	Internal/State/National	Name of State/UT	

NQAS Scorecard

Overall Score of IPHL	Area of Concern wise score	
50%	Service Provision	50%
	Patient Rights	50%
	Inputs	50%
	Support Services	50%
	Clinical Services	50%
	Infection Control	50%
	Quality Management	50%
	Outcome	50%

Major Gaps Observed	
1	
2	
3	
4	
5	

Strengths/Good Practices	
1	
2	
3	
4	
5	

Recommendations/Opportunities for improvement	
1	
2	
3	
4	
5	

Assessor's Guide for IPHL

Reference No.	Area of Concern and Standards	Score in %
	Area of Concern - A Service Provision	
Standard A1	Facility Provides Integrated Diagnostic Laboratory Services as per mandate	50%
Standard A2	Facility provide support services to linked spokes	50%
	Area of Concern - B Patient Rights	
Standard B1	The service provided at facility are accessible and affordable	50%
Standard B2	The service provided at facility are acceptable	50%
Standard B3	The facility has defined framework for ethical management including dilemmas confronted during delivery of services at public health facilities.	50%
	Area of Concern - C Inputs	
Standard C1	The facility has infrastructure for delivery of assured services, and available infrastructure meets the prevalent norms	50%
Standard C 2	The facility ensures the physical safety of the infrastructure.	50%
Standard C3	The facility has established Programme for fire safety and other disaster	50%
Standard C4	The facility has adequate qualified and trained staff, required for providing the assured services to the current case load	50%
Standard C 5	Facility ensures reagents and consumables required for assured list of services	50%
Standard C 6	The facility has equipment & instruments required for assured list of services.	50%
Standard C7	Facility has a defined and established procedure for effective utilization, evaluation and augmentation of competence and performance of staff	50%

	Area of Concern - D Support Services	
Standard D1	The facility has established Programme for inspection, testing and maintenance and calibration of Lab	50%
Standard D2	The facility has defined procedures for storage, inventory management and dispensing of consumables and reagents	50%
Standard D3	The facility provides safe, secure and comfortable environment to staff, patients and visitors.	50%
Standard D4	The facility has established Programme for maintenance and upkeep of the facility	50%
Standard D5	The facility ensures 24X7 water and power backup as per requirement of service delivery, and support services norms	50%
Standard D6	The facility ensures support to all linked labs as per service mandate	50%
Standard D7	Facility has defined and established procedures for Financial Management	50%
Standard D8	Facility is compliant with all statutory and regulatory requirement imposed by local, state or central	50%
Standard D9	Roles & Responsibilities of administrative and clinical staff are determined as per govt. regulations and standards operating procedures.	50%
Standard D10	Facility has established procedure for monitoring the quality of outsourced services and adheres to contractual obligations	50%
	Area of Concern - E Clinical Services	
Standard E1	The laboratory has defined procedures for registration of Patients at the laboratory	50%
Standard E2	Facility has established mechanism for referral linkages to maintain continuity of services	50%
Standard E3	The facility has established and defined procedure for pre-testing activities	50%
Standard E4	The facility has established and defined procedure for testing activities	50%
Standard E5	Laboratory has defined and established procedure for the post testing processes	50%
Standard E6	The facility has established mechanism for internal and external validation of testing procedures	50%
Standard E7	Facility has defined and established procedures for maintaining, updating of patients' clinical records and their storage	50%
Standard E8	The facility has defined and established procedures for Emergency Services and Disaster Management	50%
Standard E9	Facility provides National health program as per operational/Clinical Guidelines	50%
	Area of Concern - F Infection Control	
Standard F1	Facility has infection prevention control program and procedures in place	50%
Standard F2	Facility has defined and Implemented procedures for ensuring hand hygiene practices and antisepsis	50%
Standard F3	Facility ensures standard practices and materials for Personal protection	50%
Standard F4	Facility has standard Procedures for processing of equipments and instruments	50%
Standard F5	Physical layout and environmental control of the laboratory ensures infection prevention	50%
Standard F6	Facility has defined and established procedures for segregation, collection, treatment and disposal of Bio Medical and hazardous Waste.	50%
	Area of Concern - G Quality Management	
Standard G1	The facility has defined mission, vision, values, quality policy and objectives, and prepares a strategic plan to achieve them	50%
Standard G2	The facility has established organizational framework for quality improvement	50%
Standard G3	The facility has documented, implemented and updated Standard Operating Procedures for all key processes and support services	50%
Standard G4	The facility has established internal & external quality assurance programmes for laboratory functions	50%
Standard G 5	The facility seeks continual improvement by practising Quality method and tools	50%
Standard G6	The facility maps its key processes and seeks to make them more efficient by reducing non value adding activities and wastages	50%
Standard G7	The facility has defined, approved and communicated Risk Management framework for existing and	50%
Standard G8	The facility has established procedures for assessing, reporting, evaluating and managing risk as per Risk Management Plan	50%
Standards G9	The facility has established system for patient and employee satisfaction	50%
	Area of Concern - H Outcome	
Standard H1	The facility measures Productivity Indicators and ensures compliance with State/National benchmarks	50%
Standard H2	The facility measures Efficiency Indicators and ensure compliance with State/National benchmarks	50%
Standard H3	The facility measures Clinical Care & Safety Indicators and ensure compliance with State/National	50%
Standard H4	The facility measures Service Quality Indicators and ensure compliance with State/National benchmarks	50%

National Quality Assurance Standards						Version Number: NQAS/IPHL-2024/00
Assessor's Guide for Integrated Public Health Laboratory (IPHL)						
Reference No.	**Measurable Element**	**Checkpoint**	**Compliance**	**Assessment Method**	**Means of Verification**	**Remarks**
Area of Concern - A Service Provision						
Standard A1	**Facility provides Integrated Diagnostic Laboratory Services as per mandate**					
ME A1.1	Facility provides comprehensive set of Laboratory services	Availability of Haematology services	1	SI/RR	Hb%, TC, DC, Platelet, CBC, ESR, BG & Rh typing, Blood cross matching, Peripheral blood film, Reticulocyte count, AEC, Fibrinogen degradation products, D-Dimer, Coobs test direct & indirect with titre, Sickling test for screening of sickle cell anaemia rapid sickle cell test, DCIP test for screening HbE hemoglobinopathy, G6PD enzyme deficiency, Prothrombin time (PT) & International Normalised Ratio (INR), Activated partial thromboplastin time, Mixing study for Factor Deficiency & inhibitors Haemophilia, Haemoglobin electrophoresis, HPLC,	
		Availability of Biochemistry services	1	SI/RR	GTT, S.Bilirubin (Total, Direct & Indirect), S.Creatinine, Blood urea, SGOT, SGPT, S.Alkaline Phosphatase, S.Total protein, S.Albumin & AG ratio, S.Globulin, S.Total cholesterol, S.Triglycerides, VLDL, HDL, LDL, GGT, Uric acid, S.Amylase, S.Iron, S.Total Iron binding capacity, S.LDH, HbA1C, CRP, S.Electrolytes, S.Ionised Calcium, Atrterial blood gas test, Urinary protein, Urine for microalbumin, creatinine & protein, Thyroid profile, Ferritin, Troponin-I/ Troponin-T, S.PSA, CSF & body fluid	
		Availability of Microbiology services	1	SI/RR	Wet mount & gram stain for RTI/STD, KOH mount for fungal microscopy, Slit skin smear, Gram staining for clinical specimen, Throat swab for Diphtheria, Stool hanging drop for Vibrio Cholera, Blood/body fluid culture, Urine/other cultures, Diphtheria culture, Culture of stool, Bacterial identification & AST	
		Availability of Cytology services	1	SI/RR	FNAC, Pap smear, CSF & body fluid counts cytology	
		Availability of Histopathology services	1	SI/RR	Histopathology, Tissue biopsy	
		Availability of Clinical Pathology services	1	SI/RR	UPT, Urine test for pH, specific gravity, leucocyte esterase, glucose, bilirubin, urobilinogen, ketone, protein, nitrite, Urine microscopy, Stool for ova, cyst & occult blood, Semen analysis	
		Availability of Serology services	1	SI/RR	RPR/VDRL, HIV 1 & 2, Widal, Leptospirosis, Typhus, Measles, Leishmaniasis, Bacterial meningitis, PCR for influenza, COVID-19 & emerging infectious diseases	
		Availability of Water culture test services	1	SI/RR	Culture for coliforms & RDTs to support outbreak investigation, Microbiological analysis of Water (H2S test for screening)	
ME A1.2	The facility provides Laboratory services for communicable diseases	Availability of lab services for vector borne disease	1	SI/RR	rk39 for Kala Azar, ELISA for JE & Chikungunya, NS1 & IgM for dengue, Malaria, Filaria, Dengue NS1 & IgM	
		Availability of lab services for Tuberculosis	1	SI/RR	Microscopy for AFB CB-NAAT for mycobacteria	
		Availability of lab services for HIV	1	SI/RR	CD4/CD8 count, HIV 1 & 2	
		Availability of lab services for Leprosy	1	SI/RR	Slit skin smear	
		Availability of lab services for viral hepatitis	1	SI/RR	Hepatitis B surface antigen, Viral load for HBV & HCV, HCV antibody, Hep-A & E,	
ME A1.3	The facility provides Laboratory services for non-communicable diseases	Availability of services for DM	1	SI/RR	FBS, PPBS, RBS, HbA1c	
		Availability of services for NAFLD/ Stroke/ Chronic kidney disease	1	SI/RR	Liver function test, Lipid profile, kidney function test, CT & BT	
		Availability of services for STEMI	1	SI/RR	C-Reactive protein, Troponin-I/ Troponin-T, D-Dimer	
		Availability of services for Cancer	1	SI/RR	Histopathology, Tissue biopsy, PAP smear, FNAC	
ME A1.4	Facility provides services to support public health functions	The clinical, Public health or any other lab services are mapped and restructured to provides comprehensive services under IPHL	1	SI/RR/OB	Existing functional labs like NACP, NTEP, NVBDCP, NVHCP, IDSP etc are converged/integrated with IPHL	

		provides laboratory services for public health programmes	1	SI/RR/OB	For NACP, NTEP, NVBDCP, NVHCP, IDSP etc.	
		Support block and district surveillance units	1	SI/RR/OB	provides accurate and timely data to detect, prevent and respond to public health threats	
ME A1.5	Facility provides laboratory based surveillance services for Infectious & Non-infectious diseases	Availability of services for surveillance of infectious and non-infectious diseases	1	SI/RR/OB	1. Mechanism/System at place for surveillance & monitoring of epidemic & endemic diseases	
		Availability of services for Microbiological surveillance of facilities	1	SI/RR/OB	Hospital Acquired Infections- 1. Active surveillance test 2. AMR surveillance 3. Antibiogram 4. Drug resistant bacterial pathogens	
		Availability of services for outbreak surveillance	1	SI/RR/OB	1. Tracing of the source infection like pyrexia of unknown origin 2. Detection of inapparent infections/carriers 3. Early detection of outbreak 4. Retrospective diagnosis like Rheumatic heart disease 5. Detection of new disease agents like SARS, COVID, emerging/remerging bacterial & viral diseases	
ME A1.6	Services are available for the time period as mandated	24x7 all lab services are available	1	SI/RR/OB	Check for: 1. Laboratory services are available at night 2. Look for number of lab tests performed at night	
Standard A2	**Facility provides support services to linked spokes**					
ME A 2.1	Facility provides technical support services to Block Public Health Labs & other peripheral labs	Availability of technical support services to BPHL and other peripheral labs	1	SI/OB	1. Sample collection, testing and referral 2. Functional linkage with spokes	
		IPHL provides support for monitoring, capacity building of BPHL & peripheral laboratory staff	1	SI/OB/RR	1. Implementation of Quality Management System 2. Capacity building support	
ME A 2.2	Facility provides information management support to respond to public health needs & threats	Availability of Laboratory Information management system	1	SI/OB	Use of LIMS for tracking samples, report the test results, storage, analysis & retrieval of lab data If LIMS is not available, paper based record may give partial compliance	
Area of Concern - B Patient Rights						
Standard B1	**The services provided at the facility are accessible and affordable**					
ME B1.1	The facility has user friendly and uniform signage system	Availability of adequate and clear signages for IPHL	1	OB	1. Name of the IPHL is displayed prominently 2. Directional signages from the entrance of the hospital/IPHL is displayed 3. Signages for sample collection and internal sectional areas are properly displayed	
		Availability of adequate and clear signages for sample collection area	1	OB	1. Directional signages for sample collection area is displayed from the different part of the hospital *-Give full compliance if collection area is a part of main IPHL*	
		Signages are user friendly & uniform in colour	1	OB	Signages and service information is displayed in local language	
		Restricted area signage are displayed	1	OB	Restricted access to visitors	
		IPHL layout is displayed at the entrance	1	OB	IPHL is the part of hospital layout if located in hospital	
ME B1.2	The facility displays its services, entitlements and relevant information	List of services available are displayed at the entrance	1	OB	Verify with scope of IPHL	
		Timing for collection of samples are displayed	1	OB	1. Lab is functional around the clock especially for haematology & biochemistry (can be functional in 3 shifts 2. Timing for OPD sample collection starts from 8AM	
		Timing for delivery of reports are displayed	1	OB	Turn around time for report collection is displayed	
		Patients & visitors are sensitised and educated for testing requirements	1	OB/PI	1. Test specific instructions are displayed 2. Patient/relatives are informed about pre-testing requirements (If applicable)	
ME B1.3	Access to facility is providesd without any physical barrier & friendly to specially-abled people	IPHL provides barrier free services to patient	1	OB	1. Approach road to IPHL/hospital is accessible without congestion 2. Internal pathway & corridors of IPHL/hospital are accessible without obstruction	
		Availability of Ramp with rails/ lift in lab building & sample collection area	1	OB	Give full compliance if building & sample collection area is at ground floor	
		There is no discrimination on basis of social & economic status of patients	1	OB/PI	Check Laboratory has defined policy for ensuring non discrimination on basis of social and economic status of the patient	

ME B1.4	There is an established procedure for having consent before conducting any procedure	Check procedure for having consent and counselling of the patient wherever required	1	OB/PI	1. Informed Consent & counselling is taken before HIV testing, 2. Written consent is taken for biopsy and any other invasive procedure 3. Consent is taken by treating physician on standardised format in case of histopathological	
ME B1.5	The facility has defined and established grievance redressal system in place	Availability of complaint box	1	OB	1.Complain box is available in proximity to IPHL/sample collection area/reporting receiving area (may be shared with main hospital) 2. Process to complete resolution of the complain is defined and displayed 3. Staff is aware about complaints pertaining to the lab & mechanism of the complain re-addressal	
		Information abut complain re-addressal is displayed	1	OB	104/state specific number	
ME B1.6	The facility provides cashless services as per prevalent government norms/schemes	IPHL provides free diagnostic services as per guidelines/state mandate	1	OB/PI	As per the mandate of free diagnostic services	
		Check patient has not incurred any expenditure on diagnostics	1	OB/PI	Ask patient randomly (At least 5)	
		Cashless investigations for patients/beneficiaries	1	OB/PI	JSSK, Ayushman Bharat, applicable national & state specific govt. schemes	
Standard B2	**The service providesd at facility are acceptable**					
ME B2.1	Adequate visual privacy is providesd at every point of care	Availability of screen/ partition at sample collection area	1	OB	Privacy is maintained at OPD areas	
		Adequate privacy is maintained during sample collection	1	OB	IPD, Emergency & Critical areas	
ME B2.2	Services are providesd in manner that are sensitive to gender	Separate queue for female and specially abled patients	1	OB	IPHL and sample collection areas / report receiving areas	
		Laboratory has defined policy for non discrimination on basis of gender	1	OB		
ME B2.3	Confidentiality of patients records and clinical information is maintained for every patient, especially of those having social stigma	Laboratory has system to ensure the confidentiality of the reports generated	1	OB	1. Lab staff do not discuss the lab result outside 2. Special precautions are taken for the test results of having social stigma like HIV, Leprosy etc	
		Laboratory Records are kept at secure place	1	OB	General staff/visitors do not have access to the lab reports	
		HIV positive reports/pregnancy reports are communicated	1	OB	As per NACO guidelines/state guidelines	
ME B2.4	The facility ensures the behaviours of staff is dignified and respectful, while delivering the services	Behaviour of staff is empathetic and courteous	1	OB		
		Check there is no overcrowding at OPD sample collection area	1	OB	Patients are called one by one/First come first serve basis/calling system in sample collection area (Except for emergencies)	
Standard B3	**The facility has defined framework for ethical management including dilemmas confronted during delivery of services at public health facilities.**					
ME B3.1	Ethical norms and code of conduct for medical and paramedical staff have been established	Check code of conduct is defined	1	OB/RR	Check for any circular, policy, notice, government order issued that explains the code of conduct for staff such as specialists, technicians and other support staff	awareness and updated copy of code of conduct
		Check if staff is aware of code of conduct	1	SI	Check doctors and lab technicians are aware of code of conduct	
ME B3.2	There is an established procedure for sharing of laboratory/patient data with individuals and external agencies including non governmental organization.	Check IPHL has defined protocols for data sharing	1	RR/SI	Check list of agencies are available with IPHL wit which data is shared For any other agency a formal permission is sought from competent authorities before sharing the data including international agencies, press and NGOs	
ME B3.3	There is an established procedure for obtaining informed consent from the patients in case facility is participating in any clinical or public health research	Check hospital ensures that informed consent is taken from patient participating in any clinical or public Health research	1	RR/SI	Check for policy or practice	
ME B3.4	There is an established procedure to ensure laboratory services during strikes or any other mass protest leading to dysfunctional laboratory services.	Laboratory has defined strategy to resume the basic emergency and patient care services during strikes	1	RR/SI	1. Check laboratory has made buffer stock and alternate source of supplies for reagents and consumables 2. Strategy and coordination with local disruption to maintain laboratory functions	

ME B3.5	Facility has established a framework for identifying, receiving, and resolving ethical dilemmas' in a time-bound manner through ethical committee/ locally applicable rules	Check ethical issues management framework is defined	1	RR	(a) Check the adequacy of the framework & it address the ethical issues and decision making in declaring results (b) Check facility's ethical management framework address issues like sample collection, transfer, testing, resulting, disclosure of information or any professional conflict which may not be in patient's	
		Check the list of ethical issues is available and regularly updated	1	RR/SI	Check when the list was last updated. Engage with the available medical professionals to check what type of ethical dilemmas they are facing while performing their job & how they are dealing with dilemma's.	
		Check regular review of identified and reported ethical issue is done and decisions are communicated to concerned staff	1	RR/SI	1. Check the facility has defined mechanism identification and reporting of the ethical issues/ dilemmas confronted during services delivery 2. Check the timely resolution of the identified and reported ethical issues is done 3. Check information regarding ethical dilemma's & its handling is also given to new joiner's	
Area of Concern - C Inputs						
Standard C1	**The facility has infrastructure for delivery of assured services, and available infrastructure meets the prevalent norms**					
ME C1.1	Facility has adequate space as per work load	Adequate space is available in central sample collection area	1	OB	Adequate area for waiting, registration and sample collection, report dissemination (if done from sample collection area) is available in the central Sample collection area	BSL-2, pressure control
		Laboratory space is adequate for carrying out activities	1	OB	Adequate area is available for performing tests, sample storage, keeping equipment, report dissemination and storage of reagents and records etc. is available	
		Adequate space is available for keeping staff amenities	1	OB	1. Adequate space/ office for four specialists, staff room, change room, and restrooms are available 2. Toilet of staff are with eye wash and body wash facility	
ME C1.2	Patient amenities are providesd at sample collection area as per patient load	Service counters are available as per patient load	1	OB	1. Availability of adequate no. of registration, sample collection and report collecting counters as per patient load. 2. Check availability of at least at least 3 sample collection counter	
		Availability of sitting arrangement of sub waiting area	1	OB	Check adequate sitting arrangement as per patient load is available in waiting area	
		Availability of functional toilets	1	OB	In proximity to central sample collection area May be shared with main OPD/Hospital building	
		Availability of drinking water	1	OB	In proximity to central sample collection area May be shared with main OPD/Hospital building	
ME C1.3	Facility has layout and demarcated areas as per functions	Dedicated central sample collection area	1	OB	1. Dedicated area of sample collection with the provision of reception, registration and waiting area 2. Separate negative pressure room for the collection of microbiology samples 3. Separate room for FNAC, - with provision of bed Check adequate privacy is maintained in each sample collection point	for infectious patient
		Demarcated sample receiving and reporting area	1	OB	1. Check that samples received from spokes are collected in a systematic way 2. Check that samples received from the central sample collection lab or IPDs or sent through dumb waiter are collected in a systematic way	
		Demarcated area for sample processing	1	OB	(1) routine testing and public health-related diagnostic facility is located at one place. (2) Clearly marked areas for Haematology, Biochemistry, Clinical pathology, cytology, microbiology, mycobacteriology, serology, media preparation etc.	
		Demarcated reporting area	1	OB	1. Designated report writing area (in main lab) 2. Designated report collecting area (In the central sample collection area / in main lab)	
		Designated washing and waste disposal area	1	OB	1. In the central sample collection area 2. In sample processing areas	
		Designated eyewash station	1	OB	Standalone facility or attached to sink for eyewash in case of chemical splash in eye/ body	

		Availability of auxiliary/accessory area	1	OB	Small store room, cold room, server and electrical room etc (electrical room - may be shared with main hospital building)	
ME C1.4	The facility has infrastructure for intramural and extramural communication	Availability of functional telephone and Intercom Services	1	OB	Check availability of landline or other alternatives for intramural and extramural communication is available	
		Availability of functional modules for Hospital or laboratory information management	1	OB	Check hardware and software is available for HIS/LIMS	
ME C1.5	The facility and departments are planned to ensure structure follows the function/processes (Structure commensurate with the function of the hospital)	Unidirectional flow of services	1	OB	1. Sample collection- Sample receiving-Sample processing at respective area- Analytical area- report generation, review & authorization-Report delivery. 2. Ensure logical flow of specimens from receipt to disposal	
Standard C 2	**The facility ensures the physical safety of the infrastructure.**					
ME C2.1	The facility ensures the seismic safety of the infrastructure	Non structural components are properly secured	1	OB	Check for fixtures and furniture like cupboards, cabinets, and heavy equipment's , hanging objects are properly fastened and secured	
ME C2.2	The facility ensures infrastructure in place for safe sample transportation	Dumb waiters are installed to transport the samples from collection area to testing area	1	OB	Give full compliance if sample is transported manually ensuing all the sample transportation protocols	
		Alarm system is used to indicate the sample drop	1	OB	Specially from critical areas like emergency IPD, ICU and emergency	
		Process is defined and followed for Periodic Maintenance of dumb waiters	1	OB/RR	Regular cleaning, operations, maintenance and trouble shooting in case of malfunctioning	
		Functional lift is available for easy access to IPHL	1	OB	(1) May be shared with the main hospital building. Give full compliance if the building is on ground /first floor/ ramp facility (2) Check for lift licence if lift available in lab (3) Periodic maintenance of lift	
ME C2.3	The facility ensures safety of electrical establishment	Check there is no loose hanging wires and temporary connection	1	OB	In Lab and sample collection areas	
		Adequate electrical socket is available	1	OB	(1) For safe and smooth operation of lab equipment. (2) Check extensions are not used to run heavy equipment	
		Power Audit and Earthing is done regularly	1	OB/RR	Check six monthly once at least	
		Constant out put voltage is providesd to the equipment	1	OB	Automatic voltage regulators are installed	
		Facility has mechanism for periodical check / test of all electrical installation	1	OB/RR	by competent electrical Engineer	
ME C2.4	Physical condition of buildings are safe for providing mandated lab services	Work benches are chemical resistant	1	OB	Check bench tops are impervious to water and resistant to moderate heat, organic solvents, acids, alkalis, chemicals.	
		Floors of the Laboratory are non slippery and even surfaces and acid resistant	1	OB		
		Windows have grills and wire meshwork	1	OB		
Standard C3	**The facility has established Programme for fire safety and other disaster**					
ME C3.1	The facility has plan for prevention of fire	Fire exits with signage are defined to permit safe escape to its occupant at the time of fire	1	OB	The department has sufficient no. of fire exits with fire exit signage	
		Check that the fire exits are visible and routes to reach the exit are clearly marked.	1	OB	(1) Check that fire exit/evacuation plans are displayed (2) Fir exits are clutter-free	
		Laboratory has plan for safe storage and handling of potentially flammable materials.	1	SI/RR	Check Material safety data sheet is available	

		Fire Safety audit is done by competent authorities	1	RR/SI	May be along with main Hospital building/separately	
ME C3.2	The facility has adequate fire fighting Equipment	Check fire Extinguishers are installed in IPHL and sample collection area	1	OB	Class A , Class B, C type or ABC type	
		No fire extinguisher is expired in lab, circulation area, waiting, area, Corridors	1	OB	Check the expiry date for fire extinguishers are displayed on each extinguisher along with due date for the next refilling is clearly mentioned.	
ME C3.3	The facility has a system of periodic training of staff and conducts mock drills regularly for fire and other disaster situation	Check for staff competencies for operating fire extinguisher	1	SI	(1) Check staff is aware of PASS- Pull the pin, A- Aim at the base of fire, S-Squeeze the lever, S -Sweep side to side (2) Staff is aware of RACE R- Rescue, A- Alarm, C- Confine, E- Extinguish	
		Check periodic mock drills is conducted	1	SI/RR	May be part of hospital's regular mock drill.	
Standard C4	**The facility has adequate qualified and trained staff, required for providing the assured services to the current case load**					
ME C4.1	The facility has adequate specialist/qualified personnel as per service provision	The organogram or hierarchical structure of the laboratory is defined	1	OB/RR	(1) Check organogram is displayed (2) Clearly showing the interrelationship of the staff	
		Availability of Specialist	1	OB	1-Pathologist 1-Microbiologist 1-Biochemist	
ME C4.2	The facility has adequate technicians/paramedics as per	Availability of Medical Lab Technologist/ Lab Technician	1	OB/RR	11 lab technicians/ as per case load	
ME C4.3	The facility has adequate support / general staff	Availability of Data Entry Operator/Data analyst	1	OB/RR	As per case load	
		Availability of Sanitation staff/ Housekeeping staff	1	OB/RR	As per case load	
		Availability of Security Guard	1	OB/RR	As per case load	
Standard C 5	**Facility ensures reagents and consumables required for assured list of services**					
ME C5.1	The facility has adequate reagents and controls at point of use	Availability of reagents and chemicals	1	OB/ RR	Reagents for auto analysers, ELISA Readers reagents, Acetone, Alcohol, distilled water, Microscope gel etc.	
		Availability of control	1	OB/RR	Quantitative / Qualitative Lyophilized / ready to use Assayed/unassayed etc	
		Availability of stains	1	OB/ RR	Iodine Solution, Gram Romanowsky, StainZiehl-Nielsen, Acridine orange, Acridine orange	
ME C5.2	The facility has adequate consumables at point of use	Availability Laboratory materials	1	OB/ RR	Blood collection tubes, Swabs, needles, Syringes, Glass slides, Glass marker/paper stickers, Lancets etc.	
ME C5.3	Emergency drug trays are maintained at every point of care, where ever it may be needed	Emergency Drug Tray is maintained	1	OB/ RR	(1) At central sample collection area (2) Normal Saline (NS), Glucose 25%,Ringer Lactate (RL),Dextrose 5%, Adrenaline, Potassium Chloride,Calcium Gluconate,Sodium Bicarbonate,Inj Pheniramine,Inj Hydrocortisone Hemisuccinate/ Hydrocortisone Sodium Succinate ,Inj Phenobarbitone,Inj Phenytoin,Inj Diazepam,Inj Midazolam,Salbutamol Respiratory,Ipratropium ,Inj Dopamine,I.V Infusion set,	
Standard C 6	**The facility has equipment & instruments required for assured list of services.**					
ME C 6.1	Availability of equipment & instruments for diagnostic procedures being undertaken in the facility	Availability of functional equipment & instruments for examination & monitoring	1	OB	Thermometer, Stethoscope, BP apparatus, Weighing scale, Torniquets, Spirit/antisepsis, cotton swabs at sample collection area	
		Availability of equipment for clinical pathology	1	OB	Binocular Microscope, Urine analyser Centrifuge Bunsen burner with gas supply	
		Availability of equipment for haematology	1	OB	Binocular Microscope Automated Cell Counter (3 part/5 part) with nucleated RBC flag Automated Coagulometer Automated ESR analyser Haemoglobin HPLC machine (variant analyser)	

		Availability of equipment for cytology	1	OB	Binocular Microscope Centrifuge	
		Availability of equipment for biochemistry	1	OB	Automated Biochemistry analyser ISE based Electrolyte analyser Automated Hormone Immunoassay analyser (CLIA Based)	
		Availability of equipment for bacteriology	1	OB	Binocular Microscope Incubator Automated blood culture Automated bacterial ID/AST system Biosafety Cabinet Class II A2 (model conforming to NSF standards) Bunsen burner with gas supply Computer with scanner, printer, UPS Culture media	
		Availability of equipment for mycobacteriology	1	OB	Binocular Microscope (LED) Fluorescent Microscope Biosafety Cabinet Class II A2 with thimble ducting (model conforming to NSF standards) NAAT machine Tissue homogenizer Bunsen burner with gas supply	
		Availability of equipment for serology	1	OB	ELISA reader and washer VDRL rotator/shaker	
		Availability of equipment for molecular biology/virology	1	OB	Real Time PCR machine Biosafety Cabinet Class II A2 (model conforming to NSF standards) PCR Workstation, ELISA reader and ELISA washer Microcentrifuge PCR hood/PCR workstation	
		Availability of equipment for media preparation room	1	OB	Electronic balance Hot plate Autoclave Bunsen burner with gas supply	
		Availability of functional equipment under NVBDCP	1	OB	Autoclave (Vertical & Horizontal), Biosafety cabinet, Hot air oven, Incubators Binocular, Microscopes, ELISA reader & washer, Micropipette water bath, Centrifuge, Mixer/Rotator	
		Availability of functional equipment under NACP	1	OB	Pipettes, Centrifuge, HIV test kits, test tubes	
		Availability of functional equipment under NTEP	1	OB	Autoclave, Analytical & Precision balance, Bottle washer, Biological Safety Cabinet class 2A with thimble ducting, Electric micro incinerator, Hot plate Incubator, Microscope Binocular, Microliter Pipette, Centrifuge, PH meter, Hot air oven	
		Availability of functional equipment & instrument for testing samples	1	OB	Biosafety Cabinet Class II A2 with thimble ducting, Cell counter, Hormone, Electrolyte and Urine analyser, ESR tubes, Micropipettes, Electrophoresis unit, PCR machine, Blood gas analyser, NAAT machine, Glassware and RDKs	

ME C 6.2	Availability of functional equipment and instruments for support services	Availability of equipment for cleaning	1	OB	Buckets for mopping, mops, duster, waste trolley, deck brush	
		Availability of equipment for sterilization and disinfection	1	OB	Autoclave - Horizontal & Vertical	
		Availability of equipment for Data Management	1	OB	Computer, Printer, UPS	
ME C 6.3	Departments have patient furniture and fixtures as per load and service provision	Availability of equipment for storage of sample and reagents	1	OB	Refrigerator, Deep freezer, Test tube racks	
		Availability of fixtures at lab	1	OB	Illumination at work station, Electrical fixtures, Air Conditioners etc.	
		Availability of furniture	1	OB	(1) Lab stools, Work bench's, rack and cupboard for storage of reagent, , Chair, tables in Lab. (2) Patient stool, Chairs, tables in sample collection area	
Standard C7	**Facility has a defined and established procedure for effective utilization, evaluation and augmentation of competence and performance of staff**					
ME C7.1	Criteria for Competence assessment and performance appraisal are defined for all clinical and Para clinical staff	Check parameters for assessing skills and proficiency of clinical staff has been defined	1	SI/RR	Check objective checklist has been prepared for assessing the competence of specialists, Lab technician and paramedical staff based on job description defined for each cadre of staff.	
		Check performance criteria for clinical staff & non clinical has been defined	1	SI/RR	Check if performance appraisal critical clinical staff has been defines as per state service rules/ NHM Guidelines and job description of staff	
ME C7.2	Competence assessment and performance appraisal of Clinical and Para clinical staff is done on predefined criteria at least once in a year	Check for competence assessment of clinical & paraclinical is done at least once in a year	1	RR	(1) Check for records of competence assessment including filled checklist, scoring and grading . (2) Verify with staff for actual competence assessment done (3) Check feedback is given to all staff after competence assessment	
		Check if annual performance appraisal for clinical staff is practiced	1	RR/SI	(1) Verify with records that performance appraisal has been done at least once a year for all specialists, Lab technicians and paramedic staff. (2) Check that predefined criteria have been used for the appraisal only. (3) Check feedback is given to all staff after	
ME C7.3	The Staff is providesd training as per defined core competencies and training plan	Check operator is trained for using automated diagnostic equipment	1	SI/RR	Training on automated Diagnostic Equipment's like auto analyser	
		Check lab technician are trained for sample collection	1	SI/RR	1. Like Arterial and capillary blood collection 2. For arterial blood collection-check staff is aware of modified Allen test	
		Check staff is trained for sample transportation	1	SI/RR		
		Check that staff is trained on Laboratory safety & Infection prevention and control	1	SI/RR	Bio medical Waste Management including Hand Hygiene , sterilisation, bio safety cabinet certification etc.	
		Check staff is trained for Internal and External Quality Assurance	1	SI/RR	Training on Internal and External Quality Assurance	
		Check that staff is trained for documentation preparation	1	SI/RR	Specimen handling manual, acceptance/rejection criteria, critical alerts, inventory management, result reporting format, IQC records, SOP etc	
		Check staff is trained to use LIMS	1	SI/RR	Data entry, specimen tracking ,reporting, analysis of data etc	
		Check that clinicians are trained for Laboratory-based surveillance of infectious diseases	1	SI/RR	Syndrome based approach for detection and response	

ME C7.4	Training needs are identified based on competence assessment and performance evaluation and facility prepares the training plan	Check lab. has a system for identifying the training needs and plan to address them.	1	SI/RR	(1) Check that Lab head/ designated in charge has listed the gaps found during the competence assessment and performance appraisal exercise . (2) These gaps in performance and competence are factored in while developing training plan for staff. (3) Check the records of training need assessment	
		Check annual training calendar is prepared & updated	1	SI/RR	(1) Check induction and refresher training is providesd to all staff (2) Training calendar is prepared according to the result of competency and performance assessment & training need assessments	
ME C7.5	There is established procedure for utilization of skills gained thought trainings by on -job supportive supervision	Staff is skilled to run automated equipment's	1	SI/RR	(1) Check supervisors make periodic rounds of department, and monitor that staff is working according to the training imparted. (2) Also staff is providesd on job training wherever there is still gaps	
		Staff is skilled for maintaining Laboratory records	1	SI/RR	(1) Check supervisors make periodic rounds of department and monitor that staff is working according to the training imparted. (2) Also staff is providesd on job training wherever there is still gaps	
Area of Concern - D Support Services						
Standard D1	**The facility has established Programme for inspection, testing and maintenance and calibration of Lab Equipment's.**					
ME D 1.1	The facility has established system for maintenance of critical Equipment	All equipment's are covered under AMC including preventive maintenance	1	SI/RR	1. Check with AMC records/ Warranty documents 2. Staff is aware of the list of equipment covered under AMC. 3. Check all lab equipment's are covered under BMMP	
		There is system of timely corrective break down maintenance of the equipment's	1	SI/RR	1. Equipment Log Books are maintained 2. Breakdown records are maintained 3. Staff is aware of contact details of the agency/person in case of breakdown. 4. Check all lab equipment's are covered under BMMP	
		Staff is skilled for trouble shooting in case equipment malfunction	1	SI	Interview few of the staff randomly	
		Periodic cleaning, inspection and maintenance of the equipment's is done	1	OB/RR	1. Done by the operator 2. Check asset list of equipment is maintained	
		Staff is aware of the Bench Aids for use of equipment	1	SI	Check for the Bench Aids for routine use of equipment	
		There is a system to label Defective/Out of order equipment's	1	OB	Defective/Out of order equipment are stored appropriately until it has been repaired	
		All equipment are checked for the safety of the users	1	SI/RR/OB	1. Checking is done by a qualified person 2. Earthing is checked six monthly for all applicable equipment's 3. Safety instructions is available readily 4. There is a system of reporting of equipment related adverse event	
		Equipment acceptance testing is done upon installation or after preventive maintenance	1	RR	Preventive maintenance as per manufacturer's instructions	
		IT equipment are covered under corrective and preventive maintenance program	1	RR/SI	There is system of timely corrective break down maintenance of the for computers and other IT equipment	
ME D1.2	The facility has established procedure for internal and external calibration of measuring Equipment	All the measuring equipment's/ instrument are calibrated	1	OB/ RR	Recalibration done at least every six months	
		There is system to label/ code the equipment to indicate status of calibration/ verification when recalibration is due	1	OB/ RR	Check for the bar code or any record of calibration status	
		Calibrators are available for Automated haematology analysers	1	SI/RR	1. As per the manufacturer instructions 2. Check when last calibration was done for the analyser	
		In house calibration is done by using reference material or comparative techniques	1	RR/OB/SI	1.List of equipment that are internal calibrated 2. Reference material used for internal calibration demonstrate traceability to SI Units or appropriate measurement standards	
		Laboratory has system to update correction factor after calibration wherever required	1	SI/RR	Check the records	

		Staff is aware of when to recalibrate the equipment's	1	SI/RR	Check for: 1. A change of reagent lot 2. If QC results are outside of the acceptable limits 3. After major maintenance or service 4. When recommended by the manufacturer	
		Records pertaining to the calibration is maintained for each equipment	1	RR/OB	Check for Internal Calibration Records External Calibration Certificate Raw data generated during the calibration Certificate of Traceability	
ME D1.3	Operating and maintenance instructions are available with the users of equipment	Staff is aware of equipment Installation Qualification (IQ), Operational Qualification (OQ) and Performance Qualification (PQ)	1	RR/SI	Laboratory has maintained the records related to Installation Qualification (IQ), Operational Qualification (OQ) and Performance Qualification (PQ) for all the testing equipment's	
		Up to date instructions for operation and maintenance of equipment's are readily available with staff	1	RR/SI	Check staff is aware of the instructions	
Standard D2	**The facility has defined procedures for storage, inventory management and dispensing of consumables and reagents**					
ME D2.1	There is established procedure for forecasting and indenting consumables, reagents and controls	There is established system of timely indenting of consumables, reagents and controls	1	SI/RR	Stock level are daily updated Requisition are timely placed	
ME D2.2	The facility ensures proper use and storage of consumables and reagents	Reagents and consumables are stored appropriately	1	OB/RR	Check reagents are kept away from water and sources of heat, direct sunlight All reagents, consumables, stains, media, kits, and antimicrobials should be stored as recommended by	
		There is process for storage of reagents, kits and material requiring controlled temperature	1	OB/RR	Check for: 1. Temperature of refrigerators are kept as per storage requirement 2. Temperature chart records are maintained and updated periodically 3. Regular defrosting is done, as applicable 4. Reagents are not stored on door shelves of the	
		Standard operating procedures are referred to prepare the working solutions and all the prepared solutions are labelled	1	RR/SI	Check for availability of SOPs Working solutions are labelled having details: 1.Name of the solution 2.Date and Time of preparation 3.Content of the solution 4.Strength or concentration 5.Storage conditions 6.Expiration date 7.Prepared by (name)	
		Reagents are accompanied with relevant SOP	1	OB/RR	Details relevant to usage like sensitivity, specificity, measuring range, shelf life, SDS, storage and disposal	
		Reagents are labelled appropriately	1	OB/RR	Reagents label contain name, strength or concentration, date of preparation/opening, date of expiry, storage conditions, warning and opened by - initial/sign	
		Laboratory has established procedure for acceptance testing of all the reagents before putting into the use	1	RR	1. New lot of reagents is verified for performance before use in the tests 2. Records of lot Verification of reagents	
ME D2.3	The facility ensures management of expiry and near expiry reagents	No expired reagent found	1	OB/RR	Check randomly for expiry of the reagents	
		Expiry and near expiry reagent are maintained	1	RR	Check the records	
ME D2.4	The facility has established procedure for inventory management techniques	Hospital implements scientific inventory management system according to their needs	1	OB/RR	Based on First Expiry First Out (FEFO)	
		There is practice of calculating and maintaining buffer stock of reagents	1	SI/RR	1. Based on the consumption 2. Stock and expenditure registers are maintained	
		There is procedure for periodically replenishing reagents	1	SI/RR	There is no stock out of reagents	
		Description of reagents, kits and materials are maintained in the inventory log/register.	1	RR	Check for the inventory log having details of reagents , kits and material name, batch/Lot/Cat. no., date of receipt, date of expiry , date of entering into service etc	
Standard D3	**The facility provides safe, secure and comfortable environment to staff, patients and visitors.**					
ME D3.1	The facility provides adequate illumination level at workstation	Adequate illumination at work station	1	OB	Look for the presence of undesirable reflections and glare	
		Adequate illumination at sample collection area	1	OB	Look for the presence of undesirable reflections and glare	

		Adequate illumination at circulation area	1	OB	Check the illumination adequacy at the stairs	
ME D3.2	The facility has provision of restriction of visitors in IPHL	The access to laboratory's testing area is restricted to the laboratory staff only	1	OB	Look of restricted entry signage outside the testing areas Biohazard warning sign is placed at laboratory doors	
		Mycobacteriology and virology sections have controlled access entry	1	OB	Biohazard warning sign is placed at laboratory doors	
ME D3.3	The facility ensures safe and comfortable environment for service providers	Temperature control and ventilation in sample collection area	1	SI/RR	Fans/ Air conditioning/Heating/Exhaust/Ventilators as per environment condition and requirement	
		Temperature control and ventilation testing area	1	SI/RR	Fans/ Air conditioning/Heating/Exhaust/Ventilators as per environment condition and requirement	
		Availability of separate room for tissue processing	1	OB	1. For histopathology sections 2. Fume hoods are available	
		The facility has established measure for safety and security of female staff	1	SI	1. Ask female staff weather they feel secure at work place 2. No female staff is posted alone in the night 3. CASH committee is available (may be shared with	
		Pre-employment health check up is performed	1	SI/RR	Check with the records	
		The facility has Material Safety Data Sheets (MSDSs) for chemicals received by the laboratory	1	RR	MSDS sheets must contain: 1. Name of the chemical; 2. Manufacturer's information; 3. Hazardous ingredients/identity information; 4. Physical/chemical characteristics; 5. Fire and explosion hazard data; 6. Reactivity data; 7. Health hazard data; 8. Precautions for safe handling and use; and 9. Control measures.	
Standard D4	**The facility has established Programme for maintenance and upkeep of the facility**					
ME D4.1	Exterior of the facility building is maintained appropriately	Exterior of the building is plastered and painted	1	OB	1.Whitewashed in uniform colour 2. No outdated poster are pasted on the walls	
		Interior of the building is plastered & painted	1	OB	1.Whitewashed in uniform colour 2. No outdated poster/information/instruction are pasted on the walls	
ME D4.2	The facility is clean and hygienic	All areas are clean and without dirt, grease, littering and cobwebs	1	OB	Floors, walls, roof, roof topes, sinks, waiting, sample collection area and testing areas are neat and clean	
		Cleaning schedule is maintained	1	RR	1. May be shared with the main building 2. Regular inspection of cleaning work by designated person	
		Surface of furniture and fixtures are clean	1	OB	Check there is no dirt or grease on furniture	
		The facility has standard procedures for cleaning of curtains/blind & shades	1	OB/RR/SI	Check for: 1. Curtains/Blind & shades are cleaned regularly	
		Toilets are clean with functional flush and running water	1	OB	Check for: 1. Toilets in proximity to the sample collection area 2. Toilet in the staff area	
ME D4.3	Facility's infrastructure is adequately maintained	Check for there is no seepage , Cracks, chipping of plaster	1	OB		
		Window panes, doors and other fixtures are intact	1	OB		
		Periodic maintenance of the infrastructure is defined at the regular interval	1	RR/OB	Annual maintenance plan is available	
		There is no clogged/over flowing drain in facility	1	RR		
ME D4.4	The facility has policy of removal of condemned junk material	No condemned/Junk material in the lab	1	OB	1. Sample collection area 2. Processing area 3. Report collection area	
		Condemnation policy is at place	1	RR	Condemnation policy is available and staff is aware of it.	

		There is an established procedure for decommission , disposal and condemnation of the equipment if no longer in use	1	SI/OB	Decommissioning and disposal is carried out as per the manufacture instructions and as per the standard operating procedures	
ME D4.5	The facility has established procedures for pest, rodent and animal control	No stray animal/rodent/birds in lab	1	OB	1. Pest control measures are taken at regular interva 2. Anti-termite measures are taken	
Standard D5	**The facility ensures 24X7 water and power backup as per requirement of service delivery, and support services norms**					
ME D5.1	The facility has adequate arrangement storage and supply for potable water in all functional areas	Availability of 24x7 running and potable water	1	OB/SI	RO/filter water is available for drinking in sample collection and/or report collection area	
		Facility has adequate water storage facility as per requirements	1	OB/RR/SI	1. Provision to store at least three days of water requirement 2. Water tanks are cleaned at an interval of maximum three months	
		Facility periodically tests the quality of water from the source (municipal supply, bore well etc) for bacterial and chemical content	1	RR		
		Distilled deionised water is used for testing	1	OB		
		Water use for analytical purpose should be of reagent grade	1	OB		
ME D5.2	The facility ensures adequate power backup in all patient care areas as per load	Availability of power back up in laboratory	1	OB/SI	Check that UPS connection with critical equipment is providesd	
		Availability of noise less generator for the power backup	1	OB	May be shared with the main hospital building	
Standard D6	**The facility ensures support to all linked labs as per service mandate**					
ME D6.1	The facility has established procedure for providing technical support to linked labs	All spoke units are identified & downward linkage is established for tests	1	RR/SI	Check the list of linked Block Public Health Laboratories and other peripheral laboratories is available	
		Regional/state/medical college are identified & upward linkage is established for tests not conducted at IPHL	1	RR/SI	Facilities are identified for upward linkages and staff is aware of it	
		Check routine testing and public health related testing is integrated	1	RR/SI	1. Restructuring of routine and public health diagnostics is done and its functional 2. Check there is no duplication of diagnostic services	
		There is established system of integration between health and other departments	1	RR/SI	Check for established linkage between IPHL and other laboratories under various departments like Central Pollution Control Board (CPCB), FSSAI, PHED, veterinary, forensic department, etc.	
ME D6.2	The facility has established procedure for providing capacity building support to linked labs	The facility provides capacity building support to the linked labs	1	RR/OB	Check for 1. Conduct training for hub and peripheral laboratory staff 2. Check the records for type and number of trainings	
ME D6.3	The facility has established procedure for providing information management support using digital technology to linked labs and administrative authorities	The facility has functional Laboratory Information Management System (LIMS) to provides information regarding samples	1	RR/SI	1. Information regarding samples received in IPHL or sent to regional/state lab are recorded & updated for all samples including in-house samples 2. Randomly, select at least 5 samples and check for details	
		The facility has established system to report test results	1	RR/PI	1. Reports are sent via Hospital Information System, email, SMS, etc. to the patient 2. Randomly, select at least 5 samples and check for details	
		The facility has functional Laboratory Information Management System (LIMS) for data management	1	RR/SI	LIMS support all the information management functions like data collection, storage, archiving for analysis, research, information, and policy decisions to detect, prevent and respond to public health	
		There is an established linkage with Integrated Health Information Platform (IHIP)	1	RR/SI	Check for functional linkage between IPHL with IHIP to support surveillance and managing outbreaks	
Standard D7	**Facility has defined and established procedures for Financial Management**					
ME D7.1	The facility ensures the proper utilization of fund providesd to it	There is system to track and ensure that funds are received on time	1	RR/SI	As given under PM-ABHIM, XV-Finance Commission, etc.	
		Funds/Grants providesd are utilized in specific time limit	1	RR	As given under PM-ABHIM, XV-Finance Commission, etc.	

		Salary and compensation of contractual staff is given on time	1	SI		
ME D7.2	The facility ensures proper planning and requisition of resources based on its need	Facility prioritize the resource available	1	RR/SI	Requirement for funds are sent to state on time	
		Utilisation certificate is submitted on time	1	RR/SI		
Standard D8	**Facility is compliant with all statutory and regulatory requirement imposed by local, state or central government**					
ME D8.1	The facility has requisite licences and certificates for operation of facility and different activities	Availability of valid No objection Certificate from fire safety authority	1	RR	Give full compliance if the facility shares fire NoC with main hospital building	
		Availability of Biomedical Waste Management Authorisation for generating BMW as per prevalent norms/regulations	1	RR	Give full compliance if the facility shares BMW authorisation with main hospital building	
		Availability of certificate of inspection of electrical installation	1	RR		
		The facility ensure relevant processes are in compliance with statutory requirement	1	RR	Any positive report of notifiable disease is intimated to designated authorities	
ME D8.2	Updated copies of relevant laws, regulations and government orders are available at the facility	Availability of copy of Bio medical waste management rules 2016 and it's subsequent amendments	1	RR	Updated copy is available	
		Code of Medical ethics 2002	1	RR	Updated copy is available	
		Person with disability Act 1995	1	RR	Updated copy is available	
		Right to information act 2005	1	RR	Updated copy is available	
		Indian Tobacco control Act 2003	1	RR	Updated copy is available	
		HIV/AIDS prevention and control Act	1		With mandatory provision of pre and post test counselling)	Infectious Disease notification act or rule
Standard D9	**Roles & Responsibilities of administrative and clinical staff are determined as per govt. regulations and standards operating procedures.**					
ME D9.1	The facility has established job description as per govt guidelines	Staff is aware of their role and responsibilities	1	SI	Check lab staff is aware of their roles and responsibilities	
		Job description of staff is defined and communicated	1	SI/RR	Both regular and contractual staff	
ME D9.2	The facility has a established procedure for duty roster and deputation	Duty roster of specialist is prepared, updated and communicated	1	RR/SI	Check for system for recording time of reporting and relieving (Attendance register/ Biometrics etc)	
		Duty roster of lab technician is prepared, updated and communicated	1	RR/SI	Check for system for recording time of reporting and relieving (Attendance register/ Biometrics etc)	
		Duty roster of other staff is prepared, updated and communicated	1	RR/SI	1. Housekeeping staff, security staff, data entry operator, etc. may be shared with the main hospital building 2. Check for system for recording time of reporting and relieving (Attendance register/ Biometrics etc)	
		There is designated in charge for IPHL	1	SI		
ME D9.3	The facility ensures the adherence to dress code as mandated by its administration /the health department	Specialist, technician and support staff adhere to their respective dress code	1	OB	As per the state's norms	
		The facility has established procedures for credentialing of staff	1	SI/RR	Check for: 1. Minimum professional qualification for each cadre of staff has been defined in accordance with NMC norms and respective professional councils 2. Professional qualifications and experience of the doctors have been verified before inducting them into the service 3. Formal screening of health professionals for skills and core competency have been done and	
Standard D10	**Facility has established procedure for monitoring the quality of outsourced services and adheres to contractual obligations**					

ME D10.1	There is established system for contract management for out sourced services	There is procedure to monitor the quality and adequacy of outsourced services on regular basis	1	SI/RR	Verification of outsourced services (cleaning/Laundry/Security/Maintenance) providesd are done by designated in-house staff	
		Selection of outsourced agencies is done through competitive tendering process	1	RR	1. May be shared with the main hospital 2. Review the contract document	
ME D10.2	There is a system of monitoring of quality of out sourced services	Facility as defined criteria for assessment of quality of outsourced services	1	RR	Check: 1. Regular monitoring and evaluation of staff is done against defined criteria 2. Actions are taken against non compliance/deviation from contractual obligations	
		Records of blacklisted vendors are available	1	RR	May be shared with the main hospital building	
Area of Concern - E Clinical Services						
Standard E1	**The laboratory has defined procedures for registration of Patients at the laboratory**					
ME E1.1	The facility has established procedure for registration of patients visiting lab or sample collection area	IPHL has defined procedure for registration of patient	1	RR	1. Area like OPD, IPD, Emergency and other critical areas of the hospital 2. Through HIS or Manual, if process is manual, details will be filled in LIMS by Data Entry Operator (DEO)	
		Test requisition is generated by qualified Physician	1	RR/OB	Electronic or on paper	
		Patient demographic details & unique identification no. are recorded in Test Requestion form	1	OB/RR	Check for: 1. Patient demographics like Name, age, Sex, Address, etc. are recorded 2. Time of sample collection is recorded 3. Details of sample received is mentioned (in-house lab or peripheral health facilities) 4. UID of all patients (IPD/OPD) assigned by hospital is mentioned on TRF	
		Sample ID no is assigned to patient samples for tracking the sample through lab	1	OB/RR	(1) Sample ID for each sample is generated manually/BAR Code form/ LIMS ID / HIS ID. (2) Check if sample ID is alpha and/or numerical identifier	
ME E1.2	The facility has established procedure for registration of the patient's sample received from spokes/peripheral labs	Each sample received at the laboratory is registered manually or through LIMS or HIS	1	RR/OB	1. From linked peripheral health facilities (HIS/Manual), if process is manual, details will be filled in LIMS by Data Entry Operator (DEO)	
		Patient demographic details and Unique laboratory identification number are recorded	1	RR/OB	1. Unique ID for each sample is generated manually/BAR Code form/ LIMS ID / HIS ID 2.Tests requested and referring lab/ clinician details are recorded at time of registration	
Standard E2	**Facility has established mechanism for referral linkages to maintain continuity of services**					
ME E2.1	Facility has defined and established procedures for continuity of services	Laboratory has established referral linkage for the sample transferred from the BPHL/peripheral facilities	1	RR/SI	For all routine diagnostic tests and tests mandated under National Health Programmes like IDSP, NACP, NTEP, NVBDCP, NVHCP etc.	
		Laboratory has functional upward referral linkage for tests not available at the facility	1	RR/SI	Laboratory has assured linkage with State PHL/ Medical college lab for the tests not being performed in the lab	
ME E2.2	The facility has defined and established procedures for intersectoral coordination	The facility coordinates with other allied departments for intersectoral convergence	1	RR/SI	Like Central Pollution Control Board, FSSAI, PHED, Veterinary, Forensic department, etc.	
Standard E3	**The facility has established and defined procedure for pre-testing activities**					
ME E3.1	The facility has established procedure for patient preparation	Procedure for the patient preparation is defined	1	OB/SI	Haematology, Biochemistry, Histopathology, Clinical Pathology, Microbiology, etc.	
		The patient is prepared before collecting the primary sample	1	RR/OB/SI	Check that the patients are educated for necessary instructions before sample collection specially where changes may take place due to physiological barriers	
		Check with patients if instructions are give to them before sample collection	1	OB/PI	Fasting blood sugar, cessation of drugs before sample collection like hormones, special timing of sample collection, etc. OR Advised patient to sit down till sweat subside - for electrolyte or S. protein OR Patient is advised to take balanced diet a night before- Urea and urates, etc.	
ME E3.2	The facility has established procedure for sample collection from patient care areas	Procedure for the sample collection is defined	1	OB/SI	Haematology, Biochemistry, Histopathology, Clinical Pathology, Microbiology, etc.	

		IPHL has defined mechanism for sample collection within the facility or from the peripheral health facilities	1	OB/SI	It includes: 1. Sample collected from OPD 2. Samples from IPD of the district hospital 3. Samples collected from spokes/peripheral facilities	
		Check steps to collect the sample are defined and followed by Phlebotomist	1	OB/SI	1. Assembly of required material 2. Pre collection verification of patient 3. Wear PPE 4. Determine site for venepuncture: Ante cubital area - most commonly 5. Labelling of the tubes 6. Venepuncture 7. Needle removal 8. Deliver blood in respective tubes 9. Disposal of sharp 10. Verification of sample & logging of any incident	
		The procedure for venepuncture is defined and followed	1	OB/SI	1. Labelling of tubes 2. Patient is comfortable and seated on chair 3. Proper positioning of patient's arm 4. Apply torniquet with 3-inch clearance above the planned puncture site 5. Clean the venepuncture site with 30% isopropyl swab 6. Allow it to dry 7. Alert the patient before the venepuncture, ask the patient to clinch the fist and tell them to relax, make sure patient arm is in downward position 8. Smoothly insert the needle with bevel at 15-30 degree of angle 9. Remove the torniquet as soon as the blood begin	
		Sample collection for the blood culture is done as per the standard guidelines	1	OB/SI	a. Acute febrile episodes-two sets from different sites within 10 min b. Non-acute disease- 2 to 3 sets from different sites within 24 hrs, Interval not closer before 3 hrs c. Acute endocarditis- 3 sets from 3 different sites within 1-2 hr Samples are collected before use of antimicrobials	
		Staff is aware of blood culture volume requirements as per standard guidelines	1	OB/SI	1. Collection of two sets of culture using 10-20 ml blood per culture for adults 2. Blood culture volume requirement for infant and children, as per facility's guidelines	
		Sample collection other than blood is done as per protocol	1	OB/SI	Urine, Sputum, Stool, etc.	
		Order of draw, mixing and inversion are defined and followed	1	OB/SI	As per the facility's instruction Samples containing additives are mixed by inverting, ensure no shaking of the tubes	
		Instructions for collection and handling of primary sample are communicated to those responsible for collection	1	RR/SI	Check that the staff is aware of sample collection instructions like order of draw, volume of sample for different type of tests, sample collection instructions for different age group and sample collection from patients admitted in critical care unit, etc.	
		Laboratory has system to record the identity of person collecting the primary sample	1	RR/SI	Check the records for the details of person collecting the sample: 1. at sample collection area 2. for IPDs and other departments	
		Check closed or evacuated system of blood sample collection is used	1	OB/SI	Check closed system- needle, holder and evacuated tubes are used for sample collection	
		Check Phlebotomist is aware of the choice of needle gauge, site selection in vulnerable patients.	1	OB/SI	Neonates, paediatric, elderly and patients with small veins	
		Staff is trained for handling the emergency in case of any complication raised during sample collection	1	RR/SI	1. Staff is trained on BLS protocols and management of hypovolemic shock 2. Availability of emergency drug tray/crash cart 3. Immediate transport of the patient to emergency or linkage with the ambulance for patient's referral, if required	
ME E3.3	The facility has established procedure for sample labelling and documentation	Samples are labelled with at least two unique identifiers	1	RR/OB	Identifiers may include (but not limited to): Patient's name, Age, Gender, Patient unique id, Name of the test requested, time and date of sample collection or bar codes	
		Laboratory has system to trace the primary sample from requisition form	1	RR/OB/SI	Check that Patient's name/unique id of the sample is verified at each working station	

ME E3.4	The facility has a standardised Test Requisition form for the tests	Requisition of all laboratory test is given in standardised requisition form	1	RR/OB/SI	1. Requisition form contain information: Name and identification number of patient, name of authorized requester, type of primary sample, investigation requested, date and time of primary sample collection, signature of the primary sample collector and time of receipt of sample by laboratory 2. Check randomly in 1% of requisition forms for uniform data collection	
ME E3.5	The facility has established procedure for packaging and transportation of samples	Procedures are defined for packaging and transportation of samples	1	OB/SI	Haematology, Biochemistry, Histopathology, Clinical Pathology, Microbiology, etc.	
		Collected samples are packed as per the standard guidelines	1	OB	1. Samples are collected in vacutainers as per the guidelines 2. Samples are packed in triple layered container packing (particularly virology) 3. Check 1% of the samples received from the periphery and sample collection area	
		Laboratory has system in place to monitor the transportation of the sample within the facility and the peripheral facilities	1	RR/OB/SI	Transportation of sample includes: Analyte stability, temperature requirement, preservation (if any), photosensitivity (if any), time frame, special packaging requirement to avoid leakage, safety of the personnel handling the sample, tracking system for samples, etc. For infectious sample, categories are defined based	
		Samples are transported timely at the IPHL	1	OB/RR	Check for: 1. Samples are picked on the same day 2. Cumulative sample transportation time from all the spokes/peripheral health facilities to the primary receiving hub laboratory should not exceed 2 hours (starting from the point of pick-up) 3. Samples should be picked up once a day from PHCs, and twice a day from CHCs/FRUs, depending on the patient load	
		There is a defined protocol for pick-up of emergency samples	1	OB/SI	1. Pick-up of emergency samples (as per the clinical judgement of Medical Officer) is done within 1 hour from CHCs. 2. The reason for emergency sample pick up is documented by the medical officer in test requisition	
		The sample dispatch time is recorded electronically in the LIMS	1	OB/RR	Check real time data entry in the LIMS	
ME E3.6	The facility has defined criteria for sample acceptance or rejection	Check criteria is defined for sample acceptance and followed	1	RR/OB/SI	Checks staff is aware of sample acceptance criteria which include appropriate container, quantity/volum e (in case of blood/urine sample), temperature on receipt, quality of sample (in case of tissue samples), any leakage, etc. As per standard guidelines of Haematology,	
		There is defined procedure for sample acceptance of in-house samples	1	OB/SI	1. Accompanied by TRF, 2. Unequivocal traceability by request and labelling, patient UID and sample ID, 3. recording of the date and time of the receipt of the sample, 4. technician or authorised person evaluate the sample against the acceptance criteria The facility may use department-wise checklist for sample acceptance, if any	
		There is defined procedure of sample acceptance for samples received from the spokes/peripheral health facilities	1	OB/SI	1. Accompanied by TRF, 2. Unpack the patient sample and match it with TRF, if there is any inconsistency in sample label and request form then procedure is defined to deal with the discrepancies 3. Recording of the date and time of the receipt of the sample, 4. Sample colour appearance and volume are noted in TRF 5. Record sample ID no and patient information in	
		Sample preparation as per defined protocols	1	OB/SI	Check the staff is aware of normogram	

		Check criteria is defined for sample rejection and followed	1	RR/OB/SI	1. Checks staff is aware of sample rejection criteria which include Unlabelled sample, incomplete or mislabelled sample, incorrect container or preservative, insufficient sample, excessive delay in receiving the sample, leaking container, sub-optimal sample/haemolysed sample, specimen contaminated with biohazard material, Prolonged transport time 2. Check record is maintained for rejected samples along with the reasoning 3. In case of emergency, testing is performed and result is given stating that sample is compromised so may be co-related clinically As per standard guidelines of Haematology,	
		There is a defined set of activities post sample rejection	1	RR/OB/SI	Check that: 1. Primary sample collector is informed 2. Request for another sample is placed 3. Records of rejected samples are maintained 4. Rejected sample is retained based on preset	
Standard E4	**The facility has established and defined procedure for testing activities**					
ME E4.1	Facility performs tests as per established procedure	The facility performs tests as per established procedure/test kit instructions/programme specific guidelines	1	RR/SI	Laboratory has kept the list of procedure for conducting each test. Test procedure includes: Name, Scope, Purpose of examination, Method of Procedure, Reagents, equipment, glassware required, Procedural Steps, etc.	
ME E4.2	Test procedures are verified through routine quality control methods	Quality control mechanisms are defined for all test procedures	1	RR/SI	Haematology, Biochemistry, Histopathology, Clinical Pathology, Microbiology, Cytology, etc.	
		All test procedures are verified and validated before routine use	1	RR/SI	1. Check for records for validation and verification in terms of performance characteristics of quality control method like: Precision, Accuracy, Range / Analytical Measurement Range (AMR), Clinical Reportable Range (CRR) – when sample is diluted to report higher values not covered by AMR, Analytical Sensitivity, Analytical Specificity 2. For Rapid Diagnostic Tests as per manufacturer's	
ME E4.3	Facility has established procedure for Biological reference intervals & critical alert values	Critical values are defined for each specialization	1	RR/SI	Check that: 1. Staff is aware of critical values 2. Critical Values are displayed / filed for ready reference in the laboratory	
		There is an established procedure of reporting the critical alert values	1	RR/SI	Critical result reporting register including register having details of : Date, time, test details, result details, responsible laboratory staff and person notified are maintained at laboratory	
		Laboratory has defined and updated its Biological Reference Interval (BRI) and has a procedure to review the BRI	1	RR/SI	1. Procedure for establishing the BRI is documented 2. BRI is updated annually and communicated to the staff whenever there is change procedure/ method of testing 3. Check for updated BRI or clinical normative range	
Standard E5	**Laboratory has defined and established procedure for the post testing processes**					
ME E5.1	The facility has established procedure for reporting of result	The facility has a standardised format for reporting of result	1	RR/OB	Reports of the results include: Name and Unique Patient Identification Number, Date and Time of Specimen Collection, Date and Time of Test done and result reported, Name and address of the Laboratory, Name/Source of sample (e.g. – whole blood, urine etc.), Name of doctor and referee facility, Interpretation of results, method, measurement units (SI) and biological reference interval or clinical decision limit or cut-off values (as applicable), Duly signed by authorised signatory, identification of the person releasing the report, page number of total number of the pages	
		All the results are reviewed by authorised person	1	RR/OB	By technically competent and experienced designated person	
		Interim results are followed by the final reports	1	RR	Any preliminary report generated for urgent sampling, critical result intimation is followed by the final report signed by authorised signatory	
		Reports are validated by authorised person	1	RR	Microbiologist/Pathologist/Biochemist	
		The Laboratory defines the Turn Around Time (TAT) for each test both for the routine and emergency cases	1	RR/SI	TAT for each test is defined and is communicated to the patient in form of display or information material	
		IPHL has defined protocol for release of the results	1	OB/SI	Through LIMS/SMS/e-mail/hard copy	
		Staff is designated to disseminate the reports	1	OB/SI	In IPDs and other areas of the hospital	

		Staff is aware of post analytical error	1	OB/SI	Like inadequate, ambiguous report, improper data entry and manual transcription error (if LIMS is not functional), failure or delay in reporting critical values, inadequate or incorrect interpretation, validation of errors in data, improper retention of the sample, etc.	
		Reports are checked for transcription errors	1	SI/RR/OB	Tele equipment print out, workbook, datasheet with the report	
		Check notification is sent by lab in case of any delay in the reporting	1	OB/SI	Through LIMS/SMS/e-mail	
ME E5.2	The facility has established procedure for sample storage and its disposal	Samples are retained and stored for re sampling and additional examination as per standard guidelines	1	RR/SI	Check for sample retention protocols, storage conditions as mandated, record of storage is maintained, samples are labelled with time of preparation	
		Separate refrigerator is available for sample storage	1	OB	1.It is clearly mentioned on the refrigerator, "for samples only" or "for kits only" 2. Temperature is maintained for the retained samples as per the guidelines 3. System to identify the date of sample collection 4. If domestic refrigerator is used, calibrated thermometer is placed inside the refrigerator Check kits are not stored along with the samples	
		Indexing is done for all the retained samples	1	OB/SI	Retention time on the specimen as defined by the facility/locally prevalent norms in case of MLCs	
ME E5.3	The laboratory has defined procedure for revision/amendment of the reports when required	The laboratory has procedure to ensure review of results and correct interpretation before release of the results	1	RR/SI	Laboratory has clearly defined the responsibility of reviewing the test results	
		Laboratory has process of taking corrective actions for any discrepancy in the test result	1	RR/ SI	Check for the records of amendment in reports, recall of the reports whenever there is a issue related to the accuracy of the results during the review	
		Laboratory make revision/ amendments to the reports and reason of amendments of the report is documented	1	RR	1. Revision/ Amendments in the reports due to re-test/ re-sampling/ QC failure etc. are highlighted in the report. 2. Reason of amendments are documented along with the date of amendment 3. All the amended reports are stored by the laboratory in soft or hard copies	
Standard E6	**The facility has established mechanism for internal and external validation of testing procedures**					
ME E6.1	The facility has established mechanism of internal validation using quantitative methods	Internal Quality Control methods are defined for test performed in IPHL	1	RR/SI	Haematology, Microbiology, Cytology, Biochemistry, Histopathology, Clinical Pathology, etc.	
		The facility has defined performance evaluation mechanism for control material	1	RR/SI	1. Quantitative/Qualitative 2. Lyophilised/ready to use 3. Assay/unassay 4. First party/second party/third party 5. In-house/Commercial	
		Internal Quality Control is done on daily basis	1	RR/SI	Irrespective of size, lab should analyse IQC at two levels, - Two level of QCs once in the peak hour daily - One level every 8hrs (3 times a day)	
		Staff is aware of defined protocol for rejection of test run	1	RR/SI	1. When one level QC is used - Value is outside 3 SD - 2 consecutive values are outside 2 SD on the same side, but within 3 SD - 10 consecutive values or above or below the mean, but within 2 SD 2. When two level QC is used - Either QC value is outside 3 SD - Both QC values are outside 2 SD, but within 3SD/ difference between QC values is >4 SD - 10 consecutive values of the same level QC are above or below the mean, but within 2 SD - 5 consecutive values of one level & 5 consecutive values of the other level QC are above or below the mean, but within 2 SD	
		The facility has mechanism of internal validation in place when control material is not available	1	RR/SI	Check the mechanism for: 1. Retesting of any randomly chosen specimen/s 2. Replicate test of sample by different method, different machine and different person, whichever applicable	
		The facility plot Levy Jennings's (LJ) chart daily for Quality Control values	1	RR/SI	By using inbuilt software in the analysers or using excel sheet	
		Staff knows how to interpret the LJ chart	1	SI	Ask staff about test run rejection criteria as per the one or two level QC	

		Control charts are prepared and outliers are identified	1	RR/SI		
		Corrective action is taken on the identified outliers	1	RR/SI		
ME E6.2	The facility has established mechanism of internal validation using semi quantitative/qualitative methods	Quality assurance mechanisms are defined for all steps of microbiology	1	RR/SI	Bacteriology, Parasitology, Mycology, Serology, Molecular Diagnostics	
		Quality assurance mechanisms are defined for all steps of histopathology and cytology	1	RR/SI	To identify and manage the potential errors	
		IQC (Qualitative) are defined for all steps of Haematology and Clinical Pathology	1	RR/SI	Smears, ESR, Urine Analysis, Semen Analysis, Boddy fluid analysis like CSF	
ME E6.3	The facility has established mechanism of external validation	External Quality Assurance methods are defined for test performed in	1	RR/SI	Haematology, Microbiology, Cytology, Biochemistry, Histopathology, Clinical Pathology, etc.	
		IPHL has defined the ways to conduct external quality assurance	1	RR/SI	EQAS or Pear group comparison or exchange of sample or split testing	
		External Quality Assurance is done on regular basis	1	RR/SI	For monitoring, accuracy and calculating bias	
		providesrs are identified for Proficiency Testing/EQAS	1	RR/SI	Process for receiving the sample, analysis, sharing the result, evaluation of the result and notification of result is defined	
		EQAs reports are analysed and evaluated	1	RR/SI	Staff is aware of EQAS reporting system, how to evaluate, and compare	
		Staff knows how to interpret the PT/EQAS results	1	RR/SI	Z score/VIS score, etc.	
		Staff is aware about the acceptable performance criteria for the analytes	1	RR/SI	1. Target value +/- specified value 2. Percentage 3. PT group SD (2-3)	
		Corrective actions are taken on abnormal values/ Outliers	1	RR/SI	Errors are identified in pre-testing, testing, post-testing processes	
		Staff is aware of common errors commonly took place under EQAS	1	RR/SI	1. Incorrect units 2. Incorrect sample tested 3. Incorrect classification of testing methods 4. Improper reconstitution 5. Transcription errors	
		External quality assurance program implemented as per NTEP program	1	RR/SI	1. Onsite evaluation done monthly 2. Random Blinded rechecking (RBRC) done monthly	
		External quality assurance program implemented for NVBDCP	1	RR/SI		
		External quality assurance under NACP	1	RR/SI		
Standard E7	**Facility has defined and established procedures for maintaining, updating of patients' clinical records and their storage**					
ME E7.1	Adequate form and formats are available at point of use	Standard Formats available	1	RR/OB	Printed formats for requisition, consent and reporting are available	
ME E7.2	Register/records are maintained as per guidelines	All records are labelled and indexed	1	RR	All the Laboratory records have unique Id number as per document control policy of the facility. The records can be maintained as physical copies or electronically (LIMS)	
		Records and registers are maintained for laboratory	1	RR	Test registers, IQAS/EQAS Registers, Expenditure registers, Accession list etc.	
		Facility maintains the records of the samples being sent/received to/from the referral laboratory	1	RR	The records can be maintained as physical copies or electronically (LIMS)	
ME E7.3	The facility has established computerised information system to support lab functions	The facility has established Laboratory Information Management System (LIMS) to support lab functions	1	OB/RR	Look for the availability of following information through functional LIMS/HIS: 1. Samples tracking from collection to reporting 2. Reporting of test result 3. Collection, storage, archiving and analysing laboratory data for decision making 4. Reporting of analysed data to district and state administration, Ministry of Health & Family Welfare 5. Inventory management (kits and reagents etc.) If IPHL maintains paper based records, check work flow, quality and audit trail for the sample processed	

		Facility has defined policy for retrieval and archiving of digital records	1	OB/SI/RR	As per state policy	
ME E7.4	The facility ensures safe and adequate storage and retrieval of medical records	Laboratory has adequate facility for storage of records	1	OB	Check the mechanism of storage (physical copies/electronic copies)	
		Safe keeping of patient records	1	OB	Check that: 1. System clearly define who all are authorized to access the patient's physical/electronic information 2. Access is limited to authorised person only both for physical records or Password/finger print protected computer system 3. Check records are easy to retrieve 4. Any restriction/firewall to protect the individual's information from mis-use in case of LIMS	
		The facility has policy for retention period for different information & records	1	SI/RR	As per state policy	
		Facility has defined policy for records retrieval	1	SI/RR	Check the policy for both manual and electronic records as per state policy	
Standard E8	**The facility has defined and established procedures for Emergency Services and Disaster Management**					
ME E8.1	The facility has disaster management plan in place	Staff is aware of disaster plan	1	SI/RR	Check disaster management committee is at place and IPHL takes part in regular mock drills	
		Role and responsibilities of staff is defined	1	SI/RR	Check staff is aware of their role during disaster/mass causality situation	
		Emergency protocols are defined and implemented	1	SI/RR	Check the availability and awareness for managing the functionality of lab during emergencies such as fire, spill, etc.	
ME E8.2	There is procedure for handling legal cases	Samples of legal cases are identified	1	SI/RR	1. Requisition and reports are marked with MLC 2. Reports are handed over to authorized personnel only 3. Records are kept confidential	
Standard E9	**Facility provides National health program as per operational/Clinical Guidelines**					
ME E9.1	The facility has established procedure for services under various communicable disease programmes	There are established procedures for laboratory diagnosis of Tuberculosis as per prevalent guidelines	1	RR/SI	As per programmatic guidelines	
		There are established procedures for laboratory diagnosis of AIDS as per prevalent guidelines	1	RR/SI	including opportunistic infections	
		There are established procedures for laboratory diagnosis of Leprosy as per prevalent guidelines	1	RR/SI	As per programmatic guidelines	
		There are established procedures for laboratory diagnosis of viral hepatitis as per prevalent guidelines	1	RR/SI	As per programmatic guidelines	
		There are established procedures for laboratory diagnosis of Malaria as per	1	RR/SI	As per programmatic guidelines	
		There are established procedures for laboratory diagnosis of integrated vector-borne diseases as per prevalent guidelines	1	RR/SI	Filaria, Kala-azar, Dengue, Chikungunya, Zika and Japaneese Encephalitis	
ME E9.2	The facility has established procedure for services under various non-communicable disease programmes	There are established procedures for laboratory diagnosis of non-communicable diseases (hypertension, diabetes) as per prevalent guidelines	1	RR/SI	As per programmatic guidelines	
ME E9.3	Facility provides service for Integrated disease surveillance program/Integrated Health Information Platform (IHIP)	Weekly reporting of Confirmed cases on form "L" from laboratory	1	SI/RR	1. Data is submitted manually or through IHIP (integrated health information platform) 2. Collected data is analysed from BPHU or other peripheral health facilities	
		Systematic collection, analysis and interpretation of disease specific data	1	SI/RR	For surveillance and outbreak monitoring	
		IPHL provides support for surveillance to other departments during outbreak	1	SI/RR	Support specific sampling for air, water, soil/faeces, food, samples from animals, etc.	
Area of Concern - F Infection Control						
Standard F1	**Facility has infection prevention control program and procedures in place**					

ME F1.1	Facility has functional infection control committee and has a defined procedure to review the infection prevention and control practices	Infection control committee is constitute at the facility	1	RR	1. May be shared with the main hospital building (as per the MoHFW guideline) 2. ICC is approved by appropriate authority	
		Roles and responsibilities are defined and communicated to its members	1	RR/SI	IPHL staff is aware of their roles and responsibility	
		ICC meet at periodic time interval	1	SI/RR	1. Meetings are conducted Monthly, 2. Records of Infection control activities are maintained 3. Check analysis of Infection Control activities is	
ME F1.2	Facility has established procedures for regular monitoring of infection control practices	Regular monitoring of Standard precautions for infection control	1	RR	Like Hand Hygiene Audit, BMW practices, adherence with standard practices of PPE, etc.	
		IPHL supports District hospital and peripheral facilities in HAI surveillance	1	RR	1. Defined format for requisition and reporting of HAIs 2. Report of the surveillance are collated, analysed and shared with concerned health facility	
		IPHL has defined process for collection of samples for active HAI surveillance	1	RR	Like SSI, CAUTI, CLABSI, VAP, air or surface culture	
		Feedback is given to the respective health facility	1	RR/SI	Action plan is shared and discussed with concerned health facility	
ME F1.3	There is Provision of Periodic Medical Check-ups and immunization of staff	There is procedure for immunization of the staff as per schedule	1	RR/SI	Hepatitis B, Td, etc.	
		Periodic medical check-ups of the staff	1	RR/SI	At least once in a year	
Standard F2	**Facility has defined and Implemented procedures for ensuring hand hygiene practices and antisepsis**					
ME F2.1	Hand washing facilities are providesd at point of use	Availability of hand washing Facility at Point of Use	1	OB	1. Check for availability of wash basin near the point of use, ensure sink is functional 2. Elbow-operated taps are available	
		Facility ensures availability of antiseptic soap/liquid at point of use	1	OB	1. Check for availability/ Ask staff if the supply is adequate and uninterrupted 2. Contact time, 40-60 sec	
		Availability and use of alcohol hand rub	1	OB	1. Preferred method, except when hands are visibly soiled or after caring a patient with known or suspected diarrhoea 2. Contact time, at east 20-30 sec	
		Display of Hand washing Instruction at Point of Use	1	OB	Prominently displayed above the hand washing facility , preferably in Local language	
		Hand washing sink is wide and deep enough	1	OB	To prevent splashing and retention of water	
ME F2.2	Staff is trained and adhere to standard hand washing practices	Adherence to steps of Hand washing	1	OB/SI	Ask for demonstration	
		Staff aware of when to hand wash	1	OB/SI	Ask for 5 moments of hand washing	
ME F2.3	Facility ensures standard practices and materials for antisepsis	Facility ensures uninterrupted and adequate supply of antiseptics	1	OB	Check for regular supply	
		Proper cleaning of testing site as per procedure	1	OB		
Standard F3	**Facility ensures standard practices and materials for Personal protection**					
ME F3.1	Facility ensures adequate personal protection equipment's as per requirements	Availability of personal protective equipment at point of use	1	OB/SI	Gloves, Mask, Head caps, Shoe cover, Apron, N-95 respirators, Gum boots, Eye covers, etc.	
		Facility ensures adequate and regular supply of personal protective equipment	1	OB/SI	Ask the staff about regular availability of PPE	
ME F3.2	Staff adhere to standard personal protection practices	No reuse of disposable gloves and Masks	1	OB	Ask the staff that PPE is not reused like cap, Mask, Gloves, Apron, N-95 respirators etc.	
		Compliance to correct method of wearing and removing the PPE	1	SI/OB	Check for adherence to Donning & Doffing of PPE	
		Staff is aware about appropriate selection of PPE	1	SI/OB	like size, fit and proper selection based on nature of patient interaction and potential exposure to hazard with respect to area of working, e.g. face shield or chemical splash goggles in case of chemicals	

		Staff do pre-and post-inspection activity for PPE usage	1	SI/OB	1. Gloves for cracks, cuts, punctures, thin areas, discoloration 2. Goggles for scratch, chips, elasticity of headband 3. Boots for cuts, holes, teared	
Standard F4	**Facility has standard Procedures for processing of equipment's and instruments**					
ME F4.1	Facility ensures standard practices and materials for decontamination and cleaning of instruments and procedures areas	Cleaning of equipment is done as per guidelines	1	OB/SI	Haematology analyser, ESR analyser, Biochemistry analyser, electrolyte analyser, chlorometer, High pressure liquid chromatography, histopathology and other diagnostic equipment's, etc.	
		Cleaning of reusable items is done as per guidelines	1	OB/SI	Test tubes, Petri dishes, Micropipettes, Glass slides, racks, etc.	
		Decontamination of operating & Procedure surfaces	1	OB/SI	Ask staff about how they decontaminate work benches (Wiping with 0.5% Chlorine solution)	
		Equipment are decontaminated before reuse	1	OB/SI	As per manufacturer's guidelines	
ME F4.2	Facility ensures standard practices and materials for disinfection and sterilization of instruments and equipment's	Disinfection and sterilization of reusable items	1	OB/SI	Disinfection by hot air oven at 160 degree Celsius for 1 hour	
		Autoclave is used for culture media and other infected material	1	OB/SI		
Standard F5	**Physical layout and environmental control of the laboratory ensures infection prevention**					
ME F5.1	Layout of the lab is conducive for the infection prevention and control practices	Facility layout ensures separation of infectious patient at sample collection area	1	OB	1. Separate area for TB sample collection 2. Patient with acute febrile respiratory symptoms are placed at least 1m away	
		Respiratory hygiene and cough etiquettes posters are displayed	1	OB	Collection area and report receiving area	
		Facility layout ensures separation of each operating area	1	OB	Microbiology, Mycobacteriology (TB) and Molecular diagnostic lab are separated from rest of the laboratories through an access controlled entry	
		Facility layout ensures separate routes for clean and dirty items	1	OB		
		Floors and wall surfaces are easily cleanable	1	OB	Look for non-slippery floor (or epoxy grout in tiles), surfaces should be smooth & washable, seamless and impervious with sealed or welded joints	
		No fabrics or carpeting is in the laboratory	1	OB		
ME F5.2	Facility ensures availability of standard materials for cleaning and disinfection	Availability of disinfectant as per requirement	1	RR/SI	Sodium Hypochlorite, 70% Isopropyl alcohol, Phenolic compound	
		Availability of cleaning agent as per requirement	1	RR/SI	Hospital grade phenyl, disinfectant detergent solution	
		Staff know how to use cleaning solution	1	SI	Cleaning material is prepared and used as per manufacturer guidelines	
ME F5.3	Facility ensures standard practices followed for cleaning and disinfection	Staff is aware of blood spill management	1	SI	Depend upon the size of the spill, manage as per the guidelines	
		Staff is aware of microbiological spill management	1	SI	As per the guidelines	
		Three bucket system is used for cleaning of lab	1	OB	Damp mop with detergent and water followed by disinfection with 0.5% chlorine	
		Standard practice of mopping and scrubbing are followed	1	OB	Unidirectional mopping from inside out	
		Ensure used mops should be clean appropriately	1	OB/SI	Soak in 0.5% chloring solution for 30 min followed by washing with detergent	
		Cleaning equipment's like broom are not used in patient care areas	1	OB	Any cleaning equipment leading to dispersion of dust particles in air should be avoided	
ME F5.4	Facility ensures air quality of high risk area	Negative Pressure in lab	1	OB	1. Check at Highly infectious area like Mycobacteriology & Virology maintained negative pressure -2.5Pa (Particularly for TB containment lab -12.5Pa) 2. HEPA filter H13-14/99.7% efficiency with air flow speed 25-35 FPM 3. Humidity 45-65%	

		Adequate air exchanges are maintained	1	OB	1. Check separate ductless AHU is present at Mycobacteriology & Virology lab 2. Required number of Air exchange is 12-15	
		HVAC system is in place	1	OB	Other than mycobacteriology and virology	
Standard F6	**Facility has defined and established procedures for segregation, collection, treatment and disposal of Bio Medical and hazardous Waste.**					
ME F6.1	Facility ensures segregation of Bio Medical Waste as per guidelines	Availability of colour coded bins and liners at point of waste generation	1	OB	Check the availability at pre-testing, testing and post-testing areas in terms of: *Adequate number *Covered *Foot operated * Liners are non-chlorinated	
		Segregation of Anatomical and soiled waste in Yellow Bin	1	OB/SI	Human Anatomical waste, Items contaminated with blood, body fluids, dressings, cotton swabs, lab culture, specimen of microorganism, dishes used for culture, routine mask and gowns	
		Segregation of infected plastic waste in red bin	1	OB/SI	Items such as tubing, bottles, intravenous tubes and sets, syringes (without needles and fixed needle syringes) and vacutainers with their needles cut) and gloves,	
		Display of work instructions for segregation and handling of Biomedical waste	1	OB	Pictorial and in local language	
		There is no mixing of infectious and general waste	1	OB	Sample Collection area, testing area	
		Check bins are not overfilled	1	OB	Bins/liners are filled up to 2/3rd of its capacity in sample collection and testing area	
ME F6.2	Facility ensures management of sharps as per guidelines	Availability of functional needle cutters	1	OB	At point of use	
		Segregation of sharps waste including Metals in white (translucent) Puncture proof, Leak proof, tamper proof containers	1	OB/SI	Needles, blades, discarded or contaminated metal sharp	
		Used slides are disinfected before disposal	1	OB/SI	NTEP-slides are disinfected with 5% phenol/40% phenolic compound/phenolic compound	
		Availability of post exposure prophylaxis	1	SI/OB/RR	* Hepatitis B vaccination to all staff with occupational exposure to blood and body fluids * Sero-protection is verified after completion of the three dose vaccination series i.e. antibodies to HBsAg at least 10mlu/ml * Fourth dose is offered if antibody titre below 10mlu/ml	
		There is a mechanism to report the injuries or unusual incidences	1	RR/SI	All the injuries (needle-stick injury, chemical or blood splash, etc.) or unusual incidences are reported to the supervisor	
		Staff knows what to do in condition of needle stick injury	1	SI	As per NACO guidelines	
		Contaminated and broken Glass are disposed in puncture proof and leak proof box/ container with Blue colour marking	1	OB/SI	Slides, petri dishes, etc.	
ME F6.3	Facility ensures transportation and disposal of waste as per guidelines	Discarded samples are pre treated before disposal	1	OB/SI	Pre treat to sterilize with non chlorinated checmicals onsite , as per WHO guidelines on safe management of waste from HCFs, therafter sent for incineration	
		Disposal of biomedical waste as per guidelines	1	OB/SI	As per latest BMW rules	
		Transportation of bio medical waste is done in close container/trolley	1	OB/SI	Check biohazard signs are displayed on bins as well as trolley used for waste transportation	
		Storage & Transportation e-waste	1	OB/SI	Check storage and transportation of e-waste to recyclers done as per CPCB guidelines	
ME F6.4	Facility ensures management of liquid waste as per guidelines	Disinfection of liquid waste before disposal	1	OB/SI	as per the standards of liquid waste-current BMW guidelines	
		Availability of functional effluent treatment plant	1	OB/SI	check lab is well connected to ETP	
Area of Concern - G Quality Management						
Standard G1	**The facility has defined mission, vision, values, quality policy and objectives, and prepares a strategic plan to achieve them**					
ME G1.1	Facility has defined mission & vision statement	Vision and mission statement have been defined adequately	1	RR/SI	As per state and national health policy May be shared with the main hospital	

ME G1.2	Facility has defined core values of the organization	Core values of the facilities are defined	1	RR/SI	Check if core values of organization such as non discrimination, transparency, ethical clinical practices, competence etc have been defined. May be shared with the main hospital	
ME G1.3	Facility has defined Quality policy, which is in congruency with the mission & vision of facility	Quality Policy is defined and approved	1	RR/SI	Check quality policy of the facility has been defined in consultation with hospital staff and duly approved by the head of the facility . Also check Quality Policy enables achievement of mission of the facility and health department	
ME G1.4	Facility has defined quality objectives to achieve mission, vision and quality policy	SMART Quality Objectives have framed	1	RR/SI	Check short term valid quality objectivities have been framed addressing key quality issues in each department and cores services. Check if these objectives are Specific, Measurable, Attainable, Relevant and Time Bound.	
ME G1.5	Mission, Vision, Values, Quality policy and Objectives are effectively communicated to staff and users of services	Check of staff is aware of Mission , Values, Quality Policy and objectives	1	RR/SI	Interview with staff for their awareness. Check if Mission Statement, Core Values and Quality Policy is displayed prominently in local language at Key Points	
ME G1.6	Facility prepares strategic plan to achieve mission, vision, quality policy and objectives	Check if plan for implementing quality policy and objectives have prepared	1	RR/SI	Verify with records that a time bound action plan has been prepared to achieve quality policy and objectives in consultation with hospital staff . Check if the plan has been approved by the hospital management	
ME G1.7	Facility periodically reviews the progress of strategic plan towards mission, vision, policy and objectives	Check time bound action plan is being reviewed at regular time interval	1	RR/SI	Review the records that action plan on quality objectives being reviewed at least once in month by departmental in charges and during the quality team meeting. The progress on quality objectives have been recorded in Action Plan tracking sheet	
Standard G2	**The facility has established organizational framework for quality improvement**					
ME G2.1	The facility has a quality team in place	Quality circle has been formed in the Laboratory	1	RR/SI	Check if quality circle formed and functional with a designated nodal officer for quality	
		Team members are aware of their roles and responsibilities	1	RR/SI	Check staff is aware of roles and responsibilities in terms of quality activity in the facility	
ME G2.2	The facility reviews quality of its services at periodic intervals	Quality circle meets monthly and review the quality activities	1	RR/SI	Check the records	
		Minutes of meeting are recorded	1	RR/SI	1. Results for internal /External assessment are discussed in the meeting 2. Facility Quality indicators are reviewed in meeting	
		Progress on time bound action plan is reviewed	1	RR/SI	Check the meeting records	
		Follow up actions from previous meetings are reviewed	1	RR/SI	Check the meeting records	
Standard G3	**The facility has documented, implemented and updated Standard Operating Procedures for all key processes and support services**					
ME G3.1	Laboratory standard operating procedures are available	The facility has documented Quality system manual	1	RR/SI		
		The facility has documented lab safety manual	1	RR/SI		
		Standard operating procedure for the lab has been prepared and approved	1	RR/SI		
		Current version of SOP are available with process owner	1	RR/SI		
		Work instruction/clinical protocols are displayed	1	RR/OB		
ME G3.2	Standard Operating Procedures adequately describes process and procedures	Laboratory has documented process for Collection/receiving, handling and transportation of primary sample	1	RR/SI	Haematology, Microbiology, Cytology, Biochemistry, Histopathology, Clinical Pathology, etc.	work instructions
		Laboratory has documented process on acceptance and rejection of primary samples	1	RR/SI	Haematology, Microbiology, Cytology, Biochemistry, Histopathology, Clinical Pathology, etc.	
		Laboratory has documented procedure on receipt, labelling, processing and reporting of primary sample	1	RR/SI	Haematology, Microbiology, Cytology, Biochemistry, Histopathology, Clinical Pathology, etc.	

		Laboratory has documented procedure on receipt, labelling, processing and reporting of primary sample for emergency cases	1	RR/SI	Haematology, Microbiology, Cytology, Biochemistry, Histopathology, Clinical Pathology, etc.	
		Laboratory has documented system for storage of examined samples	1	RR/SI	Haematology, Microbiology, Cytology, Biochemistry, Histopathology, Clinical Pathology, etc.	
		Laboratory has documented system for testing activities	1	RR/SI	Haematology, Microbiology, Cytology, Biochemistry, Histopathology, Clinical Pathology, etc.	
		Laboratory has documented system for repeat tests due to analytical failure	1	RR/SI	Quantitative and Qualitative	
		Laboratory has documented validated procedure for examination of samples	1	RR/SI	Haematology, Microbiology, Cytology, Biochemistry, Histopathology, Clinical Pathology, etc.	
		Laboratory has documented biological reference intervals	1	RR/SI	Quantitative	
		Laboratory has documented critical reference values and procedure for immediate reporting of results	1	RR/SI	Haematology, Microbiology, Cytology, Biochemistry, Histopathology, Clinical Pathology, etc.	
		Laboratory has documented procedure for release of reports including details of who may release result and to whom	1	RR/SI	Haematology, Microbiology, Cytology, Biochemistry, Histopathology, Clinical Pathology, etc.	
		Laboratory has documented internal quality control system to verify the quality of results	1	RR/SI	Haematology, Microbiology, Cytology, Biochemistry, Histopathology, Clinical Pathology, etc.	
		Laboratory has documented External Quality assurance program	1	RR/SI	Haematology, Microbiology, Cytology, Biochemistry, Histopathology, Clinical Pathology, etc.	
		Laboratory has documented procedure for maintenance and calibration of equipment	1	RR/SI	Haematology, Microbiology, Cytology, Biochemistry, Histopathology, Clinical Pathology, etc.	
		Laboratory has documented procedure for validation of results of reagents, stains, media and kits etc. wherever required	1	RR/SI	Haematology, Microbiology, Cytology, Biochemistry, Histopathology, Clinical Pathology, etc.	
		Laboratory has documented system of resolution of complaints and other feedback received from stakeholders	1	RR/SI	Haematology, Microbiology, Cytology, Biochemistry, Histopathology, Clinical Pathology, etc.	
		Laboratory has documented system for storage, retaining and retrieval of laboratory records, primary sample, Examination sample and reports of results	1	RR/SI	Haematology, Microbiology, Cytology, Biochemistry, Histopathology, Clinical Pathology, etc.	
		Laboratory has documented procedure for internal audits	1	RR/SI	Haematology, Microbiology, Cytology, Biochemistry, Histopathology, Clinical Pathology, etc.	
		Laboratory has documented procedure for purchase of External services and supplies	1	RR/SI	Haematology, Microbiology, Cytology, Biochemistry, Histopathology, Clinical Pathology, etc.	
ME G3.3	The staff is trained and aware of the standard procedures written in the SOPs	Check staff is a aware of relevant part of SOPs	1	RR/SI	Haematology, Microbiology, Cytology, Biochemistry, Histopathology, Clinical Pathology, etc. in terms of pre-testing, testing and post-testing activities	
ME G3.4	The facility ensures documented policies and procedures are appropriately approved and controlled	Hospital has established procedure for drafting, reviewing, approving the Quality Management systems documents	1	RR/SI	(a) Check availability of requisition forms & formats for developing the required documents. A system in place to draft, review the QMS documents and approval to use the documents is given by appropriate authority. (b) Check the detailed procedure is mentioned in Quality Improvement manual and followed	
		Hospital has established procedure for controlling & updating the QMS documents	1	RR/SI	(a) Check all the QMS documents and records (both internal & external origin) are controlled. (b) Check the documents are updated as and when required	
		Hospitals has established system to provides identification number to the QMS documents and records	1	RR/SI	(a) Check system in place to retention and retrieval the all QMS documents (b) Check all documents have title, effective date, reference number etc and signed by competent authority (C) Check the system is meticulously followed in all departments	
		Master list of the documents and records is available	1	RR/SI	(a) Check master list of documents and records is maintained. (b) Check the list is updated.	

Standard G4	**The facility has established internal & external quality assurance programmes for laboratory functions**					
ME G4.1	The facility has established internal quality assurance programs for lab	Routine monitoring of lab and related areas is done by designated person	1	RR/SI	1. check the daily rounds are taken using daily round checklist 2. Corrections and corrective actions are taken immediately	
		Internal audit plan and schedule is prepared to conduct internal assessment of the lab	1	RR/SI	1. Check for annual audit plan as per defined intervals 2. Check internal audit schedule of last internal assessment 3. Check process is at place to communicate about	
		Person is identified to conduct internal and external assessment	1	RR/SI	1. Person is trained to coordinate the internal and external assessments' activities 2. Person is aware of their roles and responsibilities before, during and after the internal and external assessments	
		Internal assessors are identified	1	RR/SI	1. Internal assessors are trained to use the NQAS checklist	
		Internal assessment is done using NQAS checklist	1	RR/SI	1. Internal assessment is done at periodic interval 2. Records of internal assessment are maintained	
		Non-compliances are enumerated and recorded	1	RR/SI	Check the non compliances are presented & discussed during quality team meetings	
ME G4.2	The facility has established external quality assurance programs for lab	State assessment is done using NQAS checklist	1	RR/SI	1. Records of state assessment are maintained	
		Non-compliances are enumerated and recorded	1	RR/SI	Check the non compliances are presented & discussed during quality team meetings	
ME G4.3	Actions are planned to address gaps observed during quality assurance process	Check action plans are prepared and implemented as per internal/state/national/surveillance assessment record findings	1	RR/SI	Randomly check the details of action, responsibility, time line and feedback mechanism	
ME G4.4	Planned actions are implemented through Quality Improvement Cycles (PDCA)	Check PDCA or relevant quality method is used to take corrective and preventive action	1	RR/SI	Check actions have been taken to close the gap. It can be in form of action taken report or Quality Improvement (PDCA) project report	
Standard G 5	**The facility seeks continual improvement by practising Quality method and tools**					
ME G5.1	The facility uses method for quality improvement in services	Basic quality improvement method	1	RR/SI	PDCA & 5S	
		Advance quality improvement method	1	RR/SI	Six sigma, lean	
ME G5.2	The facility uses tools for quality improvement in services	7 basic tools of Quality	1	RR/SI	Minimum 2 applicable tools are used	
Standard G6	**The facility maps its key processes and seeks to make them more efficient by reducing non value adding activities and wastages**					
ME G6.1	The facility maps its critical processes	Process mapping of critical processes done	1	RR/SI	like delayed reports, critical alerts, work flow of the technical areas	
ME G6.2	The facility identifies non value adding activities / waste / redundant activities	Non value adding activities are identified	1	RR/SI	Non value adding activities (MUDAS), time spent in non-value added activities	
ME G6.3	Facility takes corrective action to improve the processes	Processes are rearranged as per requirement	1	RR/SI		
Standard G7	**The facility has defined, approved and communicated Risk Management framework for existing and potential risks**					
ME G7.1	Risk Management framework has been defined including context, scope, objectives and criteria	Check for availability of Laboratory Safety Chemical Hygiene Plan (CHP) to protect the staff	1	RR/SI	1. CHP includes SOP on control measures to reduce the risk of exposure to hazardous material e.g. women of childbearing age 2. Protocols for precautions to be followed in case of any accident/emergency is available and displayed appropriately 3. Frequency of periodic medical check-up for occupationally acquired diseases 4. Provision for additional personnel protection for workers dealing with reagents & material with carcinogens, toxins, chemicals, etc. 5. Specific measures taken to ensure proper and adequate performance of protective equipment, such as fume hoods	
ME G7.2	Risk Management framework defines the responsibilities for identifying and managing risk at each level of functions	Check if responsibilities for identifying and managing risk has been defined and communicated	1	RR/SI	Review risk management framework delineation of responsibilities amongst staff for identifying the risk in their work area and their management. Verify with the staff members if they are aware of their responsibilities	
ME G7.3	Risk Management Framework includes process of reporting incidents and potential risk to all stakeholders	Check if process of reporting risks and hazards have been defined	1	RR/SI	Review risk management framework for process of reporting incidents including near miss and potential risks	

ME G7.4	A comprehensive list of current and potential risk including potential strategic, regulatory, operational, financial, environmental risks has been prepared	Check if list of existing and potential risk have been prepared	1	RR/SI	Review risk management framework includes list of identified current and potential risks. These may included hazard safety, strategic, financial, statutory, operational and environmental risks.	
ME G7.5	Modality for staff training on risk management is defined	Check training on risk management has been providesd to key staff members	1	RR/SI	Verify with the training records. Training and information imparted to the staff on the hazards of chemicals in their work areas and related information.	
ME G7.6	Risk Management Framework is reviewed periodically	Check risk management framework is reviewed at least once in a year	1	RR/SI	Check with the records that quality team/ risk management committee reviews the framework at least once in a year	
Standard G8	**The facility has established procedures for assessing, reporting, evaluating and managing risk as per Risk Management Plan**					
ME G8.1	The facility has defined and communicated Risk Management framework for existing and potential risks	Risk management plan has been prepared and approved by the designated authority and there is a system of updating it at least once a	1	RR/SI	Check if a valid risk management plan is available at the facility	
		Risk Management Plan has been effectively communicated to all the staff, and as well as relevant externa stakeholders	1	RR/SI	Check if risk management plan has been communicated to all stake holders	
		Risk assessment criteria and checklist for assessment have been defined and communicated to relevant stakeholders	1	RR/SI	Check if risk assessment checklist is available with stakeholders	
ME G8.2	Periodic assessment for Physical and Electrical risks is done as per defined criteria	Check if periodic assessment of Physical and electrical safety risk is done using the risk assessment checklist	1	RR/SI	Verify with the assessment records. Comprehensive of physical and electrical safety should be done at least once in three month	
ME G8.3	Periodic assessment for Chemical and Biological hazard is done as per defined criteria	Check periodic assessment of chemical Hazard is done periodically	1	RR/SI	1. Identify the risk group category 2. Check comprehensive assessment of both manmade and natural chemical hazardous event is done at least once in year	
		Check periodic assessment of Biological Hazard is done periodically	1	RR/SI	1. Identify the risk group category 2. Check comprehensive assessment of biological hazard is done at least once in year	
ME G8.4	Periodic assessment for potential disasters including fire is done as per defined criteria	Check periodic assessment of potential disaster is done periodically	1	RR/SI	Check comprehensive assessment of both manmade and natural potential disaster is done at least once in year	
		Check periodic assessment of testing area and staff safety risk is done using defined checklist periodically	1	RR/SI	Verify with the records. A comprehensive risk assessment of all testing processes should be done using pre defined criteria at least once in three month.	
ME G8.5	Risks identified are analysed evaluated and rated for severity	Check if various risks identified during the risk assessment proceeds are formally evaluated	1	RR/SI	Risk identified should be listed and evaluated for their security and frequency for occurrence. A risk severity score / grade should be give to each risk identified and according gaps should be rated. Verify with the records	
ME G8.6	Identified risks are treated based on severity and resources available	Check if risk have high severe are prioritised.	1	RR/SI	Check risks are prioritized base on their severity rating. Verify with the records	
ME G8.7	A risk register is maintained and updated regularly to record identified risks, their severity and actions to be taken	Check if a risk register is maintained	1	RR/SI	Check hospital administration/ responsible committee maintains a risk register which risk identified, their severity, action to be taken to mitigate risk and follow up action Check for risk register has been updated timely	
Standards G9	**The facility has established system for patient and employee satisfaction**					
ME G9.1	Patient and Employee Satisfaction surveys are conducted at periodic intervals	There is a designated person to co-ordinate satisfaction survey	1	RR/SI		
		Patient feedback is taken at regular intervals	1	RR/SI/PI	1. Form is available in local language 2. Sample is adequate May be shared with the main hospital	
		There is procedure to conduct employee satisfaction survey at periodic intervals	1	RR/SI	At least once in a year	
		A mechanism is in place to take feedback from the clinicians	1	RR/SI	To correlate the accuracy of results with clinical findings at least once in 6 months	
ME G9.2	The facility analyses the patient feed back and do root cause analysis	There is procedure for compilation of patient feedback forms	1	RR/SI	1. Patient feedback is analysed on monthly basis	
		Root cause analysis is done for low performing attributes	1	RR/SI		

		Results of Patient satisfaction survey are recorded and disseminated to concerned staff	1	RR/SI		
		There is procedure for analysis of Employee satisfaction survey	1	RR/SI	Root cause analysis is done	
		There is procedure for analysis of clinician's feedback	1	RR/SI	Root cause analysis is done and action plan is prepared	
ME G9.3	The facility prepares the action plans for the areas of low satisfaction	There is procedure for preparing Action plan for improving patient satisfaction	1	RR/SI		
		There is procedure to take corrective and preventive action	1	RR/SI		
		There is procedure for preparing action plan for improving employee satisfaction	1	RR/SI		
Area of Concern - H Outcome						
Standard H1	The facility measures Productivity Indicators and ensures compliance with State/National benchmarks					
ME H1.1	Facility measures productivity Indicators on monthly basis	No. of Haematology test done per 1000 population	1	RR	Within the hospital and from peripheral health facilities	
		No. of Biochemistry test done per 1000 population	1	RR	Within the hospital and from peripheral health facilities	
		No. of Clinical Pathology test done per 1000 population	1	RR	Within the hospital and from peripheral health facilities	
		No. of histopathology & cytology test done per 1000 population	1	RR	Within the hospital and from peripheral health facilities	
		No. of microbiology test done per 1000 population	1	RR	Within the hospital and from peripheral health facilities	
		Percentage of lab test done at night	1	RR		
Standard H2	The facility measures Efficiency Indicators and ensure compliance with State/National benchmarks					
ME H2.1	Facility measures efficiency Indicators on monthly basis	VIS/Z scores or equivalent of lab	1	RR	Biochemistry & Haematology	
		Percentage of test failed in EQAS/PT/any other	1	RR		
		No of IQC failures	1	RR		
		Turn around time for emergency lab investigations	1	RR		
		Turn around time for routine lab investigations	1	RR		
		Turn around time for receiving the samples from peripheral labs in case	1	RR		
		Lab test done per technician	1	RR		
		Downtime of critical equipment breakdown	1	RR		
Standard H3	The facility measures Clinical Care & Safety Indicators and ensure compliance with State/National benchmarks					
ME H3.1	Facility measures Clinical Care & Safety Indicators on monthly basis	% of critical values reported within one hour	1	RR	Within the hospital and from peripheral health facilities	
		No of missed critical alerts	1	RR		
		No of adverse events per thousand patients	1	RR	Especially haematoma, syncope, infection, nerve damage, etc.	
		Number of sharp exposure or other occupational injuries reported	1	RR		
		Test demography	1	RR	Proportion of Haematology, biochemistry, serology, Microbiology, cytology, clinical pathology	
		Report correlation rate	1	RR	Proportion of lab report co related with clinical examination	
		Proportion of false positive /false negative	1	RR	For Rapid diagnostic Kit test	
Standard H4	The facility measures Service Quality Indicators and ensure compliance with State/National benchmarks					
ME H4.1	Facility measures Service Quality Indicators on monthly basis	Waiting time at sample collection area	1	RR		
		Waiting time at report receiving area	1	RR		

		Percentage of rejected samples	1	RR	Haemolysis, specimen with illegible missing paperwork or labels, inadequate sample volume, improper transportation	
		percentage of contaminated blood cultures	1	RR		
		Patient Satisfaction Score	1	RR		
		Number of stock out incidences of reagents & consumables	1	RR		
		No of rapid diagnostic kits discarded due to unsatisfactory reasons	1	RR		