NATIONAL HEALTH MISSION
राष्ट्रीय स्वास्थ्य मिशन

सत्यमेव जयते
Ministry of Health & Family Welfare
Government of India

NHSRC

NATIONAL QUALITY ASSURANCE STANDARDS

INTEGRATED PUBLIC HEALTH LABORATORIES

2024

Ministry of Health and Family Welfare
Government of India

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NATIONAL HEALTH MISSION
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National Quality Assurance Standards for Integrated Public Health Laboratories

2024

Ministry of Health and Family Welfare,
Govt. of India

ISBN: 978-93-82655-37-4

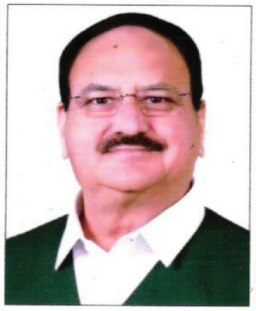
Ministry of Health & Family Welfare
Government of India
Nirman Bhawan, New Delhi, India

Designed by: Royal Press
Printed by: Kamal Printers

जगत प्रकाश नड्डा
JAGAT PRAKASH NADDA

सत्यमेव जयते

मंत्री
स्वास्थ्य एवं परिवार कल्याण
व रसायन एवं उर्वरक
भारत सरकार
Minister
Health & Family Welfare
and Chemicals & Fertilizers
Government of India



MESSAGE

The Indian Health System currently faces the triple burden of disease, i.e, the challenges of maternal and child mortality; the growing burden of non-communicable diseases and the threats of infectious diseases, like the recent COVID – 19 pandemic.

Establishment of Integrated Public Health Laboratories (IPHL) in all the districts of the country serving as hubs to smaller laboratories at block and health facility level will enable availability of rapid, reliable, and accurate test results for optimal patient care, public health surveillance and overall improved health outcomes. IPHL is expected to increase the efficiency of the health system by avoiding duplication of laboratory resources. It will channelize resources for the development of capacity for multi-disease testing under a single roof, thereby ensuring better preparedness and response to future public health emergencies/threats.

Establishing a Quality Management System (QMS) in the IPHL is imperative for ensuring accuracy and precision of the testing processes and results. The National Quality Assurance Standards (NQAS) have already paved the path of having internationally benchmarked quality standards for each level of public health care facility in India. Quality certification of IPHL will assure the beneficiaries and service providers that investigation reports are reliable and benchmarked.

I sincerely believe that the states will expedite the implementation of these standards and achieve certification for the newly established IPHL units. This will undoubtedly reinforce the government's commitment of providing quality healthcare to all people accessing these services and help build 'Quality Health Systems' to meet the dynamic health needs of our nation.

(Jagat Prakash Nadda)

कार्यालय: 348, ए–स्कंध, निर्माण भवन, नई दिल्ली–110011 • **Office:** 348, A-Wing, Nirman Bhawan, New Delhi-110011
Tele.: (O): +91-11-23061661, 23063513 • **Telefax:** 23062358 • **E-mail:** min-hfm@gov.in

प्रतापराव जाधव
PRATAPRAO JADHAV

सत्यमेव जयते

राज्य मंत्री (स्वतंत्र प्रभार)
आयुष मंत्रालय
व
राज्य मंत्री
स्वास्थ्य एवं परिवार कल्याण मंत्रालय
भारत सरकार
MINISTER OF STATE
(INDEPENDENT CHARGE) OF
MINISTRY OF AYUSH AND
MINISTER OF STATE OF
MINISTRY OF HEALTH & FAMILY WELFARE
GOVERNMENT OF INDIA

MESSAGE

Medical laboratories play an essential role in healthcare by providing critical diagnostic and therapeutic support to clinicians and physicians. In a country like India having a high-density population, there is a huge demand for a network of integrated laboratories at various levels of healthcare for providing diagnostic for disease-specific programs and for integrating healthcare surveillance supported by quality-assured laboratory data.

Keeping this in view, the Government of India launched Integrated Public Health Laboratories (IPHL) across the districts of the country. These labs provide rapid, reliable, and accurate test results to the public through defined upward and downward linkages.

Robust Quality Management Systems are required in all aspects of laboratory operations to ensure accuracy and reliability of laboratory results. The Ministry of Health and Family Welfare is introducing **"National Quality Assurance Standards for Integrated Public Health Laboratories"** to address this need.

This guideline provides a clear roadmap for effective planning and systematic implementation of quality standards at Integrated Public Health Laboratories. By adopting these standards, we will not only enhance the quality and reliability of our public health laboratories but also strengthen our overall healthcare system.

I assure that implementation of these standards in letter and spirit, will facilitate provision of quality lab reports to the public and improve our treatment outcomes. I also desire that all States/UTs implement quality standards in their laboratory and get them certified at the earliest.

(Prataprao Jadhav)

Office: 250, 'A' Wing, Nirman Bhavan, New Delhi-110011
Tele.: 011-23061016, 23061551, Telefax: 011-23062828, E-mail: mos-health@gov.in
Residence: 23, Ashoka Road, New Delhi-110001, Tele.: 011-23740412, 23740413, 23345478
Camp office: Khasdar Jansampark Karyalay, Jijamata Krida Sankul, Buldhana, Maharashtra-443001
Telefax: 07262-247777, E-mail: prataprao.jadhav@sansad.nic.in

NATIONAL HEALTH MISSION
राष्ट्रीय स्वास्थ्य मिशन

अनुप्रिया पटेल
ANUPRIYA PATEL

सत्यमेव जयते

राज्य मंत्री
स्वास्थ्य एवं परिवार कल्याण
व रसायन एवं उर्वरक
भारत सरकार
MINISTER OF STATE FOR
HEALTH & FAMILY WELFARE
AND CHEMICALS & FERTILIZERS
GOVERNMENT OF INDIA

FOREWORD

Accessibility to reliable laboratory diagnosis at all levels of healthcare is vital to ensuring effective universal healthcare to all our citizens and building a resilient health system capable of withstanding future pandemics.

The roll out of the Integrated Public Health Laboratories (IPHL) ensures a network of modern, multi-disciplinary, clinical laboratories at various levels of health care for providing diagnostics, not only for patient care and disease-specific programmes, but also for integrating healthcare surveillance supported by quality assured laboratory data. This will provide access to cost-effective laboratory systems that provide rapid, reliable, and accurate testing to large segments of the population availing public health services.

National Quality Assurance Standards (NQAS) has established itself as an internationally recognized series of standards for secondary and primary health care delivery and has been instrumental in transforming quality of care and patient safety across our public health facilities. The launch of the National Quality Assurance Standards for the Integrated Public Health Laboratories will help these laboratories to benchmark themselves against the internationally accepted best practices in quality and safety in laboratory management and testing practices.

I sincerely believe that the resultant improvement in validity of the investigation reports of the IPHL will help our health care workers in further improving the services provided by health facilities; and strengthen our health systems in combating both communicable and non-communicable diseases. This will provide a boost to our government's efforts to reduce the Out-Of-Pocket Expenditure (OOPE) by making reliable laboratory investigations accessible to the community.

(Anupriya Patel)

June 22, 2024
New Delhi

अपूर्व चन्द्रा, भा.प्र.से.
सचिव
APURVA CHANDRA, IAS
Secretary

सत्यमेव जयते

आज़ादी का अमृत महोत्सव

भारत सरकार
स्वास्थ्य एवं परिवार कल्याण विभाग
स्वास्थ्य एवं परिवार कल्याण मंत्रालय
Government of India
Department of Health and Family Welfare
Ministry of Health and Family Welfare

MESSAGE

Medical laboratories are important to modern medicine, playing a pivotal role in clinical decision-making, by aiding physicians in confirming diagnoses, tracking treatment progress, and optimizing patient management. Laboratory diagnostics are also vital for public health surveillance and identification of emerging and re-emerging disease-causing pathogens.

The National Health Mission (NHM) launched the Free Diagnostics Service Initiative to ensure availability and access to diagnostic tests at public health facilities and reduce the out-of-pocket expenditure incurred by patients on diagnostics. In addition to the implementation, efforts are also being made to ensure quality of services being provided for these interventions. In this direction, the Ministry of Health and Family Welfare (MoHFW) introduced the LIFE (Laboratory Improvement for Excellence-National Initiative for District Hospital Laboratory Quality Improvement) initiative in 2017 to tackle training and quality gaps within District Hospital Labs. The National Quality Assurance Standards (NQAS) framework currently includes a separate checklist for laboratories containing all the established procedures for pre-testing, testing & post-testing activities.

The COVID-19 pandemic highlighted the need for enhanced collaboration between health and related sectors for swift responses to outbreaks and improved public health action. This led to the creation of Integrated Public Health Laboratories (IPHL) nationwide, planned for 730 districts across States/UTs in a phased manner.

Reliable laboratory services are vital for a robust healthcare system, emphasizing the need for quality assurance across public health laboratories. NQAS for IPHL aim to provide quality services to its users, i.e, patients and healthcare providers alike, with reliable and fast diagnostic services. Further the NQAS for IPHL aim to minimize lab errors, improve treatment efficiency and enhance quality management for high standards.

I would like to convey my thanks to all the contributors from MoHFW and NHSRC, Central Govt. Institutions, State National Health Mission, members of the academia, development partners, and all other experts for their inputs in framing this initiative.

I implore all States and UTs to accord priority to the adoption of NQAS for IPHL and enhance the quality of the IPHL developed in their States/UTs.

(Apurva Chandra)

Date : 19.6.2024
Place : New Delhi

Room No. 156, A-Wing, Nirman Bhawan, New Delhi-110 011
Tele : (O) 011-23061863, 23063221, E-mail : secyhfw@nic.in

आराधना पटनायक, भा.प्र.से.
अपर सचिव एवं मिशन निदेशक (रा.स्वा.मि.)
Aradhana Patnaik, IAS
Additional Secretary & Mission Director (NHM)

सत्यमेव जयते

आज़ादी का अमृत महोत्सव

भारत सरकार
स्वास्थ्य एवं परिवार कल्याण मंत्रालय
निर्माण भवन, नई दिल्ली-110011
Government of India
Ministry of Health and Family Welfare
Nirman Bhawan, New Delhi-110011

FOREWORD

The National Health Policy 2017 clearly specifies the objective of improving the nation's health status through concerted policy action in all sectors and expanding preventive, promotive, curative, palliative, and rehabilitative services provided through the public health systems. The Policy envisages the attainment of universal access to good-quality healthcare services without anyone having to face financial hardship.

In India's ongoing efforts to strengthen healthcare services, the National Health Mission (NHM) has focused on the provision of essential, high-quality healthcare that is accessible and affordable for all since its inception. The Ministry of Health & Family Welfare (MoHFW), Government of India (GoI), began its journey towards healthcare excellence by introducing the National Quality Assurance Standards (NQAS) in 2013. Initially introduced for District Hospitals, these standards were later expanded to encompass all levels of public health facilities.

The volatile burden of emerging and re-emerging infectious diseases, particularly the COVID-19 pandemic highlighted the urgent need to strengthen the laboratory system in the public health sector. In response to this challenging scenario, the MoHFW, GoI, took a significant stride by conceptualizing the Integrated Public Health Laboratories (IPHL) under the PM-Ayushman Bharat Health Infrastructure Mission (PM-ABHIM). This initiative was aimed at improving the accessibility, efficiency, effectiveness, and quality of laboratory services.

To further advance the initiative, the MoHFW has developed the NQAS for IPHL. These standards aim to streamline patient services by offering rapid, reliable, and accurate test results cost-effectively. Furthermore, these standards will play a pivotal role in producing high-quality laboratory reports and facilitating accurate diagnosis, thereby improving clinical outcomes and fostering trust within the patient and the community.

In this journey towards excellence, I extend my heartfelt gratitude to esteemed experts who have provided invaluable support and guidance in developing these standards. Equally deserving of recognition is the dedicated efforts of the Quality and Patient Safety Division at the National Health Systems Resource Centre (NHSRC) for meticulously formulating these commendable Quality Standards for IPHL.

The technical officers at the state and district levels will enthusiastically embrace these standards, using them as a foundation for enhancing the quality of laboratory services and thus contributing to the overarching goal of a healthier, more resilient nation.

Dated: 20th June, 2024

(Aradhana Patnaik)

Tel : 011-23063618, 23061097 E-mail : asmd-mohfw@nic.in

Maj Gen (Prof) Atul Kotwal, SM, VSM
MBBS, MD (PSM), PDF (Epidemiology),
FRCP Edin, FAMS, FIPHA, FIAPSM
Executive Director

National Health Systems Resource Centre
राष्ट्रीय स्वास्थ्य प्रणाली संसाधन केंद्र
Ministry of Health and Family Welfare
Government of India

Message

Integrated Public Health Laboratories (IPHL) are being established under the Pradhan Mantri-Ayushman Bharat Health Infrastructure Mission to enhance and expand the capacity for rapid testing, case detection, surveillance, and outbreak management, in addition to bolstering clinical laboratory services.

The National Quality Assurance Standards (NQAS) initiative, introduced in 2013 for District Hospitals (DH), laid the way for organised attempts to enhance the quality of care of the Indian public health system, and NQAS have now been developed for all levels of health facilities till the Ayushman Arogya Mandir- Sub Health Centres. They are formulated in alignment with international benchmarks and are accredited by the International Society for Quality in Healthcare (ISQua). Since its inception, the NQAS has helped evaluate the quality of healthcare delivery through collaborative efforts of the Ministry of Health and Family Welfare and the State Health Departments.

The IPHL under NQAS will be assessed on eight Areas of Concern, 50 standards and 170 Measurable Elements. To obtain National Certification, the IPHL would be required to obtain a minimum score of 70% at the national level assessment. The IPHL would also undergo surveillance assessment to determine its sustainability, and after three years the lab will undergo re-certification to develop a culture of quality sustenance. There are 5 set criteria for certification of these IPHL, and they will be assessed at both State and National Level to ensure the utmost quality. This robust system of assessment with the focus on pre-analytic, analytic and post-analytic indicators will result in the provision of quality services to the users by reducing the turnaround time.

Laboratory standards and assessment checklist are a vital part of the Assessor's Guidebook for DH-2020, and would continue to be applicable to those labs at the DH which are not converted into IPHL. The NQAS certification for IPHL will be applicable for all the laboratories set up providing diagnostic services as per IPHL guidelines.

I extend my heartfelt gratitude to the Hon'ble Minister of Health and Family Welfare for his leadership and direction. I would also like to convey my gratitude to the Secretary (H & FW), AS&MD (NHM), Joint Secretary (Policy) and experts who have provided invaluable support in developing these standards. I also express my appreciation towards the Quality and Patient Safety division for their untiring efforts in formulating NQAS for IPHL. These standards will undoubtedly play a pivotal role in elevating the quality of these laboratories and the services they provide.

Maj Gen (Prof) Atul Kotwal

NIHFW Campus, Baba Gang Nath Marg, Munirka, New Delhi - 110067
(T): 011 - 2610 8983, E-mail: atul.kotwal@nhsrcindia.org

List of Abbreviations

1	AFB	Acid Fast Bacilli
2	AIDS	Acquired Immune Deficiency Syndrome
3	AMC	Annual Maintenance Contract
4	AMR	Antimicrobial Resistance
5	AoC	Area of Concern
6	AST	Aspartate Aminotransferase
7	BG	Blood Group
8	BLS	Basic Life support
9	BMW	Biomedical Waste Management
10	BPHL	Block Public Health Laboratory
11	BPHU	Block Public Health Unit
12	BRI	Biological Reference Interval
13	BSL-II	Bio Safety Level-2
14	BT	Bleeding Time
15	CB- NAAT	Cartridge Based Nucleic Acid Amplification Test
16	CBC	Complete Blood Count
17	CD 4/8 Count	Cluster of Differentiation 4/8
18	CHC	Community Health Centre
19	CHP	Chemical Hygiene Plan
20	CLIA	Chemiluminescence Immunoassay
21	CMC	Comprehensive Maintenance Contract
22	COVID-19	Coronavirus Disease- 2019
23	CPCB	Central Pollution Control Board
24	CQSC	Central Quality Supervisory Committee
25	CRP	C Reactive Protein
26	CSF	Cerebrospinal Fluid
27	CT	Clotting Time
28	DC	Differential Count
29	DCIP	Dichlorophenolindophenol
30	DEO	Data Entry Operator
31	DH	District Hospital
32	DQAC	District Quality Assurance Committee
33	DQAU	District Quality Assurance Unit
34	ELISA	Enzyme Linked Immunoassay
35	EQAS	External Quality Assurance System
36	ESR	Erythrocyte Sedimentation Rate

37	ESS	Employee Satisfaction Survey
38	ETP	Effluent Treatment Plant
39	FBS	Fasting Blood Sugar
40	FEFO	First Expiry First Out
41	FNAC	Fine Needle Aspiration Cytology
42	FRU	First Referral Unit
43	FSSAI	Food Safety and Standards Authority of India
44	G6PD Enzyme	Glucose-6-Phosphate Dehydrogenase
45	GTT	Glucose Tolerance Test
46	H2S test	Hydrogen Sulphide Test
47	Hb	Haemoglobin
48	HbA1C	Glycosylated Haemoglobin
49	HBV	Hepatitis B Virus
50	HCFs	Health Care Facilities
51	HCV	Hepatitis C Virus
52	HDL	High Density Lipoprotein
53	HIS	Hospital Information System
54	HIV	Human Immunodeficiency Virus
55	HPLC	High- Performance Liquid Chromatography
56	HR	Human Resource
57	HWC	Health and Wellness Centre
58	ICC	Infection Control Committee
59	ICU	Intensive Care Unit
60	IDSP	Integrated Disease Surveillance Program
61	IgM	Immunoglobulin M
62	IHIP	Integrated Health Information Platform
63	IPD	In Patient Department
64	IPHL	Integrated Public Health Laboratory
65	IPHS	Indian Public Health Standards
66	IQAS	Internal Quality Assurance System
67	IQC	Internal Quality Control
68	ISQua	International Society for Quality in Healthcare
69	IT	Information Technology
70	JSSK	Janani Shishu Suraksha Karyakram
71	KOH	Potassium Hydroxide
72	LASA	Look Alike Sound Alike
73	LDL	Low Density Lipoprotein
74	LED	Light Emitting Diode

75	LIMS	Laboratory Information Management System
76	LJ Chart	Levey Jennings Chart
77	LQMS	Laboratory Quality Management System
78	LT	Laboratory Technician
79	ME	Measurable Element
80	MLC	Medico Legal Case
81	MoHFW	Ministry of Health and Family Welfare
82	MSDS	Material Safety Data Sheet
83	NACO	National AIDS Control Organisation
84	NACP	National AIDS Control Program
85	NCD	Non- Communicable Diseases
86	NGO	Non-governmental organization
87	NHM	National Health Mission
88	NHSRC	National Health System Resource Centre
89	NQAP	National Quality Assurance Program
90	NQAS	National Quality Assurance Standards
91	NS1	Non-Structural Protein 1
92	NSF	National Sanitation Foundation
93	NTEP	National Tuberculosis Elimination Program
94	NVBDCP	National Vector Borne Disease Control Program
95	NVHCP	National Viral Hepatitis Control Program
96	OB	Observation
97	OPD	Out Patient Department
98	OT	Operation Theatre
99	PAP Smear	Papanicolaou Smear
100	PCR	Polymerase Chain Reaction
101	PDCA	Plan- Do- Check- Act
102	PHC	Primary Health Centre
103	PHED	Public Health Engineering Department
104	PI	Patient Interview
105	PM-ABHIM	Pradhan Mantri – Ayushman Bharat Health Infrastructure Mission
106	POCT	Point of care tests
107	PPBS	Post Prandial Blood Sugar
108	PPE	Personal Protective Equipment
109	PSA	Prostate Specific Antigen
110	PSS	Patient Satisfaction Survey
111	PT	Prothrombin Time
112	QA	Quality Assurance

113	QC	Quality Control
114	QI	Quality Improvement
115	QMS	Quality Management System
116	QPS	Quality and Patient Safety
117	RBC	Red Blood cell Count
118	RBS	Random Blood Sugar
119	RDT	Rapid Diagnostic Test
120	Rh type	Rhesus type
121	RO	Reverse Osmosis
122	RPR	Rapid Plasma Reagin
123	RR	Record Review
124	RT- PCR	Real Time reverse transcriptase – polymerase Chain Reaction
125	RTI	Respiratory Tract Infection
126	SARS	Severe Acute Respiratory Syndrome
127	SD	Standard Deviation
128	SGOT	Serum Glutamic-Oxaloacetic Transaminase
129	SGPT	Serum Glutamate-Pyruvate Transaminase
130	SI	Staff Interview
131	SMS	Short Message Service
132	SOP	Standard Operating Procedure
133	SQAC	State Quality Assurance Committee
134	SQAU	State Quality Assurance Unit
135	STD	Sexually Transmitted Diseases
136	TAT	Turn Around Time
137	TB	Tuberculosis
138	TLC	Total Leucocyte Count
139	TRF	Test Requisition Form
140	UID	Unique Identification Number
141	UPHC	Urban Primary Health Centre
142	UPS	Uninterruptible Power Supply
143	UPT	Urine Pregnancy Test
144	UTI	Urinary Tract Infection
145	VDRL	Venereal Disease Research Laboratory
146	VIS	Variance Index Score
147	VLDL	Very Low-Density Lipoprotein
148	WHO	World Health Organization

Table of Contents

Introduction

Medical laboratory services are an integral part of modern medicine and are considered pivotal for the clinical decision-making. Healthcare Diagnostic techniques have evolved tremendously over the years; in earlier days, patient diagnoses were more dependent on signs and symptoms gleaned by physicians. Medical laboratories have revolutionised the whole scenario, becoming indispensable to clinical practices. The importance of laboratory services was highlighted during the global coronavirus pandemic, and the crisis has further fostered the market size of laboratory services.

Medical laboratories or clinical laboratories offer a vast array of lab-based procedures, and it helps physicians to confirm their diagnosis, check the progress of treatment, and manage patients more efficiently. Laboratory services in public health institutes involve a wide range of parameter and different types of laboratory tests. In public healthcare facilities, the tests performed by the hospital laboratories vary depending on their services. Most commonly, Rapid Diagnostic Kit (RDK), basic haematology, including microscopy and Biochemistry, are provided at the primary care level. While more advanced services, including microbiology and histopathology, are provided in secondary and tertiary care institutions.

To cater burden of emerging infectious diseases, increased prevalence of non-communicable diseases (NCD), and current healthcare industry needs, it is crucial to strengthen the laboratory systems in the public health sector. It necessitates catering to the patient's needs without much hassle and providing rapid, reliable, and accurate test results cost-effectively. To ensure the accessibility, efficiency, effectiveness, and quality of laboratory services Ministry of Health and Welfare, GoI supported establishing Integrated Public Health Laboratories (IPHL) under PM-Ayushman Bharat Health Infrastructure Mission (PM-ABHIM). Indian Public Health Laboratories (IPHL) are envisaged in 730 districts of States/UTs in a phased manner. It includes establishing a network of integrated public health laboratories (IPHL) at the various levels (especially regional, state, district, and block levels). IPHL provides hospital-specific, disease-specific laboratory diagnosis and strengthens healthcare surveillance with quality-assured laboratory data. It also ensures the integration of the district public health lab, human resource (HR), equipment, and infrastructure to avoid duplication and disconnect.

To improve and sustain quality in public healthcare facilities and various programs, National Quality Assurance Standards (NQAS) were launched by the Ministry of Health and family welfare, GoI, in 2013. In the beginning, these standards were for district Hospitals, subsequently including, Community health centre (both rural & urban), primary health centres (both rural and urban), Health and wellness centre – health Sub-centre, Comprehensive lactation management centre, Adverse events following immunisation, etc. NQAS aims to instil a culture of quality and safety in health systems by developing quality standards and tools that are pro-public health, flexible, evidence-based, and current as per professional knowledge. The NQAS standards are aligned with the national and international benchmarks defined by the Indian Public health standards, World Health Organization (WHO) respectively. National Quality Assurance Standards are accredited by the International Society for Quality in Healthcare (ISQua), Certification of Integrated Public Health Laboratory against and quality standards for Laboratory services are an integral part of the NQAS framework.

National Quality Assurance Standards aims to provide quality services to its users (patient and healthcare providers), stimulate district and block-level public health laboratories to demonstrate competency, and continually maintain and improve quality standards.

Objectives:

National Quality Assurance Standards for Integrated Public Health Laboratories aim to:

- Ensure the availability of comprehensive, accurate, rapid and quality diagnostics services.
- Reduce errors in laboratory processes and improve the efficiency of the treatment.
- Establish and improve quality management systems, leading to high service standards.
- Ensure excellence in relation to the current knowledge and technical development in laboratory functions.

Scope

The National Quality Assurance Standards (NQAS) for IPHL would be applicable to standalone IPHL in a district or co-located with the District Hospital.

As per NQAS for District Hospital 2020 version, Laboratory standards and assessment checklist are part of the Assessor's Guidebook for a District Hospital. It includes quality improvement in sample collection, transportation, testing, reporting and clinical decision-making for all the tests mandated in District Hospital.

NQAS-DH-2020 standards and assessor's guidebook would continue to be applicable to such labs. which are not converted into IPHL. While NQAS certification for IPHL will be mandatory for all the laboratories set up providing diagnostic services as per IPHL guidelines.

Background

Integrated Public Health Laboratories:

Delivery of accessible, equitable and quality care without any financial exclusion remains one of the stated objectives of the Ministry of Health & family welfare. India's population is facing the double burden of communicable and non-communicable diseases leading to high mortality and morbidity, significantly impacting human life and economic growth. The country needs to devise effective healthcare solutions that not only boost control of the existing burden of diseases like HIV, TB, and Malaria but also prepare to effectively detect, prevent, control, and manage emerging infectious diseases and their health threats. This calls for identifying cost-effective and efficient healthcare diagnosis and delivery mechanisms.

Laboratory services are essential and fundamental part of the health systems. It plays a vital role before, during and after treatment. Lack of access to high-quality diagnostic tests may deprive the patient from accessing life-saving treatments and reduce the opportunities to prevent onward transmission and spread of diseases. Without effective public health laboratory systems, public health responses will be delayed, and global health security will be threatened. Non-availability/sub-standard laboratory services in public health facilities, forces the users to use private health facilities, which results into out-of-pocket expenditure and financial hardships. Therefore, access to appropriate, high-quality laboratory support is vital in healthcare service provision, including surveillance, disease prevention, and control programs.

To bolster laboratories' infrastructure and disease surveillance capabilities in India, integrated public health laboratories (IPHL) are envisaged to be set up at district and block levels under Pradhan Mantri Ayushman Bharat Infrastructure Mission (PM- ABHIM). IPHL aims to provide comprehensive laboratory support for communicable and non-communicable diseases along with Haematology, Biochemistry, Clinical Pathology, Cytopathology, Histopathology, Microbiology, and outbreak investigation support. The epicentre of IPHL will be a district with defined upward (Medical college) and downward (block public health laboratories and other peripheral laboratories) linkages. IPHLs mandate establishing networks at various levels of health care for providing diagnostics for disease-specific programmes and integrating healthcare surveillance supported by quality-assured laboratory data.

"Integrated Public Health Laboratory (IPHL)' extends to a laboratory providing comprehensive services, including infectious diseases diagnostics along with testing of haematology, chemical biochemistry, microbiology, and pathology parameters with bio-safety level-2, all combined under one umbrella. IPHL involves physical, functional and data integration of different sections of the district hospital laboratories.

- The physical integration includes establishing a central sample collection facility in a patient-friendly location.
- The functional integration includes the operation of various vertical program sections as the coordinated limbs of a single body, i.e., the district public health laboratory, in the process sharing space, human resources and equipment, thus avoiding duplication and disconnect.
- The data integration will be through an integrated Laboratory Information Management System (LIMS) to monitor the data flow under various programs, facilities, and departments to feed into the IHIP platform for coordinated public health action.

National Quality Assurance Standards

Advent of the National Health Mission and, subsequently, National Health Policy ensure the availability of accessible, affordable, and quality healthcare. With the influx of enormous resources, the country has developed state-of-the-art facilities equipped with requisite modern equipment and instruments, manned by the highly skilled workforce, and ensuring the availability of free drugs and diagnostics. Despite all such efforts, poor quality of care has been the biggest obstacle in satisfying the patient's needs.

Various models of Quality of care have been implemented in the country to overcome these challenges. However, none could cater for the particular requirements of public healthcare institutions in terms of service delivery, viz., healthcare facility's quality and standard compliance as per National disease control programme, immunisation, outreach services etc. To meet the specific requirements, there was a need for a Quality system which is pro-public health, and to fulfil the void, National Quality Assurance Program (NQAP) was launched in 2013.

Under the ambit of the National Quality Assurance Program, Standards of Care for various levels of health facilities, viz. District Hospitals, Community Health Centres (FRU), Primary Health Centres (24*7), Urban Primary Health Centres, and Health and wellness standards-Sub Centre have need framed. The uniqueness of the National Quality Assurance standards is its measurement system which has been uniformly built upon Areas of Concern, Standards, Measurable Elements and Checkpoints. Standards under each level of healthcare institution (DH/CHC/PHC/HWC) have been arranged under Eight (8) broad themes, namely, Area of Concern viz. Service Provision, Patient Rights, Inputs, Support Services, Clinical Services, Infection Control, Quality Management and Outcomes in the system. Depending upon the services provided in available hospital departments, the quality of care using the NQAS departmental checklist is measured and improved. E.g., In district Hospitals, a gamut of 21 departmental checklists is available, viz—emergency, OPD, IPD, Laboratory, OT, ICU, and Labour room.

NQAS for Integrated Public Health Laboratories (IPHL)

To ensure the provision of Quality in IPHL, standards of quality under 8 Areas of concern have been framed. Area of concern wise list & intent standards of care has been explained in subsequent pages (15 onward) of this guidebook.

The standards of Quality of Care apply to fully functional IPHLs, located within the district Hospital or as standalone. The existing laboratory checklists under NQAS DH will remain applicable to laboratories providing district Hospital services only and has yet to upgrade to IPHL. Once the laboratory in the district hospital increases its scope as per IPHL, it can apply separately or along with DH NQAS for IPHL certification.

Institutional Arrangement for Improving Quality in IPHL

Implementing the National Quality Assurance Program is well supported by a sturdy institutional framework ranging from the National to the facility level. Details of institutional arrangement under quality may be referred from "Operational Guidelines for Improving Quality in Public Healthcare facilities"[1].

1 https://qps.nhsrcindia.org/quality-assurance-framework/operational-guidelines

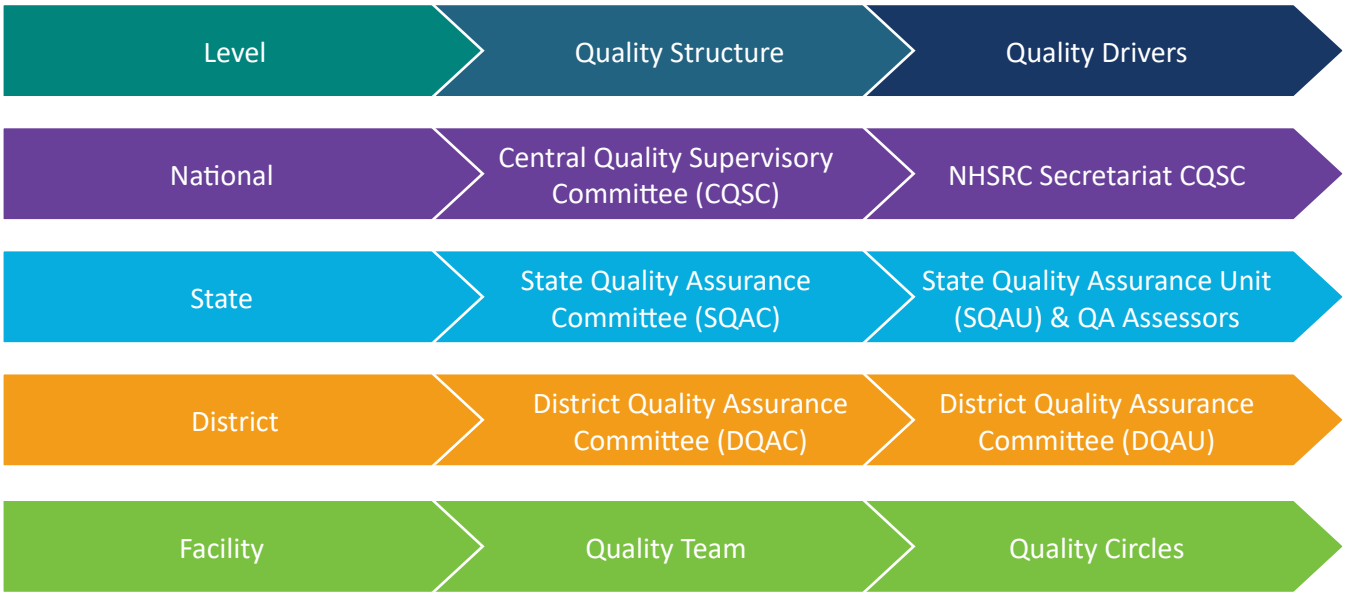


Figure1: Represent the institutional arrangement under National Quality Assurance Program

It is envisaged that the district quality assurance unit and district Hospital level quality team will support the IPHL quality circles to implement quality standards, find gaps, undertake prioritisation, and take up rapid improvement activities (PDCA) for their resolution.

The District QA committee and the nodal officer responsible for operationalisation and monitoring of IPHL will supervise the IPHL quality activities and will be responsible for setting targets, monitoring Key performance indicators, and orienting staff for quality standards and its implementation activities.

Quality Certification of IPHL under NQAS

Under National Quality Assurance Program, there is an arrangement for two categories of certifications; State Certification, wherein the state team conducts the assessment and once the facility is state-certified, it would be eligible for National Certification. The second category is National Certification, where the team of national external assessors conducts the assessment. Upon external assessment from the national level, if the facility meets all criteria laid down by Central Quality Supervisory Committee, the facility shall be awarded a National Certificate which is valid for three years, subject to clearance of annual surveillance assessments. However, if a facility does not meet all laid criteria, in that case facility is quality certified with conditionality. A similar, certification mechanism will be followed for NQAS in IPHL. The step-by-step procedure may be referred Operational Guidelines Improving the quality in Public Health facilities 2021.

NQAS for the Assessment of IPHL

NQAS for IPHL is broadly divided into 8 Areas of concern: Service provision, Patient Rights, Inputs, Support Services, Clinical Services, Infection Control, Quality Management Systems and Outcome. 8 Area Concerns has fifty (50) Standards and one hundred seventy (170) Measurable elements. The intent of each Area of concern and the list of standards are enumerated below:

Service Provision

IPHL is pivotal in ensuring comprehensive laboratory services to the population in its catchment area. The scope of IPHL is to provide routine district hospital laboratory services, diagnostic facilities for various communicable and non-communicable diseases, including national programmes TB, for HIV, malaria, viral hepatitis etc., and collecting and testing clinical specimens of human origin as well as samples of water, food and air during outbreaks and reporting of that information in real-time as part of public health surveillance systems.

The area of concern – services provision measures the availability of functional integrated diagnostic laboratory services. "Availability" of functional services means; services are functional and are being utilised by the end-users because the mere availability of infrastructure or human resources does not always ensure the availability of the functional services. For example, as per staff, the facility may have functional NCD services, but if there are hardly any diagnostic tests undertaken, it may be assumed that the services are unavailable or non-accessible to users. Compliance with these standards and measurable elements should be checked, preferably by observing the delivery mechanism of the services, reviewing the relevant records, and checking outcomes after service delivery There are following two (2) standards and measurable elements in this area of concern:

Reference No.	Standards & Measurable Element
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
ME A1.2	The facility provides Laboratory services for communicable diseases
ME A1.3	The facility provides Laboratory services for non-communicable diseases
ME A1.4	Facility provides services to support public health functions
ME A1.5	Facility provides laboratory based surveillance services for Infectious & Non-infectious diseases
ME A1.6	Services are available for the time period as mandated
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
ME A 2.2	Facility provides information management support

Patient Rights

Mere availability of services does not necessarily meet the need of the community, unless the available services are accessible to the users, and are provided with dignity and confidentiality. Access includes physical access as well as financial access. Evidence suggests that patients' experience and outcomes improve when they are involved in the care. So, the availability of information is critical for access and enhancing patients' satisfaction. Area of concern Patients' rights include parameters such as service availability without a physical barrier, consent having, maintenance of privacy & confidentiality of patients and their records, ensuring availability of mandated free services and provisioning of financial protection. There are three (3) standards in Patient Rights area of concern.

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
ME B1.2	The facility displays its services, entitlements and relevant information
ME B1.3	Access to facility is provided without any physical barrier & friendly to specially-abled people
ME B1.4	There is an established procedure for having consent before conducting any procedure
ME B1.5	The facility has defined and established grievance redressal system in place
ME B1.6	The facility provides cashless services as per prevalent government norms/schemes
Standard B2	**The service provided at facility are acceptable**
ME B2.1	Adequate visual privacy is provided at every point of care
ME B2.2	Services are provided in manner that are sensitive to gender
ME B2.3	Confidentiality of patients records and clinical information is maintained for every patient, especially of those having social stigma
ME B2.4	The facility ensures the behaviours of staff is dignified and respectful, while delivering the services
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
ME B3.2	There is an established procedure for sharing of laboratory/patient data with individuals and external agencies including non-governmental organization.
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
ME B3.4	There is an established procedure to ensure laboratory services during strikes or any other mass protest leading to dysfunctional laboratory services.
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

Inputs

To provide required services in IPHL, it becomes pertinent to ensure the availability of requisite infrastructure, equipment, instrument, human resource, consumables etc. So, area of concern: Inputs predominantly cover the facility's structural part. Standards have been framed in concurrence with operational Guidelines for Integrated Public Health Laboratories (IPHL) and Indian Public Health Standards (IPHS). While assessing the infrastructure component, one may encounter the term –viz. 'adequate' and 'as per load 'has been given in the requirements for many standards & measurable elements, as it would be hard to assess the stringent infrastructural norms for the facility as that should be commensurate with the patient load. There are seven (7) standards in this area of concern.

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
ME C1.2	Patient amenities are provided at sample collection area as per patient load
ME C1.3	Facility has layout and demarcated areas as per functions
ME C1.4	The facility has infrastructure for intramural and extramural communication
ME C1.5	The facility and departments are planned to ensure structure follows the function/ processes (Structure commensurate with the function of the hospital)
Standard C 2	**The facility ensures the physical safety of the infrastructure**
ME C2.1	The facility ensures the seismic safety of the infrastructure
ME C2.2	The facility ensures infrastructure in place for safe sample transportation
ME C2.3	The facility ensures safety of electrical establishment
ME C2.4	Physical condition of buildings are safe for providing mandated lab services
Standard C3	**The facility has established Programme for fire safety and other disaster**
ME C3.1	The facility has plan for prevention of fire
ME C3.2	The facility has adequate firefighting Equipment
ME C3.3	The facility has a system of periodic training of staff and conducts mock drills regularly for fire and other disaster situation
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
ME C4.2	The facility has adequate technicians/paramedics as per requirement

ME C4.3	The facility has adequate support / general staff
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
ME C5.2	The facility has adequate consumables at point of use
ME C5.3	Emergency drug trays are maintained at every point of care, where ever it may be needed
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
ME C 6.2	Availability of functional equipment and instruments for support services
ME C 6.3	Departments have patient furniture and fixtures as per load and service provision
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
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
ME C7.3	The Staff is provided training as per defined core competencies and training plan
ME C7.4	Training needs are identified based on competence assessment and performance evaluation and facility prepares the training plan
ME C7.5	There is established procedure for utilization of skills gained thought trainings by on -job supportive supervision

Support Services

The support services are the backbone of IPHL, and desired clinical outcomes cannot be envisaged in the absence of support services. Area of concern- Support services include maintenance and upkeep of infrastructure & equipment; storage & dispensing of reagents and consumables, safety and security of patients, visitors and staff and availability of water and power back for smooth lab functioning.

It also emphasizes, ensuring all requisite support to the linked BPHU and peripheral laboratories in terms of capacity building, hand holding and monitoring, along with ensuring lab. fulfil all prevalent statutory and regulatory requirements. Support services have total ten (10) standards.

Area of Concern - D Support Services	
Standard D1	**The facility has established Programme for inspection, testing and maintenance and calibration of Lab Equipment**
ME D 1.1	The facility has established system for maintenance of critical Equipment
ME D1.2	The facility has established procedure for internal and external calibration of measuring Equipment
ME D1.3	Operating and maintenance instructions are available with the users of equipment
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
ME D2.2	The facility ensures proper use and storage of consumables and reagents
ME D2.3	The facility ensures management of expiry and near expiry reagents
ME D2.4	The facility has established procedure for inventory management techniques
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
ME D3.2	The facility has provision of restriction of visitors in IPHL
ME D3.3	The facility ensures safe and comfortable environment for service providers
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
ME D4.2	The facility is clean and hygienic
ME D4.3	Facility's infrastructure is adequately maintained
ME D4.4	The facility has policy of removal of condemned junk material
ME D4.5	The facility has established procedures for pest, rodent and animal control

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
ME D5.2	The facility ensures adequate power backup in all patient care areas as per load
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
ME D6.2	The facility has established procedure for providing capacity building support to linked labs
ME D6.3	The facility has established procedure for providing information management support using digital technology to linked labs and administrative authorities
Standard D7	**Facility has defined and established procedures for Financial Management**
ME D7.1	The facility ensures the proper utilization of fund provided to it
ME D7.2	The facility ensures proper planning and requisition of resources based on its need
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
ME D8.2	Updated copies of relevant laws, regulations and government orders are available at the facility
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
ME D9.2	The facility has an established procedure for duty roster and deputation
ME D9.3	The facility ensures the adherence to dress code as mandated by its administration / the health department
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
ME D10.2	There is a system of monitoring of quality of outsourced services

Clinical and Diagnostic Services

Clinical services are the most important area of Concern as the ultimate purpose of the existence of an integrated public health laboratory is to provide accurate, precise, reproducible, and reliable results for clinical decision-making. It is the area of concern that ensure and assess quality in the key laboratory processes, viz., registration of patient, pretesting, testing and post-testing, activities including internal and external verification and validation of laboratory processes. In each set of standards, internal and external validation of key processes, i.e., QA of control materials used in the laboratory, use of control charts to ensure processes are stable, running levels of QC depending upon the number of tests performed by the laboratory, use of the external quality assurance methods inter-laboratory comparison etc. is an integral part of clinical services.

The area of concern also ensures the services not available in IPHL are provided through referral labs. in medical college or other linked laboratories, maintaining and updating the records using IT-based management systems. Linkage of all the processes, from the collection of the sample to the delivery of reports using IT platforms, ensures a reduction in common errors, and increase effectiveness and efficiency in the laboratory functioning. There are a total of nine (9) standards that measures the quality of clinical services.

Area of Concern - E Clinical and Diagnostic 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
ME E1.2	The facility has established procedure for registration of the patient's sample received from spokes/peripheral labs
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
ME E2.2	The facility has defined and established procedures for intersectoral coordination
Standard E3	**The facility has established and defined procedure for pre-testing activities**
ME E3.1	The facility has established procedure for patient preparation
ME E3.2	The facility has established procedure for sample collection from patient care areas
ME E3.3	The facility has established procedure for sample labelling and documentation
ME E3.4	The facility has a standardised Test Requisition form for the tests
ME E3.5	The facility has established procedure for packaging and transportation of samples
ME E3.6	The facility has defined criteria for sample acceptance or rejection
Standard E4	**The facility has established and defined procedure for testing activities**
ME E4.1	Facility performs tests as per established procedure
ME E4.2	Test procedures are verified through routine quality control methods
ME E4.3	Facility has established procedure for Biological reference intervals & critical alert values

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
ME E5.2	The laboratory has defined procedure for revision/amendment of the reports when required
ME E5.3	The facility has established procedure for sample storage and its disposal
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 quality control using quantitative methods
ME E6.2	The facility has established mechanism of internal quality control using semi quantitative/qualitative methods
ME E6.3	The facility has established mechanism of external quality assurance
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
ME E7.2	Register/records are maintained as per lab policy
ME E7.3	The facility has established computerised information system to support lab functions
ME E7.4	The facility ensures safe and adequate storage and retrieval of medical records
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
ME E8.2	There is procedure for handling legal cases
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
ME E9.2	The facility has established procedure for services under various non-communicable disease programmes
ME E9.3	Facility provides service for Integrated disease surveillance program/Integrated Health Information Platform (IHIP)

Infection Control

The area of concern ensures laying down the infection prevention practices and their conformance. The infection control pertains to monitoring basic infection control practices, ensuring compliance with hand hygiene practices, and using Personal Protective Equipment (PPE), etc. It also covers standard practices for maintenance of hygiene, sterilisation, and disinfectant as well as management of Biomedical waste, including liquid waste management. Infection Control areas of concern have six (6) standards.

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
ME F1.2	Facility has established procedures for regular monitoring of infection control practices
ME F1.3	There is Provision of Periodic Medical Check-ups and immunization of staff
Standard F2	**Facility has defined and Implemented procedures for ensuring hand hygiene practices and antisepsis**
ME F2.1	Hand washing facilities are provided at point of use
ME F2.2	Staff is trained and adhere to standard hand washing practices
ME F2.3	Facility ensures standard practices and materials for antisepsis
Standard F3	**Facility ensures standard practices and materials for Personal protection**
ME F3.1	Facility ensures adequate personal protection equipment's as per requirements
ME F3.2	Staff adhere to standard personal protection practices
Standard F4	**Facility has standard Procedures for processing of equipment and instruments**
ME F4.1	Facility ensures standard practices and materials for decontamination and cleaning of instruments and procedures areas
ME F4.2	Facility ensures standard practices and materials for disinfection and sterilization of instruments and equipment's
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
ME F5.2	Facility ensures availability of standard materials for cleaning and disinfection
ME F5.3	Facility ensures standard practices followed for cleaning and disinfection
ME F5.4	Facility ensures air quality of high risk area
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
ME F6.2	Facility ensures management of sharps as per guidelines
ME F6.3	Facility ensures transportation and disposal of waste as per prevalent guidelines
ME F6.4	Facility ensures management of liquid waste as per prevalent guidelines

Quality Management System

Quality management requires a set of interrelated activities that assure the quality of services according to set standards and strive to improve upon it through systematic planning, implementation, monitoring, assessment, identification of non-compliances and acting upon them. The standards in this area of concern are the opportunities for improvement to enhance the quality of services and patient satisfaction.

Area of concern-Quality management system covers aspects like the establishment of organisational framework for quality improvement, measurement, assessment, and usage of patient satisfaction; compliance to display and usage of work instructions; regular assessment using NQAS, and other monitoring checklists for the improvement and sustenance of Quality system. There are nine (9) standards in the quality management system.

	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
ME G1.2	Facility has defined core values of the organization
ME G1.3	Facility has defined Quality policy, which is in congruency with the mission & vision of facility
ME G1.4	Facility has defined quality objectives to achieve mission, vision and quality policy
ME G1.5	Mission, Vision, Values, Quality policy and Objectives are effectively communicated to staff and users of services
ME G1.6	Facility prepares strategic plan to achieve mission, vision, quality policy and objectives
ME G1.7	Facility periodically reviews the progress of strategic plan towards mission, vision, policy and objectives
Standard G2	**The facility has established organizational framework for quality improvement**
ME G2.1	The facility has a quality team in place
ME G2.2	The facility reviews quality of its services at periodic intervals
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
ME G3.2	Standard Operating Procedures adequately describes process and procedures
ME G3.3	The staff is trained and aware of the standard procedures written in the SOPs
ME G3.4	The facility ensures documented policies and procedures are appropriately approved and controlled
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
ME G4.2	The facility has established external quality assurance programs for lab
ME G4.3	Actions are planned to address gaps observed during quality assurance process

ME G4.4	Planned actions are implemented through Quality Improvement Cycles (PDCA)
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
ME G5.2	The facility uses tools for quality improvement in services
Standard G6	**The facility maps its key processes and seeks to make them more efficient by reducing nonvalue adding activities and wastages**
ME G6.1	The facility maps its critical processes
ME G6.2	The facility identifies non value adding activities / waste / redundant activities
ME G6.3	Facility takes corrective action to improve the processes
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
ME G7.2	Risk Management framework defines the responsibilities for identifying and managing risk at each level of functions
ME G7.3	Risk Management Framework includes process of reporting incidents and potential risk to all stakeholders
ME G7.4	A comprehensive list of current and potential risk including potential strategic, regulatory, operational, financial, environmental risks has been prepared
ME G7.5	Modality for staff training on risk management is defined
ME G7.6	Risk Management Framework is reviewed periodically
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
ME G8.2	Periodic assessment for Physical and Electrical risks is done as per defined criteria
ME G8.3	Periodic assessment for Chemical and Biological hazard is done as per defined criteria
ME G8.4	Periodic assessment for potential disasters including fire is done as per defined criteria
ME G8.5	Risks identified are analysed evaluated and rated for severity
ME G8.6	Identified risks are treated based on severity and resources available
ME G8.7	A risk register is maintained and updated regularly to record identified risks, their severity and actions to be taken
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
ME G9.2	The facility analyses the patient feedback and do root cause analysis
ME G9.3	The facility prepares the action plans for the areas of low satisfaction

Outcome

Measurement of the quality is critical for improvement of processes and outcomes. For the desirous functioning of a facility, it becomes imperative to measure its indicators which can help in knowing the productivity, efficiency, and utilization of the facility as a unit. These indicators not only show the "outcomes" of the service delivery but also support the team to carry out improvement by implementing change ideas as per the requirement. Indicators may be reported through a portal/ dedicated IT platform. Other than just measuring indicators it is important to analyse the data for overall improvement using quality tools and methods. Outcome areas of concern have total of four (4) standards.

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
ME H1.2	The facility endeavours to improve its productivity indicators to meet the benchmark
Standard H2	**The facility measures Efficiency Indicators and ensure compliance with State/ National benchmarks**
ME H2.1	Facility measures efficiency Indicators on monthly basis
ME H2.2	The facility endeavours to improve its efficiency indicators to meet the benchmark
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
ME H3.2	The facility endeavours to improve its clinical care & safety indicators to meet the benchmark
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
ME H4.2	The facility endeavours to improve its service quality indicators to meet the benchmark

Measurement System under National Quality Assurance Standards

A robust quality management system, confidence in providing accurate and reliable lab results, better operational control, and enhanced customer satisfaction are the principles of high-quality laboratory services. There are numerous ways/standards defined to measure the quality in laboratories. Measurement is the essence of any standards as it involves efforts to reduce subjectivity and ensure that all the critical to-quality components have been addressed holistically.

Further, the endeavour to measure the Quality in public health laboratories is much more difficult, due to the involvement of a wide range of vertical Programmes and implementation support available from states and districts. It is realised that there would always be some kind of 'trade-off' when measuring the quality. One may have small and simple tools, but that may not be able to capture all micro details. Alternatively, one may devise all-inclusive detailed tools, encompassing the micro-details, but the system may become highly complex and difficult to apply across Public Health Facilities.

Since the inception of NQAP, the country has realised the importance of measurement of quality standards. Therefore, the Quality Framework and Standards are linked to the measurement system under NQAP. The proposed system has incorporated best practices from the contemporary systems and contextualised as per the needs of the Integrated Public Health laboratories and Indian Public Health standards.

Quality Standards for IPHL

Quality Standards for IPHL are arranged under 8 Areas of Concern. There are 50 Standards. Each Standard has specific Measurable Elements (i.e., 170 ME). These standards and Measurable Elements are assessed through an IPHL checklist.

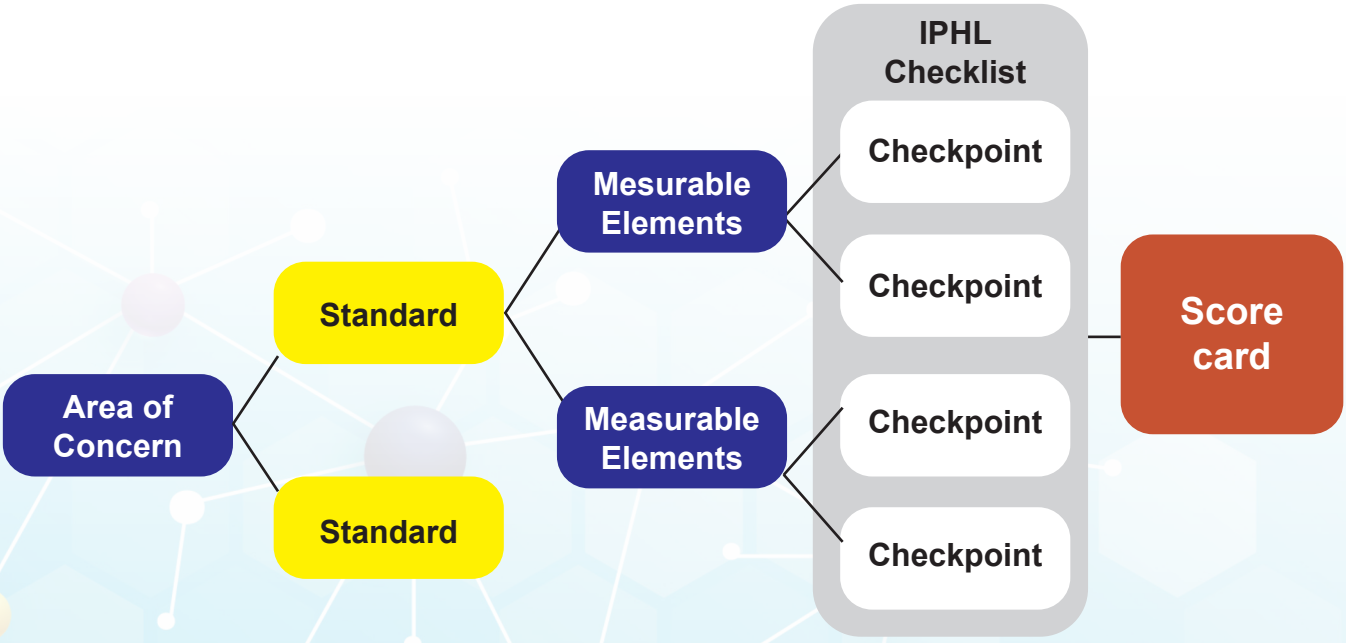


Figure 2: Representing the Arrangement of AoC, Standard, Measurable element, and Checkpoints

The filled checklist would generate Scorecard, which will include an overall score for the IPHL. A scorecard can also be generated with Areas of Concern wise and Standard wise scores.

IPHL Score Card			
Area of Concern wise Score			IPHL Score
A	Service Provision	50%	50%
B	Patient Rights	50%	
C	Inputs	50%	
D	Support Services	50%	
E	Clinical Services	50%	
F	Infection Control	50%	
G	Quality Management	50%	
H	Outcome	50%	

Figure 3: Schematic representation of Area of Concern wise and Overall IPHL score card

Reference No.	Standards & Measurable Element	IPHL Score
Area of Concern - A Service Provision		
Standard A1	Facility Provides Integrated Diagnostic Laboratory Services as per mandate	50%
Standard A2	Facility provides 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 C2	The facility ensures the physical safety of the infrastructure.	50%
Standard C3	The facility has established Programme for fire safety and other disaster	50%

Figure 4: Schematic representation of Standard wise scorecard

Assessment Protocols & Scoring System

Checklists are the main tools for the assessment. Before undertaking any assessment, assessors should familiarise themselves with the checklists beforehand. The layout of the checklist is given below:

National Quality Assurance Standards Checklist 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		SI/RR	Hb%, TC, DLC, Platelet, Red Cell Indices, ESR, BG & Rh typing, Blood cross matching, Peripheral blood film, Reticulocyte count, AEC, Prothrombin time (PT) & International Normalised Ratio (INR), Activated partial thromboplastin time	
		Availability of Biochemistry services		SI/RR	Fibrinogen Degradation Product (FDP) test, D-Dimer, Coombs 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	

Figure 5: Represent Anatomy of the Checklist

(a) Title of the checklist denotes the name of Integrate Public Health lab for which the checklist is intended.

(b) The horizontal bar in grey colour contains the name of the Area of concern to which the underlying standards belong.

(c) Yellow horizontal bar contains the statement of the standard being measured.

(d) Extreme left column of the checklist in blue colour contains the reference number of Standard and Measurable Elements. The Reference number helps in the identification and traceability of a standard.

(e) Second column contains the text of the measurable element for the respective standard.

(f) The column next to measurable elements on the right side has checkpoints for measuring compliance to the respective measurable element and the standard.

(g) Next right to the checkpoints, a blank column is available where the finding of assessment in terms of Compliance (2 marks), Partial Compliance (1 mark) and Non-Compliance (0 marks) should be written.

(h) Next right to the blank column is the assessment method column. This denotes the 'HOW' to gather the information. Generally, there are four primary methods for assessment - SI means staff interview, OB means observation, RR means record review & PI, Patient Interview.

(i) Column next to the assessment method contains means of verification. It denotes what to see in a particular Checkpoint. It may be a list of equipment or procedures to be observed, example questions which may be asked to the interviewee or some benchmark, which could be used for comparison, or reference to some other guideline or legal document. It may be left blank as checkpoints may be self-explanatory.

(j) Next right to the means of verification, a remark section is given. It needs to be filled by the assessor whenever partial or non-compliance is given.

Assessment Methods

Assessor should read measurable elements and checkpoints; and try to gather information and evidence to assess the compliance to the requirement of measurable element and checkpoint. Information can be gathered by four methods that is Observation (OB), Record review (RR), Patient interview (PI) and Staff Interview (SI)

- **Observations (OB) –** Compliance with many measurable elements can be assessed by directly observing the articles, process, and surrounding environment. E.g. Enumeration of articles like equipment, reagents, consumables etc. Displays like signage, work instructions, and important information. Patient amenities, chair, drinking water, complaint box etc. An environment like seepage, overcrowding, and cleanliness. Procedures like measuring collection of samples, counselling, segregation of biomedical waste etc.
- **Staff Interview (SI) -** Interaction with the staff help in assessing the knowledge and skill level, required for performing job functions. Examples -Competency testing - Asking staff how to perform certain diagnostic procedures. Demonstration – Asking staff to demonstrate activities like hand washing techniques or newborn resuscitation. Awareness -Asking staff about awareness of quality policy and quality objectives and Feedback about the adequacy of supplies, work safety issues etc.
- **Record Review (RR) -** – All processes, especially certain tests not performed regularly, cannot be observed. A review of records may generate more objective evidence and triangulate the finding of the observation. For example, on the day of assessment, regents, controls etc., may be available in adequate quantity, but reviewing the expenditure register would reveal the consumption pattern of consumables. Examples of record reviews are -Review of laboratory records for critical alerts, a culture report for microbial surveillance, minutes of the quality circle meeting, safety audit checklists, risk assessment and mitigation plan, reports of the mock drill, control charts- correction factor etc.
- **Patient Interview (PI) -**Interaction with patients & relatives may be useful in getting information about the quality of services and their experience at the facility. It should include Feedback on the quality of services, turnaround time, staff behaviour, waiting times, out-of-pocket expenditure, satisfaction of clients/individuals etc.

Scoring System

After assessing all the measurable elements, checkpoints and marking compliance, the department/ facility scores can be calculated.

Rules of Scoring

2 marks for each compliance

1 mark for each partial compliance

0 Marks for every Non-Compliance

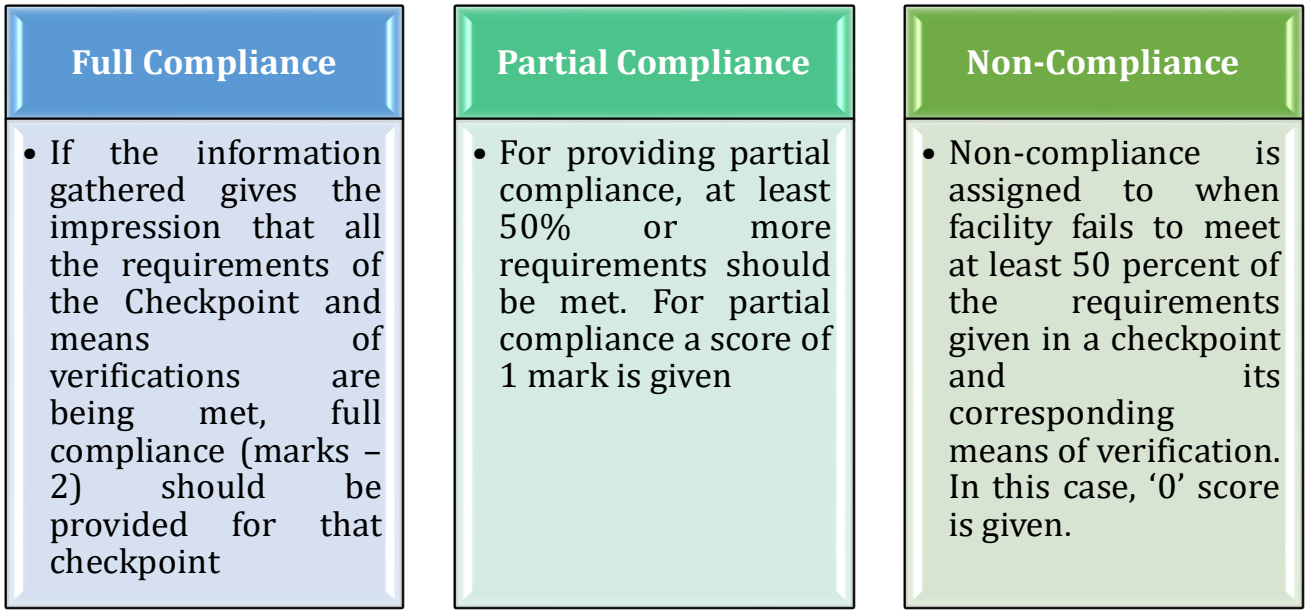


Figure 6: Representing the Scoring rules

All checkpoints have equal weightage to keep scoring simple. Once scores have been assigned to each checkpoint, the Standard wise score can be calculated standard-wise by adding the individual scores for each checkpoint. The final score should be given in percentage to compare it with other public health laboratories.

The calculation of the percentage is as follows:

The score obtained X 100/ No of checkpoints in checklist X 2

Scores can be calculated manually, or scores can be entered into excel sheet given.

Certification Process

The NQAS for IPHL will be used as an assessment and certification tool. Once the laboratory substantially improves during internal assessment and achieves at least 70% or more in NQAS assessment tools, it may become eligible for State & National certification. The criteria and process of certification are explained below.

Steps of the State-level Certification Process:

a. District Quality Assurance unit/ facility level quality team will inform the State Quality Assurance unit (SQAU) about its readiness for state assessments. The SQAU would verify the score and supporting documents and initiate the process of state-level certification.

b. State certification may be conducted with the help of a team constituted of national assessors & internal assessors available in the state. If the number of national assessors in the state is less, the Internal assessor, along with a representative of IPHL (from another district- Pathologist/ microbiologist etc) and a district/state consultant, can conduct the assessment.

c. On meeting all the criteria for state certification, the facility would be declared as '**State level Certified'** by SQAC.

Steps of the National Level Certification Process

a. Once the IPHL is State Certified, the SQAC would send the application in the format given in Operational Guidelines for Improving Quality in Public Health Facilities 2021, along with the requisite documents to Director NHM, MoHFW, requesting the external assessment. NHSRC would check the application and supporting documents before a team of assessors is deputed as per assessment norms.

b. The Certification Unit, NHSRC, shall coordinate the assessment process. The national assessor would submit their findings, and a report is prepared, and submitted to MoHFW with recommendations for certification.

c. NQAS certification of IPHL will remain valid for three years. After completing the first and second years of the national certification, the state would organise a surveillance assessment. Its compliance report will be submitted to the certification unit of the Quality & Patient Safety Division, NHSRC.

d. In the third year, Laboratories would be reassessed by a team of National assessors. In addition, National Health System Resource Centre (NHSRC) and MoHFW may also undertake surprise assessments to ascertain the sustenance of improvement activities.

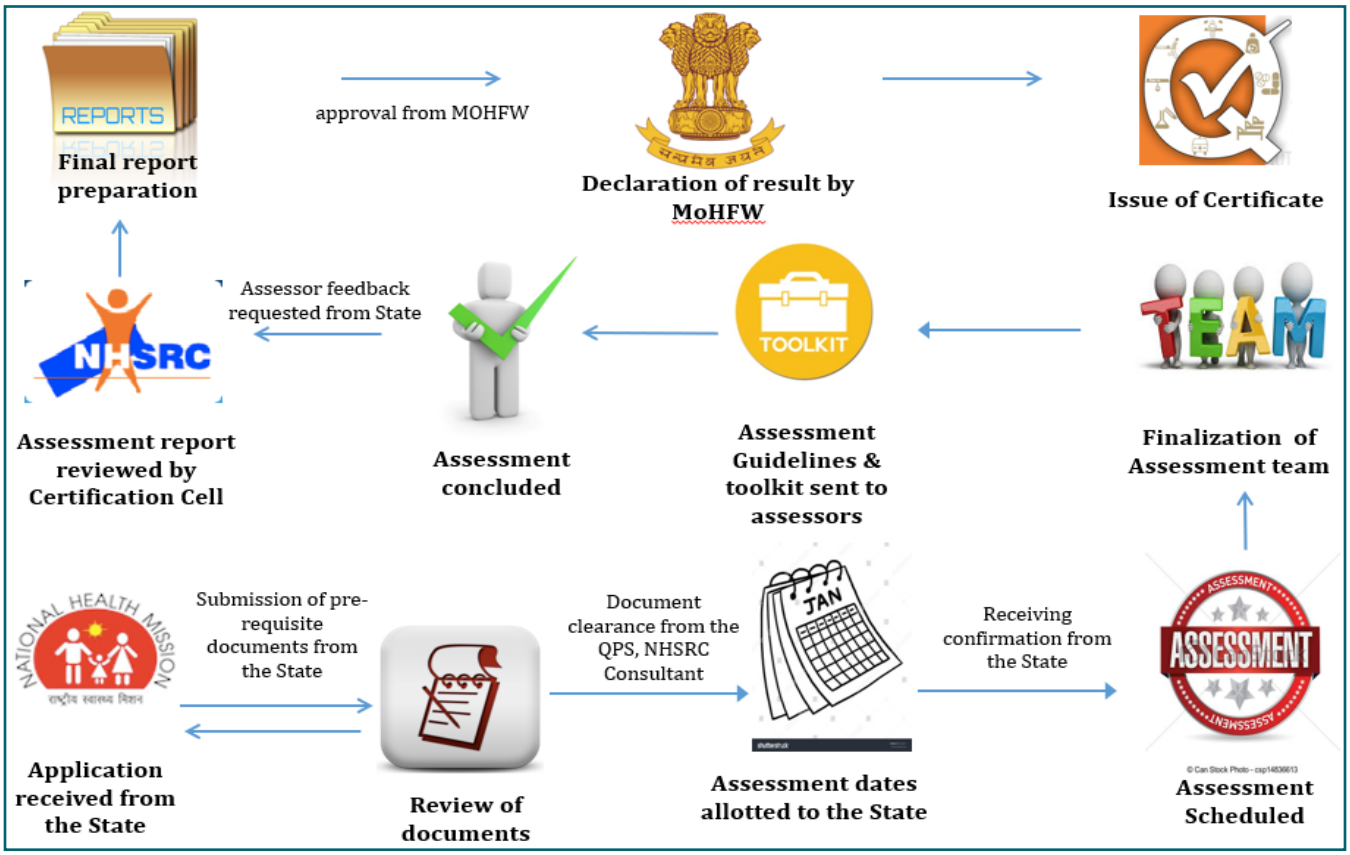


Figure 7 : National Certification Process

Certification criteria:

NQAS for IPHL applies to the laboratories where the facility for testing routine and public health-related diagnostic facilities is in one place.

The certification criteria applicable to National & State levels is mentioned below:

National Level Certification: The national certificate is awarded by MoHFW, per the norms defined by the CQSC. Detailed criteria for National certification are as follows:

Criteria 01- An aggregate score of IPHL is >70%

Criteria 02- An aggregate score of each AoC>70%

Criteria 03- A score of core standards (A1, E3, E4, E5 and E6) >70% (An increment of 5% on every Surveillance audit & Re-certification)

Criteria 04- Individual standard-wise score is >50%

Criteria 05- Patient satisfaction score of 70% in the preceding Quarter or more or Score of 3.5 on Likert Scale.

For state-level certification score of above-criteria may be reduced by 5%

Award of Certification

(a) Certification: If the IPHL meets all of the above-mentioned five criteria.

(b) Certification with conditionality: If an IPHL aggregate score is 70% or more (Criterion I), and also meets at least three criteria out of the remaining four (Criterion II, III, IV & V)

(c) Deferred: The certification may be deferred until follow-up assessments if IPHL's overall score is 70% in external assessment but does not meet the criteria for conditional certification.

Surveillance Assessment:

The State Quality Assurance Unit shall conduct annual surveillance for two years after attaining National certification. State Quality Assurance Committee reserves the right to conduct more frequent surveillance in case of complaints/concerns against the facility.

The facility has to submit a gap analysis report and a time-bound action plan to close the gaps found during the National assessment & surveillance audit to the QPS team of NHSRC.

Re-certification:

To develop a culture of quality sustenance, the facility is expected to undergo recertification as defined in Operational Guidelines for Improving Quality in Public Health Facilities 2021.

NQAS Checklist for Assessment of IPHL

NQAS Checklist for Assessment of IPHL

National Quality Assurance Standards

Checklist for Integrated Public Health Laboratory (IPHL)

Reference No.	Measurable Element	Checkpoint	Compliance	Assessment Method	Means of Verification
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 Basic Haematology services		SI/RR	Hb%, TC, DLC, Platelet, Red Cell Indices, ESR, BG & Rh typing, Blood cross matching, Peripheral blood film, Reticulocyte count, AEC, Prothrombin time (PT) & International Normalised Ratio (INR), Activated partial thromboplastin time
		Availability of specialised Haematology services		SI/RR	Fibrinogen Degradation Product (FDP) test, D-Dimer, Coombs 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
		Availability of advanced Haematology services		SI/RR	Mixing study for Factor Deficiency & inhibitors in Haemophilia, Haemoglobin electrophoresis, Hb-HPLC, Serum Electrophoresis & free light chain assay, Plasma fibrinogen & Serum protein electrophoresis immunofixation, Flow cytometry immunophenotyping/Special stains like MPO stain/ NSE stain/ leukocyte alkaine phosphatase (LAP) score

Reference No.	Measurable Element	Checkpoint	Compliance	Assessment Method	Means of Verification
		Availability of basic Biochemistry services		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.LDH, HbA1C, CRP, S.Electrolytes, Thyroid profile
		Availability of specialised Biochemistry services		SI/RR	S.Amylase, S.Iron, S.Total Iron binding capacity, S.Ionised Calcium, Arterial blood gas test, Urinary protein, Urine for microalbumin, creatinine & protein, Ferritin, Troponin-I/ Troponin-T, S.PSA, CSF & body fluid analysis
		Availability of Microbiology services		SI/RR	1. Microscopy- Wet mount & gram stain for RTI/STD, KOH mount for fungal microscopy, Slit skin smear, Gram staining for clinical specimen 2. Culture- 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, Culture for coliforms, Microbiological analysis of Water (H2S test for screening)
		Availability of Cytology services		SI/RR	FNAC, Pap smear, CSF & body fluid counts cytology, Cell block

Reference No.	Measurable Element	Checkpoint	Compliance	Assessment Method	Means of Verification
		Availability of Histopathology services		SI/RR	Histopathology, Tissue biopsy Give full compliance, if processing of histopathology tests are outsourced
		Availability of Clinical Pathology services		SI/RR	UPT, Urine test for pH, specific gravity, leucocyte esterase, glucose, albumin, bilirubin, urobilinogen, ketone, protein, nitrite, Urine microscopy, Stool for ova, cyst & occult blood, Semen analysis, Porphobilinogen
		Availability of Serology services		SI/RR	1. RPR/VDRL, HIV 1 & 2, Widal, Leptospirosis, Typhus, Measles, Leishmaniasis, ASLO, Rheumatoid Factor (RA), Weilfelix
		Availability of Molecular Biology/ Virology services		SI/RR	PCR for influenza, COVID-19 & emerging infectious diseases (as and when required)
ME A1.2	The facility provides Laboratory services for communicable diseases	Availability of lab services for vector borne disease		SI/RR	rk39 for Kala Azar, ELISA for JE & IgG for Chikungunya, NS1 & IgM for dengue, Malaria, Filaria, Dengue NS1 & IgM As per the endemicity in the geographical area
		Availability of lab services for Tuberculosis		SI/RR	Microscopy for AFB CB-NAAT
		Availability of lab services for HIV		SI/RR	CD4/CD8 count, HIV 1 & 2 Give full compliance, if the facility has established linkages with medical colleges for availability of lab services for CD4/CD8 count

Reference No.	Measurable Element	Checkpoint	Compliance	Assessment Method	Means of Verification
		Availability of lab services for Leprosy		SI/RR	Slit skin smear
		Availability of lab services for viral hepatitis		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		SI/RR	FBS, PPBS, RBS, HbA1c
		Availability of services for NAFLD/ Stroke/ Chronic kidney disease		SI/RR	Liver function test, Lipid profile, kidney function test, PT-INR
		Availability of services for STEMI		SI/RR	C-Reactive protein, Troponin-I/ Troponin-T, D-Dimer
		Availability of services for Cancer		SI/RR	Histopathology, Tissue biopsy, PAP smear, FNAC, Immuno histochemistry
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		SI/RR/OB	Existing functional labs like NACP, NTEP, NVBDCP, NVHCP, IDSP, NIDDCP, NPPCF, etc are converged/integrated with IPHL
		Provides referral laboratory services for public health programmes		SI/RR/OB	For NACP, NTEP, NVBDCP, NVHCP, IDSP etc. from lower down to IPHL and from IPHL to higher facilities
		Support block and district surveillance units		SI/RR/OB	Upload th data in IHIP to detect and respond to public health threats

Reference No.	Measurable Element	Checkpoint	Compliance	Assessment Method	Means of Verification
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		SI/RR/OB	1. Mechanism/System at place for surveillance & monitoring of epidemic & endemic diseases 2. Check system is in place to detect outbreaks by routine lab investigations 3. Appropriate and sufficient number of clinical samples reached to IPHL and etiological diagnosis is made
		Availability of services for Microbiological surveillance of facilities		SI/RR/OB	Active surveillance for Hospital Acquired Infections- 1. AMR surveillance 2. Formulation of Antibiogram
		Availability of services for outbreak surveillance		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		SI/RR/OB	Check for: 1. Laboratory services are available at night 2. Look for number of lab tests performed at night 3. Critical alerts are informed at night

Reference No.	Measurable Element	Checkpoint	Compliance	Assessment Method	Means of Verification
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		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		SI/OB/RR	1. Implementation of Quality Management System 2. Capacity building support
ME A 2.2	Facility provides information management support	Availability of Information management system in linked spokes or peripheral health facilities		SI/OB	Use of LIMS/HIS/ any other IT platform for tracking samples, reporting of the test results, storage, analysis & retrieval of lab data OR If IT system is not available, paper based record may be kept. Partial compliance may be given after verifying the data & information sharing and receiving process followed (manual)
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		OB	1. Name of the IPHL is displayed prominently at the entrance 2. Directional signages from the entrance of the hospital/IPHL is displayed 3. Internal sectional signages are displayed in processing and reporting area of IPHL

Reference No.	Measurable Element	Checkpoint	Compliance	Assessment Method	Means of Verification
		Availability of adequate and clear signages for sample collection area		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		OB	1. Signages and service information is displayed in bilingual language including the local language 2. Signages are visible clearly
		Restricted area signage are displayed		OB	Access to authorized personnel only
		IPHL layout is displayed at the entrance		OB	Central Sample collection area and reporting area 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		OB	Verify with scope of IPHL
		Timing for collection of samples are displayed		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		OB	Turnaround time for report collection is displayed
		Relevant information pertaining to IPHL is displayed		OB	Name, Scope of services, Patient's rights & responsibilities, relevant contact details, user charges, if any, etc.

Reference No.	Measurable Element	Checkpoint	Compliance	Assessment Method	Means of Verification
		Patients & visitors are sensitised and educated for testing requirements		OB/PI	1. Test specific instructions are displayed 2. Patient/relatives are informed about pre-testing requirements (If applicable) 3. Good lab practice to have bilingual information sheets/flyers available for specific test like urine culture and lipid profile, F, PP, GTT etc.
ME B1.3	Access to facility is provided without any physical barrier & friendly to specially-abled people	IPHL provides barrier free services to patient		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		OB	Give full compliance if sample collection area and testing area are at ground floor
		There is no discrimination on basis of social & economic status of patients		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		OB/PI/ RR	1. Informed Consent & counselling is taken before HIV testing, 2. Written consent is taken by treating physician on standardised format in case of histopathological/ cytology procedures (Check TRF clearly mentioned whether consent is taken) 3. Written consent is taken for invasive procedures

Reference No.	Measurable Element	Checkpoint	Compliance	Assessment Method	Means of Verification
ME B1.5	The facility has defined and established grievance redressal system in place	Availability of complaint box		OB/RR	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 complaint is defined and displayed bilingual 3. Staff is aware about complaints pertaining to the lab & mechanism of the complaint re-addressal 4. Lab ensures that actions are taken against the complaints within the defined time interval
		Information about complaint re-addressal is displayed		OB	104/state specific number/ CM Portal
ME B1.6	The facility provides cashless services as per prevalent government norms/schemes	IPHL provides free diagnostic services as per guidelines/ state mandate		OB/PI	As per the mandate of free diagnostic services
		Check patient has not incurred any expenditure on diagnostics		OB/PI	Ask patient randomly (At least 5)
		Cashless investigations for patients/ beneficiaries		OB/PI	JSSK, Ayushman Bharat, applicable national & state specific govt. schemes
Standard B2	**The service provided at facility are acceptable**				
ME B2.1	Adequate visual privacy is provided at every point of care	Availability of screen/ partition at sample collection area		OB	Privacy is maintained at OPD areas
		Adequate privacy is maintained during sample collection		OB	IPD, Emergency & Critical areas

Reference No.	Measurable Element	Checkpoint	Compliance	Assessment Method	Means of Verification
ME B2.2	Services are provided in manner that are sensitive to gender	Separate queue for female and specially abled patients		OB	1. IPHL and sample collection areas / report receiving areas 2. Give the full compliance, if token system is followed
		Laboratory has defined policy for non-discrimination on basis of gender		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		OB/RR	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, etc.
		Laboratory Records are kept at secure place		OB	General staff/visitors do not have access to the lab reports
		HIV positive reports are communicated		OB/SI	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		OB/PI	
		Check there is no overcrowding at OPD sample collection area		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		OB/RR	1. 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 2. Check that updated copy for code of conduct is available

Reference No.	Measurable Element	Checkpoint	Compliance	Assessment Method	Means of Verification
		Check if staff is aware of code of conduct		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		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 written informed consent is taken from patient participating in any clinical or public Health research		RR/SI	Check for policy or practice, consent form is available in the language which is understandable by the patient
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		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			(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 is

Reference No.	Measurable Element	Checkpoint	Compliance	Assessment Method	Means of Verification
				RR	sues like sample collection, transfer, testing, resulting, disclosure of information or any professional conflict which may not be in patient's best interest - May be as per guidance of the main hospital
		Check the list of ethical issues is available and regularly updated		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		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 dilemmas & 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		OB	Adequate area for waiting, registration and sample collection, report dissemination (if done from sample

Reference No.	Measurable Element	Checkpoint	Compliance	Assessment Method	Means of Verification
					collection area) is available in the central Sample collection area
		Laboratory space is adequate for carrying out activities		OB	1. Adequate area is available for performing tests, sample storage, keeping equipment, washing, sterilization, waste storage before disposal, report dissemination and storage of reagents and records etc. is available 2. Check testing areas have adequate space for sample processing and there is no cluttering of equipment at the work stations
		Adequate space is available for keeping staff amenities		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 provided at sample collection area as per patient load	Services counters are available as per patient load		OB	1. Availability of adequate no. of registration, sample collection and report collecting counters as per patient load. 2. Sample collection counters are adequate as per patient load (3-4) - separate counter for Female and elderly patients 3. No overcrowding in sample collection area

Reference No.	Measurable Element	Checkpoint	Compliance	Assessment Method	Means of Verification
		Availability of sitting arrangement in the waiting area		OB	Check adequate sitting arrangement as per patient load is available in waiting area
		Availability of functional toilets		OB	Availability of separate male and female toilets in proximity to central sample collection area (for urine sample collection) May be shared with main OPD/Hospital building
		Availability of drinking water		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		OB	1. Dedicated area of sample collection with the provision of reception, registration and waiting area 2. Check negative pressure is maintained in microbiology sample collection area 3. Demarcated room/ area for FNAC, - with provision of bed Check adequate privacy is maintained in each sample collection point 4. Demarcated area for sputum collection

Reference No.	Measurable Element	Checkpoint	Compliance	Assessment Method	Means of Verification
		Demarcated sample receiving area		OB/RR	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 3. Check the records of quarterly audit of preanalytical in spokes and wards
		Demarcated area for sample processing		OB	(1) routine testing and public health-related diagnostic facility is located at one place. (2) Demarcated areas for Haematology, Biochemistry, Clinical pathology, cytology, microbiology, mycobacteriology, serology, media preparation, histopathology, etc. - Effective separation with adjacent laboratory sections in which there are incompatible activities (dirty/clean areas, separate microbiology, and common testing area) - designated room for specialized testing (e.g. TB testing and PCR)
		Demarcated reporting area		OB	1. Designated report writing area (in main lab) 2. Designated report collecting area (In the central sample collection area / in main lab)

Reference No.	Measurable Element	Checkpoint	Compliance	Assessment Method	Means of Verification
		Designated washing and waste disposal area		OB	1. In the central sample collection area 2. In sample processing areas
		Designated eye-wash station		OB	Standalone facility or attached to sink for eyewash in case of chemical splash in eye/ body
		Availability of auxiliary/accessory area		OB	Small store 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		OB	Check availability of landline/intercom/mobile/WhatsApp, etc. for intramural and extramural communication is available
		Availability of functional modules for Hospital or laboratory information management		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		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		OB	Check for fixtures and furniture like cupboards, cabinets, and heavy equipment's , hanging objects are properly fastened and secured

Reference No.	Measurable Element	Checkpoint	Compliance	Assessment Method	Means of Verification
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		OB	Give full compliance if sample is transported manually ensuring all the sample transportation protocols
		Alarm system is used to indicate the sample drop		OB	1. Specially from critical areas like emergency IPD, ICU and emergency 2. Provision of special colour coding or electronic flag in LIMS for critical samples
		Process is defined and followed for Periodic Maintenance of dumb waiters		OB/RR	1. Regular cleaning, operations, maintenance and trouble shooting in case of malfunctioning 2. Specimens are transported in clean sample carriers if manually transported - Give full compliance if dumb waiter is not required/not installed and alternate effective system is in place for sample transportation
		Functional lift is available for easy access to IPHL		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		OB	In Lab and sample collection areas

Reference No.	Measurable Element	Checkpoint	Compliance	Assessment Method	Means of Verification
		Adequate electrical socket is available		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		OB/RR	Check six monthly once at least
		Constant out put voltage is provided to the equipment		OB	Automatic voltage regulators are installed
		Facility has mechanism for periodical check / test of all electrical installation		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		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		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		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.		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.		SI/RR	Check Material safety data sheet is available

Reference No.	Measurable Element	Checkpoint	Compliance	Assessment Method	Means of Verification
		Fire Safety audit is done by competent authorities		RR/SI	May be along with main Hospital building/separately
ME C3.2	The facility has adequate firefighting Equipment	Check fire Extinguishers are installed in IPHL and sample collection area		OB	1. Class A , Class B, C type or ABC type in sample collection, processing and reporting area 2. Check dry CO2 type extinguisher/s in the testing areas for electrical fires
		No fire extinguisher is expired in lab, circulation area, waiting, area, Corridors		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		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		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		OB/RR	(1) Check organogram is displayed (2) Clearly showing the interrelationship of the staff

Reference No.	Measurable Element	Checkpoint	Compliance	Assessment Method	Means of Verification
		Availability of Specialist		OB	1-Pathologist 1-Microbiologist 1-Biochemist Give full compliance if at least two specialists are available
ME C4.2	The facility has adequate technicians/ paramedics as per requirement	Availability of Medical Lab Technologist/ Lab Technician		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		OB/RR	As per case load
		Availability of Sanitation staff/ Housekeeping staff		OB/RR	As per case load
		Availability of Security Guard		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, chemicals and rapid diagnostic kits		OB/ RR	Reagents for auto analysers, ELISA Readers reagents, culture media, Acetone, Alcohol, distilled water, Microscope gel, RDK for malaria, dengue, etc.
		Availability of control		OB/RR	Quantitative / Qualitative Lyophilized / ready to use Assayed/unassayed etc Check the availability of controls for basic haematology and biochemistry tests if a facility is appearing for quality certification for the first time and for all tests subsequently

Reference No.	Measurable Element	Checkpoint	Compliance	Assessment Method	Means of Verification
		Availability of stains		OB/ RR	Iodine Solution, Haematoxylin-eosin, Gram Romanowsky, StainZiehl- Nielsen, Acridine orange, Albert stain, India ink, calcofluor white, KOH
ME C5.2	The facility has adequate consumables at point of use	Availability of Laboratory consumables		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		OB/ RR	Must aware of basic lifesaving skills, foot end elevation, IV line set up, etc. OR If standalone, emergency drug tray is maintained and staff is trained to use it
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 in sample collection area		OB	Stethoscope, BP apparatus, Povidone iodine, Syringe, Vacutainers, Vaccum needles and needle holder, Torniquets, Spirit/antisepsis, cotton swabs at sample collection area
		Availability of equipment for clinical pathology		OB	1. Binocular Microscope, Urine analyser, Centrifuge, Bunsen burner with gas supply, etc. 2. Check the availability of equipment as per load 3. Check back-up of the critical equipment is available in case of malfunction

Reference No.	Measurable Element	Checkpoint	Compliance	Assessment Method	Means of Verification
		Availability of equipment for haematology		OB	1. Binocular Microscope, Automated Cell Counter (3 part/5 part) with nucleated RBC flag, Automated Coagulometer, Automated ESR analyser, Haemoglobin HPLC machine (variant analyser), Serum electrophoresis and Hb electrophoresis 2. Check the availability of equipment as per load 3. Check back-up of the critical equipment is available in case of malfunction
		Availability of equipment for cytology		OB	1. Binocular Microscope, Centrifuge 2. Check the availability of equipment as per load 3. Check back-up of the critical equipment is available in case of malfunction
		Availability of equipment for biochemistry		OB	1. Automated Biochemistry analyser, ISE based Electrolyte analyser, Automated Hormone Immunoassay analyser (CLIA Based) 2. Check the availability of equipment as per load 3. Check back-up of the critical equipment is available in case of malfunction
		Availability of equipment for media preparation room		OB	Electronic balance Hot plate Autoclave Ph meter Bunsen burner with gas supply

Reference No.	Measurable Element	Checkpoint	Compliance	Assessment Method	Means of Verification
		Availability of equipment for bacteriology		OB	1. 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, Hot air oven, inoculating loop, lamp 2. Check the availability of equipment as per load 3. Check back-up of the critical equipment is available in case of malfunction
		Availability of equipment for mycobacteriology		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 and molecular biology/virology		OB	Centrifuge ELISA reader and washer VDRL rotator/shaker 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

Reference No.	Measurable Element	Checkpoint	Compliance	Assessment Method	Means of Verification
		Availability of functional equipment under NVBDCP		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		OB	Pipettes, Centrifuge, HIV test kits, test tubes
		Availability of functional equipment under NTEP		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		OB	Biosafety Cabinet Class ll 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		OB	Buckets for mopping, mops, duster, waste trolley, deck brush
		Availability of equipment for sterilization and disinfection		OB/RR	Autoclave - Horizontal & Vertical
		Availability of equipment for Data Management		OB	Computer, Printer, UPS, bar code scanner/reader, etc.

Reference No.	Measurable Element	Checkpoint	Compliance	Assessment Method	Means of Verification
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		OB	Refrigerator, Deep freezer, Test tube racks
		Availability of fixtures at lab		OB	Illumination at work station, Electrical fixtures, Air Conditioners etc.
		Availability of furniture		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		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		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		RR	(1) Check for records of competence assessment including filled checklist, scoring and grading . (2) Verify with staff for actual competence assessment done

Reference No.	Measurable Element	Checkpoint	Compliance	Assessment Method	Means of Verification
					(3) Check on job assessment for test performance, recording and reporting of results, review of intermediate test results, worksheets, QC results etc., observe for instrument handling, maintenance, and function check. Competence assessment for test performance through re-testing of previously analysed samples, etc. (4) Check feedback is given to all staff after competence assessment
		Check if annual performance appraisal for clinical staff is practiced		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 performance assessment
ME C7.3	The Staff is provided training as per defined core competencies and training plan	Check operator is trained for using automated diagnostic equipment		SI/RR	Training on automated Diagnostic Equipment's like auto analyser

Reference No.	Measurable Element	Checkpoint	Compliance	Assessment Method	Means of Verification
		Check lab technician are trained for sample collection		SI/RR	Check training record 1. Lab technicians is trained on venous blood collection, collection of microbiology samples like throat swab, nasopharyngeal swab, pus samples, slit skin etc. 2. Staff nurses or designated person for sample collection in wards are trained for Arterial blood collection and capillary blood collection (in case lab technician are not collecting the blood from wards)
		Check staff is trained for sample transportation		SI/RR	Check training records
		Check that staff is trained on Laboratory safety & Infection prevention and control		SI/RR	Check records of training on biosafety (use and donning, doffing of PPE; use of biosafety cabinets etc), biomedical waste management, hand hygiene, disinfection and sterilization, bio safety cabinet certification etc.
		Check staff is trained for Internal and External Quality Assurance		SI/RR	Check records of training on Internal and External Quality Assurance
		Check that staff is trained for documentation preparation		SI/RR	Specimen handling manual, acceptance/ rejection criteria, critical alerts, inventory management, result reporting format, IQC records, SOP etc

Reference No.	Measurable Element	Checkpoint	Compliance	Assessment Method	Means of Verification
		Check staff is trained to use LIMS and IHIP		SI/RR	Data entry, specimen tracking ,reporting, analysis of data etc
		Check that clinicians are trained for Laboratory-based surveillance of infectious diseases		SI/RR	Check records of training on syndromic diagnostic approach, preparation of line list and generation of early warning signals
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.		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		SI/RR	(1) Check induction and refresher training is provided 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		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 provided on job training wherever there are skill gaps

Reference No.	Measurable Element	Checkpoint	Compliance	Assessment Method	Means of Verification
		Staff is skilled for maintaining Laboratory records		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 provided 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/ CMC including preventive maintenance		SI/RR	1. Check with AMC/ CMC 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 (check the linkage with BMMP programme as applicable) 4. Preventive Maintenance activities and schedule is available
		There is system of timely corrective break down maintenance of the equipment's		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

Reference No.	Measurable Element	Checkpoint	Compliance	Assessment Method	Means of Verification
		Staff is skilled for trouble shooting in case equipment malfunction		SI	Interview few of the staff randomly
		Periodic cleaning, inspection and maintenance of the equipment's is done		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		SI	Check for the Bench Aids for routine use of equipment
		There is a system to label Defective/ Out of order equipment's		OB	Defective/Out of order equipment are stored appropriately until it has been repaired
		All equipment are checked for the safety of the users		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		RR	1. Acceptance testing details should be part of installation report 2. Post preventive/ breakdown maintenance acceptance testing should be documented in service reports. 3. Post preventive/ breakdown maintenance appropriate QC / calibrators must be run and outputs reviewed as a part of acceptance testing

Reference No.	Measurable Element	Checkpoint	Compliance	Assessment Method	Means of Verification
		IT equipment are covered under corrective and preventive maintenance program		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		OB/ RR	Recalibration done at least every six months or as per OEM specifications.
		There is system to label/ code the equipment to indicate status of calibration/ verification when recalibration is due		OB/ RR	Check for the bar code or any record of calibration status
		Calibrators are available and used for the automated analysers		SI/RR	1. Haematology analysers, Coagulation analysers, Microbiology analysers, etc. 2. Calibrators are available 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		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		SI/RR	Check the records

Reference No.	Measurable Element	Checkpoint	Compliance	Assessment Method	Means of Verification
		Staff is aware of when and how to recalibrate the equipment's		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		RR/OB	Check for Internal Calibration Records External Calibration Certificate Raw data generated during the calibration Certificate of Measurement 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)		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		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		SI/RR	Stock level are daily updated Requisition are timely placed

Reference No.	Measurable Element	Checkpoint	Compliance	Assessment Method	Means of Verification
ME D2.2	The facility ensures proper use and storage of consumables and reagents	Reagents, control and other consumables are stored appropriately		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 the manufacturer.
		There is process for storage of reagents, kits and material requiring controlled temperature		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 refrigerator
		Standard operating procedures are referred to prepare the working solutions and all the prepared solutions are labelled		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 (in case controls and calibrators are provided by the manufacturers) 7.Prepared by (name)

Reference No.	Measurable Element	Checkpoint	Compliance	Assessment Method	Means of Verification
		Reagents, controls and other consumables are accompanied with relevant SOP		OB/RR	Details relevant to usage like sensitivity, specificity, measuring range, shelf life, SDS, storage and disposal
		Reagents and control are labelled appropriately		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		RR/SI	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 consumables found		OB/RR	Check randomly for expiry of the reagents, controls and other consumables
		Expiry and near expiry reagent are identified and stored separately		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		OB/RR	Based on First Expiry First Out (FEFO)
		There is practice of calculating and maintaining buffer stock of reagents and controls		SI/RR	1. Based on the consumption 2. Stock and expenditure registers are maintained
		There is procedure for periodically replenishing reagents, control and other consumables		SI/RR	There is no stock out of reagents

Reference No.	Measurable Element	Checkpoint	Compliance	Assessment Method	Means of Verification
		Description of reagents, kits and materials are maintained in the inventory log/register.		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		OB	Look for the presence of undesirable reflections and glare
		Adequate illumination at sample collection area		OB	Look for the presence of undesirable reflections and glare
		Adequate illumination at circulation area		OB	Check the illumination adequacy at the stairs and corridors
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		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		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		SI/RR	Fans/ Air conditioning/Heating/Exhaust/ Ventilation as per environment condition and requirement
		Temperature control and ventilation testing area		SI/RR	Fans/ Air conditioning/Heating/Exhaust/ Ventilation as per environment condition and requirement

Reference No.	Measurable Element	Checkpoint	Compliance	Assessment Method	Means of Verification
		Availability of separate room for tissue processing		OB	1. For histopathology sections 2. Fume hoods are available in tissue processing area 3. Separate ventilation for Biosafety cabinets in microbiology
		The facility has established measure for safety and security of female staff		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 the main hospital)
		The facility has Material Safety Data Sheets (MSDSs) for chemicals		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. 10. Neutralisation / Deactivation and disposal OR as provided by the manufacturer

Reference No.	Measurable Element	Checkpoint	Compliance	Assessment Method	Means of Verification
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		OB	1.Whitewashed in uniform colour 2. No outdated poster are pasted on the walls
		Interior of the building is plastered & painted		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		OB	Floors, walls, roof, roof tops, sinks, waiting, sample collection area and testing areas are neat and clean
		Cleaning schedule is maintained		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		OB	Check there is no dirt or grease on furniture
		The facility has standard procedures for cleaning of curtains/blind & shades		OB/RR/SI	Check for: 1. Curtains/Blind & shades are cleaned regularly
		Toilets are clean with functional flush and running water		OB	Check for: 1. Toilets in proximity to the sample collection area 2. Toilet in the staff area 3. Check toilets are clean and there is no foul smell in the toilets
ME D4.3	Facility's infrastructure is adequately maintained	Check for there is no seepage , Cracks, chipping of plaster		OB	
		Window panes, doors and other fixtures are intact		OB	

Reference No.	Measurable Element	Checkpoint	Compliance	Assessment Method	Means of Verification
		Periodic maintenance of the infrastructure is defined at the regular interval		RR/OB	Annual maintenance plan is available
		There is no clogged/over flowing drain in facility		RR	
ME D4.4	The facility has policy of removal of condemned junk material	No condemned/ Junk material is kept in the lab		OB	1. Sample collection area 2. Processing area 3. Report collection area
		Condemnation policy is at place		RR	Condemnation policy is available and staff is aware of it. May be shared with main hospital
		There is an established procedure for decommission, disposal and condemnation of the equipment if no longer in use		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		OB	1. Pest control measures are taken at regular interval 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		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		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

Reference No.	Measurable Element	Checkpoint	Compliance	Assessment Method	Means of Verification
		Facility periodically tests the quality of water from the source (municipal supply, bore well etc) for bacterial and chemical content		RR	
		Distilled/deionised water is used for testing		OB/RR	Testing must be done every three months
		Water used for analytical purpose is of reagent grade		OB/RR	Parameters used for water testing must be as per test requirements and manufacturer instruction in cases of automated and semiautomated analysers
ME D5.2	The facility ensures adequate power backup in all patient care areas as per load	Availability of power back up in laboratory and related areas		OB/SI	Check that UPS connection with critical equipment is provided
		Availability of noise less generator for the power backup		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		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		RR/SI	Facilities are identified for upward linkages and staff is aware of it
		Check routine testing and public health related testing is integrated		RR/SI	1. Restructuring of routine and public health diagnostics is done and its functional 2. Check there is no duplication of diagnostic services

Reference No.	Measurable Element	Checkpoint	Compliance	Assessment Method	Means of Verification
		There is established system of integration between health and other departments		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		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		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		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		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 threats in real time

Reference No.	Measurable Element	Checkpoint	Compliance	Assessment Method	Means of Verification
		There is an established linkage with Integrated Health Information Platform (IHIP)		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 provided to it	There is system to track and ensure that funds are received on time		RR/SI	As given under PM-ABHIM, XV-Finance Commission, etc.
		Funds/Grants provided are utilized in specific time limit		RR	As given under PM-ABHIM, XV-Finance Commission, etc.
		Salary and compensation of contractual staff is given on time		SI	
ME D7.2	The facility ensures proper planning and requisition of resources based on its need	Facility prioritize the resource available		RR/SI	Requirement for funds are sent to state on time
		Utilisation certificate is submitted on time		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		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		RR	Give full compliance if the facility shares BMW authorisation with main hospital building
		Availability of certificate of inspection of electrical installation		RR	

Reference No.	Measurable Element	Checkpoint	Compliance	Assessment Method	Means of Verification
		The facility ensure relevant processes are in compliance with statutory requirement		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		RR	Updated copy is available, may be shared with the main hospital
		Code of Medical ethics 2002		RR	Updated copy is available, may be shared with the main hospital
		Person with disability Act 1995		RR	Updated copy is available, may be shared with the main hospital
		Right to information act 2005		RR	Updated copy is available, may be shared with the main hospital
		Indian Tobacco control Act 2003		RR	Updated copy is available, may be shared with the main hospital
		HIV/AIDS prevention and control Act		RR	With mandatory provision of pre and post-test counselling)
		Epidemic diseases (Amendment) Ordinance 2020		RR	Updated copy is available, may be shared with the main hospital
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		SI	Check lab staff is aware of their roles and responsibilities
		Job description of staff is defined and communicated		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		RR/SI	Check for system for recording time of reporting and relieving (Attendance register/ Biometrics etc) and handover register

Reference No.	Measurable Element	Checkpoint	Compliance	Assessment Method	Means of Verification
		Duty roster of lab technician is prepared, updated and communicated		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		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		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		OB	As per the state's norms
		The facility has established procedures for credentialing of staff		SI/RR	Check for: 1. Minimum professional qualification for all 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 documented

Reference No.	Measurable Element	Checkpoint	Compliance	Assessment Method	Means of Verification
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 support services on regular basis		SI/RR	Verification of outsourced services (cleaning/Laundry/ Security/Maintenance) provided are done by designated in-house staff
		There is procedure to monitor the quality and adequacy of outsourced laboratory tests/ services on regular basis		SI/RR	Check for: 1. Check if any of the lab test/service is outsourced 2. NABL / NQAS certification of outsourced partner entity 3. Participation of outsourced partner in Proficiency Testing / Inter Laboratory Comparison Program and its results 4. Formal MOU / Service Level Agreement covering scope of services, TAT, Critical Value Reporting, Quality Management parameters etc OR If lab test/services are in-house, give full compliance
		Selection of outsourced agencies is done through competitive tendering process		RR	1. May be shared with the main hospital 2. Review the contract document

Reference No.	Measurable Element	Checkpoint	Compliance	Assessment Method	Means of Verification
ME D10.2	There is a system of monitoring of quality of out sourced services	Facility has defined criteria for assessment of quality of outsourced services		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 black-listed vendors are available		RR	May be shared with the main hospital building
Area of Concern - E Clinical and Diagnostic 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		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		RR/OB	Electronic or on paper
		Patient demographic details & unique identification no. are recorded in Test Requestion form		OB/RR	Check for: 1. Patient demographics like Name, age, Sex, Address, etc. are recorded 2. Time of sample collection is recorded 3. Name and signature of the sample collector is recorded 4. Details of sample received is mentioned (in-house lab or peripheral health facilities) 5. UID of all patients (IPD/OPD) assigned by hospital is mentioned on TRF 6. History of the patient is recorded, if required

Reference No.	Measurable Element	Checkpoint	Compliance	Assessment Method	Means of Verification
		Sample ID no is assigned to patient samples for tracking the sample through lab		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		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		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		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		RR/SI	1. Laboratory has assured linkage with State PHL/ Medical college lab for the tests not being performed in the lab 2. Check the relevant government order for assured linkages
ME E2.2	The facility has defined and established procedures for intersectoral coordination	The facility coordinates with other allied departments for intersectoral convergence		RR/SI	Like Central Pollution Control Board, FSSAI, PHED, Veterinary, Forensic department, etc.

Reference No.	Measurable Element	Checkpoint	Compliance	Assessment Method	Means of Verification
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		OB/SI	Haematology, Biochemistry, Histopathology, Clinical Pathology, Microbiology, etc.
		The patient is prepared before collecting the primary sample		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		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		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		OB/SI	It includes: 1. Sample collected from OPD 2. Samples from IPD of the district hospital 3. Samples collected from spokes/peripheral facilities

Reference No.	Measurable Element	Checkpoint	Compliance	Assessment Method	Means of Verification
		Temperature is maintained for the samples collected from the peripheral health facilities		OB/SI	1. Temperature of collected sample is maintained as defined by the refree lab 2. Check availability and use off data loggers
		Check steps to collect the sample are defined and followed by Phlebotomist		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		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 70% 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

Reference No.	Measurable Element	Checkpoint	Compliance	Assessment Method	Means of Verification
					8. Smoothly insert the needle with bevel at 15-30 degree of angle 9. Remove the tourniquet as soon as the blood begin to flow 10. In case of multiple punctures, record is maintained
		Sample collection for the blood culture is done as per the standard guidelines		OB/SI	1. Minimum two blood culture sets are collected within 24hrs based on - Clinical condition - Adequate volume - number of sets - Timing 2. Samples are collected before use of antimicrobials 3. Vacutainer holder or butterfly needles available to ensure proper collection volume. 4. Staff is aware of blood culture collection guidelines
		Sample collection other than blood is done as per protocol		SI/PI	Urine, Sputum, Stool, etc.
		Order of draw, mixing and inversion are defined and followed		OB/SI	As per the facility's instruction Samples containing additives are mixed by inverting, ensure no shaking of the tubes

Reference No.	Measurable Element	Checkpoint	Compliance	Assessment Method	Means of Verification
		Instructions for collection and handling of primary sample are communicated to those responsible for collection		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		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		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.		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		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

Reference No.	Measurable Element	Checkpoint	Compliance	Assessment Method	Means of Verification
ME E3.3	The facility has established procedure for sample labelling and documentation	IPHL has defined a procedure for labelling of the samples		RR/OB	1. The facility is using the bar code as identifier, if labelling is done manually, give partial compliance 2. If bar code is maintained, check randomly how bar codes are placed (volume of the sample is visible from outside)
		Samples are labelled with at least two unique identifiers		RR/OB	1. 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		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		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 10 requisition forms for uniform data collection

Reference No.	Measurable Element	Checkpoint	Compliance	Assessment Method	Means of Verification
ME E3.5	The facility has established procedure for packaging and transportation of samples	Procedures are defined for packaging and transportation of samples		OB/SI	Haematology, Biochemistry, Histopathology, Clinical Pathology, Microbiology, etc.
		Collected samples are packed as per the standard guidelines		OB	1. Samples are collected in vacutainers as per the guidelines 2. Samples are packed in triple layered container packing (particularly virology) 3. Check 10 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		RR/OB/SI	Transportation of sample includes: Temperature requirement, preservation (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, samples are transported in transport media, in case of delay, or categories are defined based on the risk involved

Reference No.	Measurable Element	Checkpoint	Compliance	Assessment Method	Means of Verification
		Samples are transported timely at the IPHL		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 4. Verify with the requisition slip 5. Data loggers are used for monitoring in terms of time and temperature
		There is a defined protocol for pick-up of emergency samples		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 form
		The sample dispatch time is recorded electronically in the LIMS		OB/RR	Check real time data entry in the LIMS

Reference No.	Measurable Element	Checkpoint	Compliance	Assessment Method	Means of Verification
ME E3.6	The facility has defined criteria for sample acceptance or rejection	Check criteria is defined for sample acceptance and followed		RR/OB/SI	Checks staff is aware of sample acceptance criteria which include appropriate container, quantity/volume (in case of blood/urine sample), temperature on receipt, quality of sample (in case of tissue samples), any leakage, etc. As defined by the IPHL in the standard operating procedures for Haematology, Biochemistry, Histopathology, Clinical Pathology, Microbiology, etc.
		There is defined procedure for sample acceptance of in-house samples		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

Reference No.	Measurable Element	Checkpoint	Compliance	Assessment Method	Means of Verification
		There is defined procedure of sample acceptance for samples received from the spokes/ peripheral health facilities		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 register/LIMS for further monitoring
		Sample preparation as per defined protocols		OB/SI	Check the staff is aware of processing protocols
		Check criteria is defined for sample rejection and followed		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

Reference No.	Measurable Element	Checkpoint	Compliance	Assessment Method	Means of Verification
					3. Check IPHL inform peripheral lab about the rejected sample-record is maintained that who has informed and at what time 4. 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, Biochemistry, Histopathology, Clinical Pathology, Microbiology, etc.
		There is a defined set of activities post sample rejection		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
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		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.

Reference No.	Measurable Element	Checkpoint	Compliance	Assessment Method	Means of Verification
ME E4.2	Test procedures are verified through routine quality control methods	Quality control mechanisms are defined for all test procedures		RR/SI	1. Haematology, Biochemistry, Histopathology, Clinical Pathology, Microbiology, Cytology, etc. 2. Check IPHL runs quality control at defined interval as per standard procedures
		All test procedures are verified before routine use		RR/SI	1. Check for records for 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, carry over 2. For Rapid Diagnostic Tests as per manufacturer's guidelines
ME E4.3	Facility has established procedure for Biological reference intervals & critical alert values	Critical values are defined for each specialization		RR/SI	Check that: 1. Staff is aware of critical values 2. Critical Values are displayed / filed for ready reference in the laboratory, check the documents 3. Read-back in case of telephonic or verbal communication
		There is an established procedure of reporting the critical alert values		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

Reference No.	Measurable Element	Checkpoint	Compliance	Assessment Method	Means of Verification
		Laboratory has defined and updated its Biological Reference Interval (BRI) and has a procedure to review the BRI		RR/SI	1. BRI is documented 2. BRI is updated annually and communicated to the staff whenever there is change procedure/ method of testing 3. Check for BRI or clinical normative range is written in the reports
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		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		RR/OB	By technically competent and experienced designated person

Reference No.	Measurable Element	Checkpoint	Compliance	Assessment Method	Means of Verification
		Interim results are followed by the final reports		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		RR	Microbiologist/Pathologist/Biochemist
		The Laboratory defines the Turn Around Time (TAT) for each test both for the routine and emergency cases		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 including referred/ outsourced tests		OB/SI	Through LIMS/SMS/e-mail/hard copy
		Staff is designated to disseminate the reports		OB/SI	In IPDs and other areas of the hospital
		Staff is aware of post analytical error		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		SI/RR/OB	Tele equipment print out, workbook, datasheet with the report

Reference No.	Measurable Element	Checkpoint	Compliance	Assessment Method	Means of Verification
		Check notification is sent by lab in case of any delay in the reporting		OB/SI/RR	Through LIMS/SMS/e-mail
ME E5.2	The laboratory has defined procedure for revision/amendment of the reports when required	The laboratory has procedure to ensure revision of results and correct interpretation before release of the results		RR/SI	1. Laboratory has clearly defined the responsibility of amending the test results 2. Revision/ Amendments in the reports due to re-test/ re-sampling/ QC failure etc. are highlighted in the report. 3. Reason of amendments are documented along with the date of amendment 4. All the amended reports are stored by the laboratory in soft or hard copies
		Laboratory has process of taking corrective actions for any discrepancy in the test result		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
ME E5.3	The facility has established procedure for sample storage and its disposal	Samples are retained and stored for re sampling and additional examination as per facility's policy & procedure		RR/SI	Check for sample retention protocols, storage conditions as mandated, record of storage is maintained, samples are labelled with time of preparation

Reference No.	Measurable Element	Checkpoint	Compliance	Assessment Method	Means of Verification
		Separate refrigerator is available for sample storage		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		OB/SI	Check the methodology for indexing is defined and followed
Standard E6	**The facility has established mechanism for internal and external quality assurance of testing procedures**				
ME E6.1	The facility has established mechanism of internal quality control using quantitative methods	The facility has defined performance evaluation mechanism for control material		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		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)

Reference No.	Measurable Element	Checkpoint	Compliance	Assessment Method	Means of Verification
		Staff is aware of defined protocol for rejection of test run		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 quality control in place when control material is not available		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 3. Correlation of test results with other parameters

Reference No.	Measurable Element	Checkpoint	Compliance	Assessment Method	Means of Verification
		The facility plot Levy Jennings's (LJ) chart daily for Quality Control values		RR/SI	1. Staff knows how to plot and interpret LJ chart using inbuilt software in the analysers or using excel sheet 2. Outliers are identified 3. Corrective action is taken and documented on the identified outliers according to the Westgard rule
ME E6.2	The facility has established mechanism of internal quality control using semi quantitative/qualitative methods	Quality assurance mechanisms are defined for all steps of microbiology		RR/SI	Bacteriology, Parasitology, Mycology, Serology, Molecular Diagnostics
		Quality assurance mechanisms are defined for all steps of histopathology and cytology		RR/SI	To identify and manage the potential errors
		IQC (Qualitative) are defined for all steps of Haematology and Clinical Pathology		RR/SI	Smears, ESR, Urine Analysis, Semen Analysis, Boddy fluid analysis like CSF
		Internal Quality Control processes are followed for national health programmes		RR/SI	As defined in programme guidelines (like TB, Malaria, etc.)
ME E6.3	The facility has established mechanism of external quality assurance	External Quality Assurance methods are defined for test performed in IPHL		RR/SI	Haematology, Microbiology, Cytology, Biochemistry, Histopathology, Clinical Pathology, etc. or as per the scope of services
		IPHL has defined the ways to conduct external quality assurance		RR/SI	EQAS or Peer group comparison or exchange of sample or split testing
		External Quality Assurance is done on regular basis		RR/SI	For monitoring, accuracy and calculating bias

Reference No.	Measurable Element	Checkpoint	Compliance	Assessment Method	Means of Verification
		providers are identified for Proficiency Testing/EQAS		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		RR/SI	1. Staff is aware of EQAS reporting system, how to evaluate, interpret, and compare like Z score/VIS score, etc. 2. Staff is aware about the acceptable performance criteria for the analytes 3. Corrective actions are taken on abnormal values/ Outliers
		Staff is aware of common errors that may occur under EQAS		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		RR/SI	1. Onsite evaluation done monthly 2. Random Blinded rechecking (RBRC) done monthly
		External quality assurance program implemented for NVBDCP		RR/SI	
		External quality assurance under NACP		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		RR/OB	Printed formats for requisition, consent and reporting are available

Reference No.	Measurable Element	Checkpoint	Compliance	Assessment Method	Means of Verification
ME E7.2	Register/records are maintained as per lab policy	All records are labelled and indexed		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 as per the retention criteria		RR	1. Test registers, IQAS/EQAS Registers, Expenditure registers, Accession list etc. 2. Look for state and NMC guidelines for records
		Facility maintains the records of the samples being sent/received to/from the referral laboratory		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		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

Reference No.	Measurable Element	Checkpoint	Compliance	Assessment Method	Means of Verification
		Facility has defined policy for retrieval and archiving of digital records		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		OB	Check the mechanism of storage (physical copies/electronic copies)
		Safe keeping of patient records		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		SI/RR	As per state policy
		Facility has defined policy for records retrieval		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 or contingency plan		SI/RR	Check disaster management committee is at place and IPHL takes part in regular mock drills

Reference No.	Measurable Element	Checkpoint	Compliance	Assessment Method	Means of Verification
		Role and responsibilities of staff is defined		SI/RR	Check staff is aware of their role during disaster/mass causality situation
		Emergency protocols are defined and implemented		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		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 diagnostic services under 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		RR/SI	As per programmatic guidelines
		There are established procedures for laboratory diagnosis of AIDS as per prevalent guidelines		RR/SI	including opportunistic infections
		There are established procedures for laboratory diagnosis of Leprosy as per prevalent guidelines		RR/SI	As per programmatic guidelines

Reference No.	Measurable Element	Checkpoint	Compliance	Assessment Method	Means of Verification
		There are established procedures for laboratory diagnosis of viral hepatitis as per prevalent guidelines		RR/SI	As per programmatic guidelines
		There are established procedures for laboratory diagnosis of Malaria as per prevalent guidelines		RR/SI	As per programmatic guidelines
		There are established procedures for laboratory diagnosis of integrated vector-borne diseases as per prevalent guidelines		RR/SI	Filaria, Kala-azar, Dengue, Chikungunya, Zika and Japanese 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		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		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

Reference No.	Measurable Element	Checkpoint	Compliance	Assessment Method	Means of Verification
		Systematic collection, analysis and interpretation of disease specific data		SI/RR	For surveillance and outbreak monitoring
		IPHL provides support for surveillance to other departments during outbreak		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		RR	1. May be shared with the main hospital (as per the MoHFW guideline) 2. ICC is approved by appropriate authority
		Roles and responsibilities are defined and communicated to its members		RR/SI	IPHL staff is aware of their roles and responsibility
		ICC meet at periodic time interval		SI/RR	1. Meetings are conducted Monthly, and minutes maintained 2. Records of Infection control activities are maintained 3. Check analysis of Infection Control activities is presented in meeting and actions are taken
ME F1.2	Facility has established procedures for regular monitoring of infection control practices	Regular monitoring of Standard precautions for infection control		RR/OB	Like Hand Hygiene Audit, BMW practices, adherence with standard practices of PPE, etc.

Reference No.	Measurable Element	Checkpoint	Compliance	Assessment Method	Means of Verification
		IPHL supports District hospital and peripheral facilities in HAI surveillance		RR	1. Defined format for requisition and reporting of HAIs (CLABSI, CAUTI, SSI, VAP) 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		RR	Like SSI, CAUTI, CLABSI, VAP
		Feedback is given to the respective health facility		RR/SI	1. Action plan is shared and discussed with concerned health facility 2. HAI data is reported to national / state level data bases as per guidelines
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		RR/SI	Hepatitis B, Td, etc.
		Periodic medical check-ups of the staff		RR/SI	1. Pre-employment health check-up is performed 2. 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 provided at point of use	Availability of hand washing Facility at Point of Use		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		OB/SI	1. Check for availability/ Ask staff if the supply is adequate and uninterrupted

Reference No.	Measurable Element	Checkpoint	Compliance	Assessment Method	Means of Verification
		Availability and use of alcohol hand rub		OB	1. Preferred method, except when hands are visibly soiled or after contact with patients, contact with samples, removal of gloves etc. 2. Contact time, at east 20-30 sec
		Display of Hand washing Instruction at Point of Use		OB	Prominently displayed above the hand washing facility , preferably in Local language
		Hand washing sink is wide and deep enough		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		OB/SI	Ask for demonstration
		Staff aware of when to hand wash		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		OB/RR	Check for regular supply
		Proper cleaning of testing area or surfaces as per procedure		OB	1. Cleaning protocols and appropriate use of antiseptics use for cleaning are displayed in testing areas 2. Various cleaning / antiseptic agents used are reviewed and approved by infection control committee
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		OB/SI	Gloves, Mask, Head caps, Shoe cover, Apron, N-95 respirators, Gum boots, Eye covers, etc.

Reference No.	Measurable Element	Checkpoint	Compliance	Assessment Method	Means of Verification
		Facility ensures adequate and regular supply of personal protective equipment		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		OB/SI	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		SI/OB	1. Check adherence with Donning & Doffing practice 2. Staff do pre-and post-inspection activity for PPE usage
		Staff is aware about appropriate selection of PPE		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 is aware about appropriate disposal of PPE after use		SI/OB	Check whether soiled PPEs are disposed in appropriate bins
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	Decontamination and cleaning of equipment is done as per guidelines		OB/SI/RR	Applicable to all equipment
		Cleaning of reusable items is done as per guidelines		OB/SI	Test tubes, Petri dishes, Micropipettes, Glass slides, racks, etc.

Reference No.	Measurable Element	Checkpoint	Compliance	Assessment Method	Means of Verification
		Decontamination of operating & Procedure surfaces		OB/SI	Ask staff about how they decontaminate work benches (Wiping with 0.5% Chlorine solution)
ME F4.2	Facility ensures standard practices and materials for disinfection and sterilization of instruments and equipment's	Disinfection and sterilization as appropriate for reusable items		OB/SI	Disinfection by hot air oven at 160 degree Celsius for 1 hour or other approved methods as per laboratory procedure
		Autoclave is used for culture media and other infected material		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		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		OB	Collection area and report receiving area
		Facility layout ensures separation of each operating area		OB	Microbiology, Mycobacteriology (TB) and Molecular diagnostic lab are separated from rest of the laboratories through an access controlled entry
		Floors and wall surfaces are easily cleanable		OB	Look for non-slippery floor (or epoxy grout in tiles), surfaces should be smooth & washable, seamless and impervious with sealed or welded joints

Reference No.	Measurable Element	Checkpoint	Compliance	Assessment Method	Means of Verification
		No fabrics or carpeting is in the laboratory		OB	
ME F5.2	Facility ensures availability of standard materials for cleaning and disinfection	Availability of disinfectant as per requirement		RR/SI	Sodium Hypochlorite, 70% Isopropyl alcohol, Phenolic compound
		Availability of cleaning agent as per requirement		RR/SI	Hospital grade phenyl, disinfectant detergent solution
		Staff know how to use cleaning solution		SI	1. Cleaning material is prepared and used as per manufacturer guidelines 2. Staff is aware of validity of prepared cleaning solution like hypochlorite
ME F5.3	Facility ensures standard practices followed for cleaning and disinfection	Staff is aware of blood spill management		SI/RR	1. Depend upon the size of the spill, manage as per the guidelines 2. All the blood spills are reported, check the incident reporting format
		Staff is aware of microbiological spill management		SI/RR	As per the guidelines
		Three bucket system is used for cleaning of lab		OB	Damp mop with detergent and water followed by disinfection with 0.5% chlorine
		Standard practice of mopping and scrubbing are followed		OB	Unidirectional mopping from inside out
		Ensure used mops should be clean appropriately		OB/SI	Soak in 0.5% chloring solution for 30 min followed by washing with detergent

Reference No.	Measurable Element	Checkpoint	Compliance	Assessment Method	Means of Verification
		Cleaning equipment's like broom are not used in laboratory		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		OB/RR	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% 4. Check for daily monitoring record of HVAC parameters and annual validation report from third party
		Adequate air exchanges are maintained		OB/RR	1. Check separate ductless AHU is present at Mycobacteriology & Virology lab 2. Required number of Air exchange is 12-15 and out of these, six should be fresh air exchanges per hour
		HVAC system is in place		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		OB	Check the availability at pre-testing, testing and post-testing areas in terms of: *Adequate number *Covered *Foot operated * Liners are non-chlorinated

Reference No.	Measurable Element	Checkpoint	Compliance	Assessment Method	Means of Verification
		Segregation of Anatomical and soiled waste in Yellow Bin		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		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, plastic culture plates/petric plates
		Display of work instructions for segregation and handling of Biomedical waste		OB	Pictorial and in local language
		There is no mixing of infectious and general waste		OB	Sample Collection area, testing area
		Check bins are not overfilled		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		OB	At point of use
		Segregation of sharps waste including Metals in white (translucent) Puncture proof, Leak proof, tamper proof containers		OB/SI	Needles, blades, discarded or contaminated metal sharp

Reference No.	Measurable Element	Checkpoint	Compliance	Assessment Method	Means of Verification
		Used slides are disinfected before disposal		OB/SI	NTEP-slides are disinfected with 5% phenol/40% phenolic compound/phenolic compound
		Availability of post exposure prophylaxis		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 * For HIV, as per NACO guidelines
		There is a mechanism to report the injuries or unusual incidences		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		SI/RR	As per NACO guidelines
		Contaminated and broken Glass are disposed in puncture proof and leak proof box/ container with Blue colour marking		OB/SI	Slides, glass culture plates / petri dishes, etc.
ME F6.3	Facility ensures transportation and disposal of waste as per prevalent guidelines	Discarded samples are pre-treated before disposal		OB/SI	Pre-treat to sterilize with non-chlorinated chemicals onsite , as per WHO guidelines on safe management of waste from HCFs, thereafter sent for incineration

Reference No.	Measurable Element	Checkpoint	Compliance	Assessment Method	Means of Verification
		Disposal of biomedical waste as per guidelines		OB/SI	As per latest BMW rules
		Transportation of bio medical waste is done in close container/trolley		OB/SI	Check biohazard signs are displayed on bins as well as trolley used for waste transportation
		Storage & Transportation e-waste		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 prevalent guidelines	Disinfection of liquid waste before disposal		OB/SI	as per the standards of liquid waste-current BMW guidelines
		Availability of functional effluent treatment plant		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		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 lab are defined		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

Reference No.	Measurable Element	Checkpoint	Compliance	Assessment Method	Means of Verification
ME G1.3	Facility has defined Quality policy, which is in congruency with the mission & vision of facility	Quality Policy is defined and approved		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 May be shared with the main hospital
ME G1.4	Facility has defined quality objectives to achieve mission, vision and quality policy	SMART Quality Objectives have framed		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		RR/SI/OB	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		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

Reference No.	Measurable Element	Checkpoint	Compliance	Assessment Method	Means of Verification
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		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		RR/SI	Check if quality circle is formed and its functional
		There is a designated nodal person for coordinating quality activities		RR/SI	
		Team members are aware of their roles and responsibilities		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		RR/SI	Check the records
		Minutes of meeting are recorded		RR/SI	1. Results for internal /External assessment are discussed in the meeting 2. Facility Quality indicators are reviewed in meeting 3. Action taken report is reviewed 4. Follow up actions from previous meetings are reviewed

Reference No.	Measurable Element	Checkpoint	Compliance	Assessment Method	Means of Verification
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		RR/SI	
		The facility has documented lab safety manual		RR/SI	
		Standard operating procedure for the lab has been prepared and approved		RR/SI	
		Current version of SOP are available with process owner		RR/SI	
ME G3.2	Standard Operating Procedures adequately describes process and procedures	Laboratory has documented process for Collection/ receiving, handling and transportation of primary sample		RR/SI	Haematology, Microbiology, Cytology, Biochemistry, Histopathology, Clinical Pathology, etc.
		Laboratory has documented process on acceptance and rejection of primary samples		RR/SI	Haematology, Microbiology, Cytology, Biochemistry, Histopathology, Clinical Pathology, etc.
		Laboratory has documented procedure on receipt, labelling, processing and reporting of primary sample		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		RR/SI	Haematology, Microbiology, Cytology, Biochemistry, Histopathology, Clinical Pathology, etc.

Reference No.	Measurable Element	Checkpoint	Compliance	Assessment Method	Means of Verification
		Laboratory has documented system for storage of examined samples		RR/SI	Haematology, Microbiology, Cytology, Biochemistry, Histopathology, Clinical Pathology, etc.
		Laboratory has documented system for testing and validation of samples		RR/SI	Haematology, Microbiology, Cytology, Biochemistry, Histopathology, Clinical Pathology, etc.
		Laboratory has documented system for repeat tests due to analytical failure		RR/SI	Quantitative and Qualitative
		Laboratory has documented biological reference intervals		RR/SI	Quantitative
		Laboratory has documented critical reference values and procedure for immediate reporting of results		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		RR/SI	Haematology, Microbiology, Cytology, Biochemistry, Histopathology, Clinical Pathology, etc.
		Laboratory has documented internal quality control system to verify the quality of results		RR/SI	Haematology, Microbiology, Cytology, Biochemistry, Histopathology, Clinical Pathology, etc.
		Laboratory has documented External Quality assurance program		RR/SI	Haematology, Microbiology, Cytology, Biochemistry, Histopathology, Clinical Pathology, etc.

Reference No.	Measurable Element	Checkpoint	Compliance	Assessment Method	Means of Verification
		Laboratory has documented procedure for maintenance and calibration of equipment		RR/SI	Haematology, Microbiology, Cytology, Biochemistry, Histopathology, Clinical Pathology, etc.
		Laboratory has documented the Standard Operating Procedure for maintaining the confidentiality of reports		RR/SI	Haematology, Microbiology, Cytology, Biochemistry, Histopathology, Clinical Pathology, etc.
		Work instruction/ clinical protocols are displayed		RR/OB	
		Laboratory has documented procedure for validation of results of reagents, stains, media and kits etc. wherever required		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		RR/SI	Haematology, Microbiology, Cytology, Biochemistry, Histopathology, Clinical Pathology, etc.
		Laboratory has documented system of resolution of complaints and other feedback received from stakeholders		RR/SI	Haematology, Microbiology, Cytology, Biochemistry, Histopathology, Clinical Pathology, etc.
		Laboratory has documented procedure for internal audits		RR/SI	Haematology, Microbiology, Cytology, Biochemistry, Histopathology, Clinical Pathology, etc.

Reference No.	Measurable Element	Checkpoint	Compliance	Assessment Method	Means of Verification
		Laboratory has documented procedure for purchase of External services and supplies		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		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		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		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

Reference No.	Measurable Element	Checkpoint	Compliance	Assessment Method	Means of Verification
		Hospitals has established system to provides identification number to the QMS documents and records		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		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		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		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 conduct of internal assessment and their results

Reference No.	Measurable Element	Checkpoint	Compliance	Assessment Method	Means of Verification
		Person is identified to conduct internal and external assessment		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		RR/SI	1. Internal assessors are trained to use the NQAS checklist
		Internal assessment is done using NQAS checklist		RR/SI	1. Internal assessment is done at periodic interval 2. Records of internal assessment are maintained
		Non-compliances are enumerated and recorded		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		RR/SI	1. Records of state assessment are maintained
		Non-compliances are enumerated and recorded		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		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		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

Reference No.	Measurable Element	Checkpoint	Compliance	Assessment Method	Means of Verification
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		RR/SI	PDCA & 5S
		Advance quality improvement method		RR/SI	Six sigma, lean
ME G5.2	The facility uses tools for quality improvement in services	7 basic tools of Quality		RR/SI	Minimum 2 applicable tools are used (Histogram, Control Chart, Stratification, Pareto Chart, Scatter Diagram, Fish bone, Check sheet)
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		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		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		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		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

Reference No.	Measurable Element	Checkpoint	Compliance	Assessment Method	Means of Verification
					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		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		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		RR/SI	1. Review risk management framework includes list of identified current and potential risks. These may include hazard safety, strategic, financial, statutory, operational and environmental risks. 2. The laboratory prioritize and act on identified risks. 3. Actions taken to

Reference No.	Measurable Element	Checkpoint	Compliance	Assessment Method	Means of Verification
					address risks is based on potential impact on laboratory examination results, as well as patient and personnel safety
ME G7.5	Modality for staff training on risk management is defined	Check training on risk management has been providesd to key staff members		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		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 year		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 external stakeholders		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		RR/SI	Check if risk assessment checklist is available with stakeholders

Reference No.	Measurable Element	Checkpoint	Compliance	Assessment Method	Means of Verification
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		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		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		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		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		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		RR/SI	Risk identified should be listed and evaluated for their security and frequency for occurrence. A risk severity score / grade should be given to each risk identified and according gaps should be rated. Verify with the records

Reference No.	Measurable Element	Checkpoint	Compliance	Assessment Method	Means of Verification
ME G8.6	Identified risks are treated based on severity and resources available	Check if risk have high severe are prioritised.		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		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		RR/SI	
		Patient feedback is taken at regular intervals		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		RR/SI	At least once in a year
		A mechanism is in place to take feedback from the clinicians		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		RR/SI	1. Patient feedback is analysed on monthly basis
		Root cause analysis is done for low performing attributes		RR/SI	

Reference No.	Measurable Element	Checkpoint	Compliance	Assessment Method	Means of Verification
		Results of Patient satisfaction survey are recorded and disseminated to concerned staff		RR/SI	
		There is procedure for analysis of Employee satisfaction survey		RR/SI	Root cause analysis is done
		There is procedure for analysis of clinician's feedback		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		RR/SI	
		There is procedure to take corrective and preventive action		RR/SI	
		There is procedure for preparing action plan for improving employee satisfaction		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		RR	Within the hospital and from peripheral health facilities
		No. of Biochemistry test done per 1000 population		RR	Within the hospital and from peripheral health facilities
		No. of Serology test done per 1000 population		RR	Within the hospital and from peripheral health facilities
		No. of Clinical Pathology test done per 1000 population		RR	Within the hospital and from peripheral health facilities

Reference No.	Measurable Element	Checkpoint	Compliance	Assessment Method	Means of Verification
		No. of histopathology & cytology test done per 1000 population		RR	Within the hospital and from peripheral health facilities
		No. of microbiology test done per 1000 population		RR	Within the hospital and from peripheral health facilities
		Percentage of lab test done at night		RR	The time period for night time may be included as 8PM to 8 AM
ME H1.2	The facility endeavours to improve its productivity indicators to meet the benchmark	Trends analysis of Indicators is done at Periodic Intervals		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		RR	Biochemistry & Haematology
		Percentage of test failed in EQAS/PT/ any other		RR	
		No of IQC failures		RR	
		Turnaround time for emergency lab investigations		RR	
		Turnaround time for routine lab investigations		RR	
		Turnaround time for receiving the samples from peripheral labs in case of emergency		RR	
		Lab test done per technician		RR	
		Downtime of critical equipment breakdown		RR	

Reference No.	Measurable Element	Checkpoint	Compliance	Assessment Method	Means of Verification
ME H2.2	The facility endeavours to improve its efficiency indicators to meet the benchmark	Trends analysis of Indicators is done at Periodic Intervals		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		RR	Within the hospital and from peripheral health facilities
		No of missed critical alerts		RR	
		No of adverse events per thousand patients		RR	Especially haematoma, syncope, infection, nerve damage, etc.
		Number of sharp exposure or other occupational injuries reported		RR	
		Test demography		RR	Proportion of Haematology, biochemistry, serology, Microbiology, cytology, clinical pathology
		Report correlation rate		RR	Proportion of lab report co related with clinical examination
		Proportion of false positive /false negative		RR	For Rapid diagnostic Kit test, as per the applicability
		Percentage of P-forms going into L-forms		RR	
		Percentage of Outbreaks detected by routine laboratory-based surveillance		RR	

Reference No.	Measurable Element	Checkpoint	Compliance	Assessment Method	Means of Verification
ME H3.2	The facility endeavours to improve its clinical care & safety indicators to meet the benchmark	Trends analysis of Indicators is done at Periodic Intervals		RR	
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		RR	Time motion study/ turnaround time
		Waiting time at report receiving area		RR	
		Percentage of rejected samples		RR	Haemolysis, specimen with illegible missing paperwork or labels, inadequate sample volume, improper transportation
		percentage of contaminated blood cultures		RR	
		Patient Satisfaction Score		RR	
		Number of stock out incidences of reagents & consumables		RR	
		No of rapid diagnostic kits discarded due to unsatisfactory reasons		RR	
ME H4.2	The facility endeavours to improve its service quality indicators to meet the benchmark	Trends analysis of Indicators is done at Periodic Intervals		RR	

List of Contributors

Sl. No.	Name	Designation
1.	Shri Apurva Chandra	Secretary, Health & FW, MoHFW
2.	Ms Aradhana Patnaik	Additional Secretary & Mission Director (NHM), MoHFW
3.	Maj Gen (Prof) Atul Kotwal	Executive Director, NHSRC
4.	Dr. Neha Garg	Director, NHM-II, MoHFW
5.	Dr. J N Srivastava	Advisor, QPS, NHSRC
6.	Dr. Ashoke Roy	Ex Director, RRC-NE
7.	Dr. Raj Prabha Moktan	Director, RRC-NE
8.	Dr. Kaustubh S. Giri	Deputy Secretary - NHM
9.	Dr. Tamanna Sharma	Lead Consultant, MoHFW
10.	Dr. Anil Kumar Gupta	Lead Consultant, MoHFW
11.	Ms Stella Grace	Consultant, MoHFW
Expert Group Members		
1.	Dr (Col) Jyoti Kotwal	Prof & HoD, Dept. of Haematology and Clinical Pathology, Sir Gangaram Hospital, New Delhi
2.	Dr. Naresh Goel	DDG (LS & IEC), NACO(Ret.)
3.	Wg Cdr Smita Rani	HOD, Pathology, AFCME
4.	Dr. Purva Mathur	Prof. Laboratory Medicine, JPN Apex Trauma Centre, AIIMS, New Delhi
5.	Dr. Sanjay Mishra	Regional Director Health Services, Jabalpur Division, MP
6.	Dr. Renu Gupta	Assistant Professor, Microbiology, IHBAS Hospital, Delhi
7.	Dr. Abhyuday Shakti Tiwari	Nodal Officer HAMAR Lab, OSD-NHM, Chhattisgarh
8.	Dr. Kailash Chand Jat	Laboratory Head, DH Sikar, Rajasthan
9.	Dr. Juhee Chandra	HoD, Dept. of Clinical Pathology, Jeevan Anmol Hospital, New Delhi
10.	Dr. Mayank Dwivedi	Public Health Specialist, Laboratory Advisor, CDC
11.	Dr. Indranil Roy	Public Health Specialist, Laboratory Advisor, CDC
12.	Dr. Ranjan Kumar Chaudhary	Advisor, HCT
13.	Ms. Mona Gupta	Advisor, HRH-HPIP
14.	Dr. K Madan Gopal	Advisor, PHA
15.	Dr. Deepika Sharma	Lead Consultant, QPS, NHSRC
16.	Dr. Arpita Agrawal	Sr Consultant, QPS, NHSRC
17.	Dr. Naveen Kumar	Consultant, QPS, NHSRC
18.	Dr. Annapoorna K N	Consultant, QPS, NHSRC
National Health Systems Resource Centre (NHSRC) and RRC-NE team		
1.	Mr. Anjaney Shahi	Lead Consultant, HCT
2.	Ms. Vinny Arora	Lead Consultant, Certification Unit

3.	Dr. Chinmayee Swain	Sr Consultant, QPS
4.	Dr. Anup Basistha	Ex Sr Consultant, QPS, RRC-NE
5.	Dr. Neeraj Gautam	Sr. Consultant, Certification Unit
6.	Dr. Surbhi Sethi	Sr. Consultant, ED Secretariat
7.	Dr. Abhay Dahiya	Consultant, QPS
8.	Dr. Vineeta Dhankhar	Consultant, QPS
9.	Mr. Anand Yadav	Consultant, QPS
10.	Dr. Siddhi Dhond	Consultant, QPS
11.	Dr. Ratan Shekhawat	Consultant, QPS
12.	Dr. Deepika Gaur	Consultant, Certification Unit
13.	Ms. Rachna Kumari	Consultant, Certification Unit
14.	Dr. Amrita Rastogi	Consultant, Certification Unit
15.	Ms. Sonia Verma	Consultant, Certification Unit
16.	Ms. Nasrain Nikhat Khan	Consultant, Drugs & Logistics
17.	Mr. Gulam Rafey	Consultant, Drugs & Logistics
18.	Dr. Ajay Kumar Arya	Consultant, QPS, RRC-NE
19.	Dr. Ravikar Singh	Consultant, QPS, RRC-NE
20.	Mr. Ranjith R Menon	Health Service QA Specialist, ADB
21.	Dr. Priyanka Kumari	Consultant, HRH-HPIP
22.	Dr. Harioum Sharma	Consultant, PHA
23.	Dr. Syeda Tahseen Kulsum	Consultant, CDC
24.	Dr. Aman Sharma	Junior Consultant, QPS
25.	Ms. Sowjanya Jarugula	Junior Consultant, Certification Unit
26.	Dr. Pavitra Sangwan	Short Term Jr Consultant, Certification Unit
27.	Dr Richa Verma	Ext. Consultant, QPS
28.	Ms. SL Chochoi	Ext. Consultant, QPS, RRC-NE
29.	Dr. Tanya Garg	Fellow, QPS
30.	Dr. Neha Ninawe	Fellow, QPS
31.	Ms. Sherin	Fellow, Certification Unit
32.	Ms Tripti Gupta	Fellow, Certification Unit
33.	Mr. Brajaraj Tripathy	Fellow, Drugs & Logistics
34.	Ms. Indu Suryawanshi	Secretarial Assistant, QPS

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National Health Systems Resource Centre

NIHFW Campus, Baba Gangnath Marg, Munirka, New Delhi-110067

Design & Printed at Royal Press # 93101 32888