GUIDELINES ON INTEGRATED PUBLIC HEALTH LABORATORIES

2022

सत्यमेव जयते

NATIONAL HEALTH MISSION
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Content

Abbreviations

ADA	Adenosine Deaminase
AFB	Acid Fast Bacilli
AHU	Air Handling Unit
AIIMS	All India Institute of Medical Sciences
ALT	Alanine Transaminase
AST	Aspartate Aminotransferase
BEE	Bureau of Energy Efficiency
BMW	Biomedical Waste
BSC	Bio-Safety Cabinet
BSL-2	Biosafety Level 2
CB-NAAT	Cartridge-based Nuclein Acid Amplification Test
CD4	Cluster of Differentiation 4
CDC	Centres for Disease Control and Prevention
CHC	Community Health Centre
CLIA	Chemiluminescence Immunoassay
COVID-19	Coronavirus Disease-19
CPA	Corrective and Preventive Action
CPCB	Central Pollution Control Board
CP-CPHC	Community Processes- Comprehensive Primary Healthcare
CRP	C-Reactive Protein
CSF	Cerebrospinal Fluid
CSSD	Central Sterile Supply Department
DADG	Deputy Assistant Director General
DCIP	Dichlorophenolindophenol Precipitation
DEO	Data Entry Operator
DGHS	Directorate of Health Services

DH	District Hospital
DPHL	District Public Health Laboratories
EDTA	Ethylene Diamine Tetra Acetic Acid
ELISA	Enzyme-linked Immunosorbent Assay
EQAS	External Quality Assessment Scheme
ESR	Erythrocyte Sedimentation Rate
ETP	Effluent Treatment Plant
FDP	Fibrinogen Degradation Products
FNAC	Fine Needle Aspiration Cytology
FPM	Feet Per Minute
FRU	First Referral Unit
FSSAI	Food Safety and Standards Authority of India
G6PD	Glucose 6 Phosphate Dehydrogenase
GGT	Gamma Glutamyl Transferase
GoI	Government of India
GRS	Grievance Redressal System
GTT	Glucose Tolerance Test
H2S	Hydrogen Sulphide
HbA1C	Glycosylated Haemoglobin
HCF	Healthcare Financing
HCG	Human Chorionic Gonadotropin
HCT	Healthcare Technology
HDL	High Density Lipoprotein
HEPA	High Efficiency Particulate Air
HIS	Hospital Information System
HIV	Human Immunodeficiency Virus
HMIS	Health Management Information System
HOD	Head of Department
HPLC	High Performance Liquid Chromatography
HR	Human Resource
HRH/HPIP	Human Resources for Health/Health Policy & Integrated Planning
HVAC	Heating Ventilation and Air Conditioning
HWC	Health and Wellness Center
ICAR	Indian Council of Agricultural Research
ICMR	Indian Council of Medical Research
ICU	Intensive Care Unit
ID/AST	Identification/Antibiotic Susceptibility Testing
IDSP	Integrated Disease Surveillance Programme
IHIP	Integrated Health Information Platform

INR	International Normalised Ratio
IPD	Inpatient Department
IPHL	Integrated Public Health Laboratories
IPHS	Indian Public Health Standards
IQC	Internal Quality Control
ISE	Ion Selective Electrode
IV	Intravenous
LDH	Lactate Dehydrogenase
LDL	Low Density Lipoprotein
LIMS	Laboratory Information Management System
LJ Chart	Levey Jennings Chart
LQMS	Laboratory Quality Management System
LT	Laboratory Technician
MCH	Maternal & Child Health
MD NHM	Mission Director, National Health Mission
MGIMS	Mahatma Gandhi Institute of Medical Sciences
MoH	Ministry of Health
MoHFW	Ministry of Health & Family Welfare
NABL	National Accreditation Board for Testing & Calibration Laboratories
NACO	National AIDS Control Organization
NACP	National AIDS Control Programme
NCDC	National Centre for Disease Control
NHM	National Health Mission
NHP	National Health Policy
NHSRC	National Health Systems Resource Centre
NIV	National Institute of Virology
NPCDCS	National Programme for Prevention & Control of Cancer, Diabetes, Cardiovascular Diseases & Stroke
NQAS	National Quality Assurance Standards
NSF	National Sanitation Foundation
NTEP	National Tuberculosis Elimination Programme
NVBDCP	National Vector Borne Disease Control Programme
NVHCP	National Viral Hepatitis Control Programme
OOPE	Out of Pocket Expenses
OPD	Outpatient Department
OT	Operation Theatre
PA Test	Presence Absence Test
PAP	Papanicolaou
PAPR	Powered Air-Purifying Respirators
PCR	Polymerase Chain Reaction

PGIMER	Post-Graduate Institute of Medical Education & Research
PHA	Public Health Administration
PHC	Primary Health Centre
PHED	Public Health Engineering Department
PHL	Public Health Laboratory
POCT	Point of Care Tests
PPE	Personal Protective Equipment
PSA	Prostate Specific Antigen
PT	Prothrombin Time
QA	Quality Assurance
QC	Quality Control
QI	Quality Improvement
QMS	Quality Management System
QMS	Quality Management System
RDT	Rapid Diagnostic Tests
RML	Ram Manohar Lohia
RPM	Rotations Per Minute
RRT	Rapid Response Team
SC	Subcentre
SGOT	Serum Glutamic Oxaloacetic Transaminase
SGPT	Serum Glutamic Pyruvic Transaminase
SOP	Standard Operating Procedures
SPM	State Programme Manager
T3	Triiodothyronine
T4	Thyroxine
TAG	Technical Advisory Group
TB	Tuberculosis
TOR	Terms of Reference
TRF	Test Requisition Form
TSH	Thyroid Stimulating Hormone
TWG	Technical Working Group
UPHC	Urban Primary Health Centre
UPS	Uninterrupted Power Source
VDRL	Venereal Disease Research Laboratory
VLDL	Very Low-Density Lipoprotein

CHAPTER

1

Introduction

India is increasingly facing a high burden of emerging infectious diseases along with substantially enhanced prevalence of non-communicable diseases. Mortality and disability caused by communicable diseases and other emerging infections (e.g. COVID-19) is significantly impacting human life and economic growth of the country. The country needs to devise effective healthcare solutions that not only boost control of existing diseases like HIV, TB, and Malaria, but also prepared to effectively detect, prevent, control, and manage emerging infectious diseases and threats to human health. This calls for identifying cost-effective and efficient healthcare diagnosis and delivery mechanisms.

One of the critical interventions is to establish cost-effective laboratory systems that provide rapid, reliable, and accurate test results for optimal impact on patient care and overall health outcomes. This includes establishing a network of integrated public health laboratories at various levels of health care for providing diagnostics for disease-specific programmes and for integrating healthcare surveillance supported by quality assured laboratory data. The epicentre of such laboratories will be the district with defined upwards and downwards linkages. This guideline focuses on establishing Integrated Public Health Laboratories at District Hospitals. The term **'Integrated Public Health Laboratory (IPHL)'** extends to a laboratory providing comprehensive services including infectious diseases diagnostics along with testing of hematology, chemical biochemistry, microbiology, virology and pathology parameters with bio-safety level-2, all combined under one umbrella. Development of IPHL will involve physical, functional and data integration of different sections of the district hospital laboratories. The physical integration will include establishment of a central sample collection facility in a patient-friendly location. The functional integration will require various vertical program sections to operate as the coordinated limbs of a single body i.e. the district public health laboratory, in the process sharing space, manpower and equipment and 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, departments to feed in to the IHIP platform for coordinated public health action.

An integrated model for the laboratory is crucial to increase efficiency, avoid duplication of laboratory resources, improve patient services, channelize resources for development of capacity for multi-disease testing and to equip the laboratory in terms of better preparedness and response to emerging disease threats. Further, an effective IPHL is capable of collecting and testing clinical specimens of human origin as well as samples of water, food and air during outbreaks and reporting that information in real time as part of public health surveillance systems. IPHL will also provide diagnostic facilities for various communicable and non-communicable diseases including tests envisaged under various national programmes for TB, HIV, malaria, viral hepatitis etc., that require biosafety level 2 laboratories.

1.1 Background

While the vertical disease programs have been successful in guiding the policy and field level operations to control many communicable diseases in the past, this disease-specific fragmentation of laboratory systems has led to duplications of equipment and training programs and inefficient use of human resources under the public health systems. Additionally, this disease-specific approach has not been either patient-centric or patient-friendly. It leads to multiple samples drawn from each patient and obscures correlation of results. To quickly improve efficiency and effectiveness of the laboratory services to support programmatic scale-up, it is imperative to establish integrated national laboratory systems. This will optimise access to laboratory services, quality assurance efforts, cost-effectiveness and efficient use of human resources.

Integration of services, human resource (HR), equipment, diagnostics and infrastructure are also a commitment under IPHS. Such integration is already envisioned in the framework of NHM, and this guideline is a tool to implement it. However, program specific requirements for counselling, testing, reporting, along with the defined laboratory network will remain as per the existing national programs. Similarly, networking of well-equipped laboratories to enhance public health capacity to collect, analyse and respond to the disease outbreaks, is also a commitment under National Health Policy, 2017. So, in line with the standards, norms and policy of Ministry of Health and Family Welfare (MoHFW), to augment public health surveillance, the concept of district integrated public health lab was launched as part of Pradhan Mantri Ayushman Bharat Health Infrastructure Mission (PM-ABHIM).

The major steps in the direction of establishing an integrated laboratory services were initiated in 2016 when a National Laboratory Task Force was formed under the chairmanship of Special Directorate General of Health Services (DGHS). The task force assessed 190 public health laboratories in five states (Gujarat, Tamil Nadu, Jharkhand, Madhya Pradesh, and Chhattisgarh) through a joint initiative of National Centre for Disease Control (NCDC) and Centres for Disease Control and Prevention (CDC). The gap analysis revealed lack of integration among vertical programs, lack of efficient specimen transport/referral mechanisms, lack of a well-defined system for maintenance of equipment and procurement of quality supplies and lack of structured training for laboratory staff.

In view of the initiatives taken above, a **Technical Advisory Group (TAG)** was created under the chairmanship of DGHS and Co-chairmanship of Additional Secretary and Mission Director (AS&MD), National Health Mission (NHM), MoHFW to review the status of laboratory strengthening under Integrated Disease Surveillance Programme (IDSP) and other vertical programs and develop recommendations to strengthen public health laboratories. Besides, a **Technical Working Group (TWG)** was created under the chairmanship of Director, National Centre for Disease Control (NCDC) to implement the recommendation of the TAG regarding strengthening of public health laboratories. TAG and TWG recommended integration of all vertical programs with routine diagnostic facility under one roof.

Further, the current pandemic of COVID-19 necessitated focus on strengthening laboratory-based surveillance system in an integrated manner. To improve the understanding on integrated capacity building and provide guidelines to bring uniformity of laboratory standards an Expert Group was formed to develop and facilitate "Technical and Operational guidelines on Integrated Public Health Laboratories (IPHL)" under the Chairpersonship of Director, NCDC.

1.2 Purpose of this document

This document is a technical guideline for policy makers and technical officers at national, state and district levels in organizing and setting up District Integrated Public Health Laboratories with its upward and downward linkages across the country as a part of 'Operational Guidelines of Pradhan Mantri Ayushman Bharat Health Infrastructure Mission' launched by Hon'ble Prime Minister on 25th October 2021 to help in

integration of clinical and public health requirements under one roof. It provides guidance on laboratory infrastructure including space and laboratory design, workflow, equipment, reagents/consumables, manpower, quality assurance mechanism, laboratory information system, etc. It also helps in estimating the budget requirement for setting-up of such laboratories. However, the budget requirement will differ from district to district depending upon the gap analysis.

1.3 Vision Statement

"Reduction in mortality, morbidity and Out of Pocket Expenditure (OOPE) by effectively preventing and controlling the diseases through rapid and reliable screening, early detection and laboratory diagnosis of communicable, non-communicable and other emerging diseases".

1.4 Objectives of the guidelines

- To provide guidance on standardization, integration and strengthening of comprehensive diagnostic facilities at public health laboratories at district and sub-district level for aiding clinical management and public health surveillance.
- To guide and facilitate an integrated network of laboratory services at various levels including veterinary and public health laboratories for clinical decision making.
- Capacity development and support to block public health laboratory and other peripheral laboratories.

1.5 Key functions of IPHL

An IPHL has a role in surveillance and early detection of diseases by monitoring of laboratory parameters including haematology, Clinical Biochemistry, Clinical Pathology and some other tests (histopathology, etc) which are feasible at DH. The key roles of the laboratory are as follows:

i. Provide laboratory support for communicable and non-communicable diseases by providing comprehensive laboratory services including Microbiology, Haematology, Clinical Biochemistry, Clinical Pathology, Cytology and Molecular Biology.

ii. Carryout laboratory-based surveillance for infectious and non-infectious diseases and also to support in outbreak investigation.

iii. Carryout water culture for coliforms and rapid diagnostic tests (RDTs) e.g. cholera RDT to support outbreak investigation as and when needed.

iv. Act as a hub to provide technical support to Block Public Health Laboratories and other peripheral laboratories for sample collection, testing and referral as per GoI guidelines.

v. It will also support the block and district surveillance units.

vi. Conduct training for peripheral laboratory staff as well as provide supervision and monitoring for implementation of Quality Management System.

vii. Function as a district laboratory for various public health programs including National AIDS Control Programme (NACP), NTEP, NVBDCP, NVHCP, IDSP. It will support convergence/integrating of these vertical programs at district level to optimally utilise the resources without altering the program strategies and functions.

viii. Provide accurate and timely data for analysis, research, information, and policy decisions to detect, prevent and respond to public health threats in real time.

CHAPTER 2

Laboratory Network and Linkages

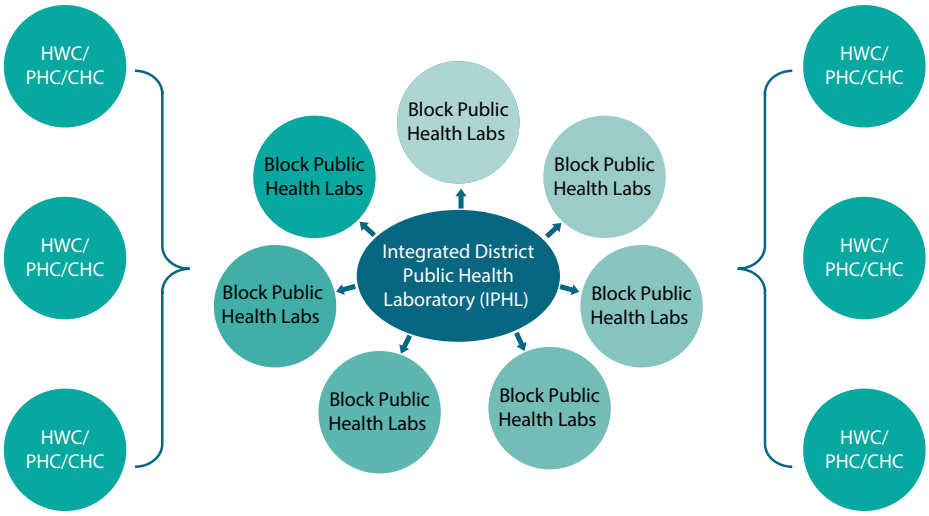
Integrated Public Health laboratories will establish multi-level linkages from blocks to districts, to state and finally to Zonal/regional and National level laboratories for providing a comprehensive set of laboratory services which can also aid in timely prediction of outbreak and supporting policy decisions. To allow IPHL seamlessly blend into the existing laboratory services network these are conceived to be interconnected with functional linkages created both upwards and downwards.

The upward and downward linkages with block and zonal/state/regional labs would be clearly defined and documented. Besides this, the IPHL will function in coordination with departments like veterinary, food safety etc. at various levels (from peripheral to zonal/regional and apex levels) with ultimate aim to facilitate coordinated public health action.

2.1 Assured Downward Linkages (Hub and Spoke model)

The IPHL at DH level will serve as the hub for block public health laboratories and shall be able to support testing of such tests which are not conducted at block level. Similarly, the Block Public Health Laboratories (BPHL) can serve as the hub for Health and Wellness Centers (HWCs) and other facilities down below (as shown in figure 1).

Figure 1: Downward Linkages of IPHL (Hub and Spoke Model)



The laboratories will be linked for a seamless specimen support, transport, testing, reporting, clinical and public health decision making. The laboratory will also have linkages with the district veterinary unit for zoonotic diseases.

2.2 Defined Upward Linkages

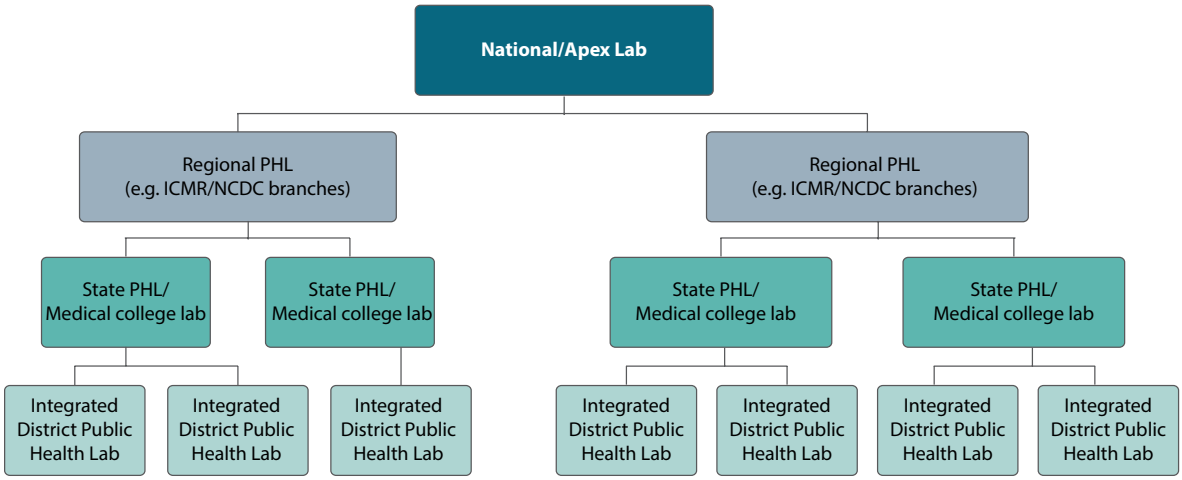
To strengthen the infectious and non-infectious disease surveillance system at the national and sub-national levels, the IPHL will be linked to zonal, state, regional and apex laboratories, which will also act as referral laboratories for various national programs like IDSP, NACP, NTEP, NVBDCP, NVHCP etc. The diagram below is notional. The number of regional laboratories to be established above State laboratories shall be decided by NCDC. The existing regional laboratories will be linked with the IPHLs. Besides this, IPHLs will have linkages with the Medical Colleges for the advance tests and also with research institutions, universities, etc., wherever feasible for the purpose of research and development.

Presently, various programs have different system of linkages for referral tests which also needs to be integrated at Medical College/ State/ Regional. This will further help not only in optimization of resources but also in maintaining quality and effective monitoring.

2.3 Integration and coordination at various Level

Achieving 'Health for All' is only possible by close integration and coordination between health and other concerned departments like veterinary, water, food and environment, forest, and climate change, etc. Such close integration and coordination at district level is to be established with existing laboratories under various departments like Central Pollution Control Board (CPCB), FSSAI, PHED, veterinary, forensic department, etc. This will help in sharing of data, and time-bound reporting of identified investigations of public health importance between the departments. This will also help building the capacity of district and block level functionaries for quick collaboration and response in identification and mitigation of health and environmental emergencies, disasters and also sharing relevant reports for routine surveillance. To institutionalize this at national level, NCDC would be the lead and convener for such activities with representatives from various agencies/departments including NHSRC. Similarly, Nodal Officers can be identified by respective departments at state and district level for coordination and information sharing.

Figure 2: Upward Linkages of IPHL (Integrated Public Health Network) Laboratory



CHAPTER 3

Services

Integrated District Public Health Laboratory (IPHL) will perform all the required clinical and public health diagnostic tests as per updated Indian Public Health Standards (IPHS) under one roof. The IPHL will support routine surveillance and outbreak investigation of infectious diseases. As and when needed, IPHL may perform environmental investigations (such as water culture for coliforms) and rapid diagnostic tests to support outbreak investigations. These services will include **(Detailed list enclosed in Annexure-I):**

Test Area	Tests to be conducted	Major Equipment Required
Clinical Pathology	Urine microscopy, chemistry and pregnancy test, Stool microscopy for ova, cysts and parasites Stool occult blood Stool Hanging drop for cholera Rapid stool test for cholera Semen analysis	Binocular Microscope, Urine analyser Centrifuge Bunsen burner with gas supply
Haematology	Microscopy of peripheral blood smear for blood cells & haemoparasites (malaria/filaria) Complete haemogram & cell count Blood grouping, cross matching, Coombs and hemoglobinopathies Coagulation profile Bone marrow examination	Binocular Microscope Automated Cell Counter (3 part/5 part) with nucleated RBC flag Automated Coagulometer Automated ESR analyser Haemoglobin HPLC machine (variant analyser)
Cytology	Fine-Needle Aspiration Cytology (FNAC) PAP smear examination CSF & body fluid cytology	Binocular Microscope Centrifuge

Test Area		Tests to be conducted	Major Equipment Required
Biochemistry		Quantitative analysis of routine biochemical parameters and special chemistry parameters (including hormones)	Automated Biochemistry analyser ISE based Electrolyte analyser Automated Hormone Immunoassay analyser (CLIA Based)
Microbiology	Bacteriology	Microscopy, Bacterial Culture & Antimicrobial susceptibility testing for clinical samples Microbiological analysis of Water (H2S test for screening, Coliform presence-absence (PA) test for confirmation)	Binocular Microscope Incubator Automated blood culture Automated bacterial ID/AST system Biosafety Cabinet Class II A2 (model conforming to NSF standards) Bunsen burner with gas supply Computer with scanner, printer, UPS Culture media
	Mycobacteriology (TB)	Microscopy for AFB CB-NAAT for mycobacteria	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
	Serology	ELISA, Rapid card tests	ELISA reader and washer VDRL rotator/shaker
	Molecular biology/ Virology (BSL-2)	Real Time PCR & Rapid diagnostic platforms for Influenza, COVID-19 and others Viral load for Hepatitis B & C	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
	Media preparation room	Preparation of culture media	Electronic balance Hot plate Autoclave Bunsen burner with gas supply
	Washing & Sterilization area	Washing & sterilization of glassware Sterilization of biomedical waste	Autoclave Hot air oven
Sample receiving and reporting area		Sample acceptance and registration Report generation and delivery	Computer with scanner, printer, UPS
Routine sampling of air or surfaces for culture is not recommended. In special circumstances air culture using slit sampler can be performed in the operation theatres (OTs) instead of settle plate test.			

The above categorization of tests is done as per the range of diagnostic services available in District Hospitals as per IPHS as well as the various national health programs. However, for tests like anaerobic, fungus or viral culture, linkages need to be established with the tertiary care institutions/State Labs.

3.1 Equipment

To deliver the services listed above, some essential equipments are required so States should ensure availability of equipment as per the list mentioned in **Annexure-II**. Diagnostic services in the District Hospitals have been strengthened from time to time by providing additional equipments, reagents, other consumables, etc. Under NHM, support for purchase of equipment have been given to the states as per IPHS and similarly, the same has also supported under the various programs. (**Annexure-III**) Since the equipment for conducting such tests are already available in the District Hospitals, the existing equipment should be utilized before procurement of any new equipment. Also, some equipment will be common among the service areas based on their utilisation/performance. So, a comprehensive gap analysis of available equipment not in the central lab but also those available under the programs need to be undertaken and accounted for before proposing purchase of any new equipment under IPHL. The requirement of reagents and consumables will depend on the equipment and testing methodologies.

All equipments of the laboratory must be covered under comprehensive Biomedical equipment Management and Maintenance Program (BMMP) of GoI and adopted by the State for their healthcare institutions. This will help in reducing downtime of the equipment and ensure their functional status and standardisation.

It is the responsibility of the laboratory staff and also the concerned department of the hospital to ensure regular cleaning, decontamination/autoclaving of the instruments and equipment being used in the laboratory. The laboratory SOP for the equipment need to define routine cleaning and disinfection protocols for all major equipments.

3.2 Environment Sampling

Routine environment surveillance and sampling shall be done by the respective departments. However, during the outbreaks, the laboratory will support some specific samplings for air, water, food, soil/feces, samples from animals, etc., based on the action plan and mutual understanding between the health and other departments. They can also build the capacity of IPHL staff for sampling and transport of certain specimens which need to be processed on priority, during emergency and disaster.

The record of the turnaround time for reporting on critical investigations by respective departments needs to be maintained and monitored at State and District level. IPHL can be evaluated two to three years after its establishment to consider its outcome and need for further expansion. For example, tests for general biomarkers of air pollution for the parameters notified in the National Ambient Air Quality Monitoring Standards 2009, (like macrophages for PM10, trans-muconic acid for benzene etc.) may be added to assess the health effects of air pollution.

3.3 Flow of services in Laboratory

The laboratory workflow should be streamlined to ensure best patient care, safety and accuracy of clinical test data. Meticulous management is required throughout the workflow to ensure error-free results. Figures 3 and 4 provide a quick overview of laboratory work and specimen flow through the laboratory.

Figure 3: Laboratory Workflow Plan

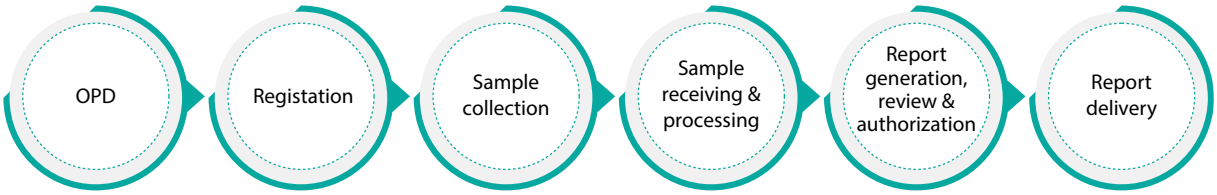
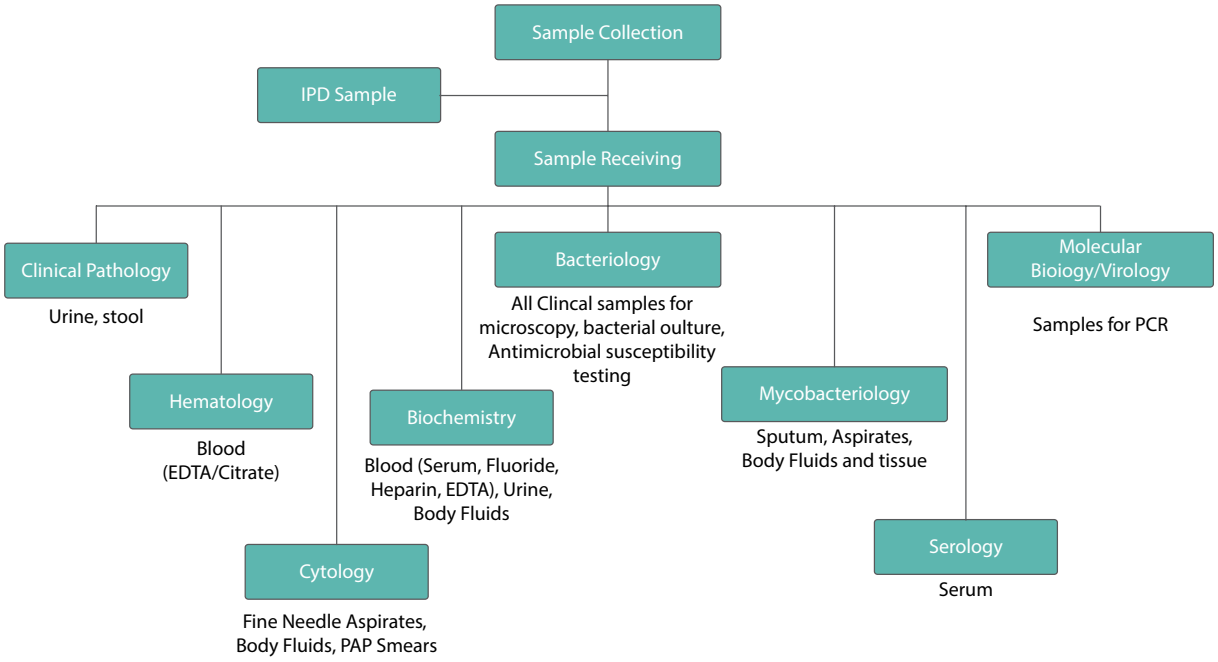


Figure 4: Service areas within the Laboratory



3.4 Laboratory Timings

The laboratory will be functional round the clock (24 X 7) especially the Hematology and Biochemistry unit. It can be functional in three shifts i.e. morning, evening and night. The timings for the sample collection of the OPD patients would be from 8 AM. However, in case of special cases, or fasting samples, laboratory technicians (LTs) on night duty may do early morning collection.

CHAPTER

4

Sample Collection and Transport

As proper collection and transport of samples is the key to good quality test results, the laboratory must take lead on training and providing guidance to all healthcare workers involved in the process. The Standard Operating Procedures (SOPs) for collection, packaging, and transportation of specific samples shall be explained in a separate manual. The present guideline provides only general principles and common protocols which need to be adhered for collection, packaging and transportation of samples. Program specific guidelines can also be consulted for any further specific details required in this regard.

4.1 Sample Collection

On the basis of collection, the samples are of three types:

a. Samples collected from OPD

b. Samples from IPD of the hospital and

c. Samples collected from spokes/peripheral facilities.

District and other hospitals which function as hub need to estimate the total load based on the OPD, bed strength and spokes attached. For instance, a 300-bedded District Hospital (estimated for a District with 20 Lakh Population) will have the capacity to conduct on an average 2200 tests per day including the samples received from spokes like CHCs, PHCs and HWCs.

Standard precautions, strict adherence to technical protocols, regular disinfection and cleaning is recommended for infection control in all critical care areas. The clinical samples/specimen should be collected by the clinical staff and nurses in their respective areas and transported to the laboratory as per the process defined in the sample handling manual of the laboratory. Blood samples should be collected in vacutainers preferably by vacutainer needle and holder to avoid leakage from containers (blood culture samples however will be added in blood culture bottles directly). Similarly, the collection and transport from block public health laboratory and other peripheral laboratories will also be undertaken as per the recommended procedures. For example: samples for coagulation tests like PT shall be drawn in a vacutainer ensuring appropriate blood to anticoagulant ratio and sample to be transported within prescribed time (4 hours) and temperature (25°C).

4.2 Specimen Packaging

Routine samples can be packed safely to avoid spillage , and spoiling the slides. For labelling, preferably pre-printed barcode labels should be utilized. While all clinical samples should be safely packed in Triple layered container packing (particularly virology) according to standard international guidelines, along with a copy of detailed history of patient on the proforma.

4.3 Sample Transportation

Transportation of samples will be from;

a. OPD/Ward/Causality/ICU to the laboratory within the same institute

b. The peripheral facilities like CHCs, PHCs, HWCs to the District IPHL located elsewhere

Generally, the samples collected are of two types- blood and compartmental Specimens (nasal, sputum, saliva, urine, etc). Thus, the transportation varies according to the type of sample and type of test. Sample transportation will be of two types;

1. Samples requiring cold chain conditions (Thermocol boxes with ice packs)
2. Samples which do not require cold chain

The general principles of transportation will include:

a. The samples should be transported under required conditions to the reference laboratory with prior intimation. The cold chain should be maintained and monitored throughout transportation wherever necessary.

b. The samples should be kept in separate boxes in upright position.

c. Transportation boxes must have the biohazard stickers on it.

d. Specimen data forms, letters and other types of information should be kept intact.

e. The spokes (PHC/SC/UPHCs) should be set up in such a manner that cumulative sample transportation time from multiple health facilities to the primary receiving hub laboratory should not exceed 2 hours (starting from the point of pick-up)

f. Samples should be picked up from the health facilities on the same day and transported to the hub laboratory/mother laboratory for testing.

g. Samples should be picked up once a day from PHCs, and twice a day from CHCs/FRUs, depending on the patient load.

h. Pick-up of emergency samples (as per the clinical judgement of Medical Officer) should be done within 1 hour from CHCs.

i. For CHCs, the reason for emergency sample pick up should be provided by the health facility in a form, which will ensure that the service provider sends a transportation person out of turn for only those samples which actually require urgent report.

j. The samples should be picked up from PHCs essentially not before 12 PM. In CHCs, FRUs and 24 X7 PHCs, the first round of sample pick up should be around 11 AM and second round of sample pick up should be around 4 PM.

k. The sample dispatch time should be recorded electronically in the LIMS and monitored till the report is generated and delivered to patients.

Transportation of samples from the spokes to the hub can be done as per the provisions suggested in the Guidance document for implementing Laboratory Services in the States under Free Diagnostic initiatives. However, while transporting the samples, adequate precautions and safety of samples should be strictly maintained.

Reports from hub to spokes can be sent through LIMS or other electronic modes. A record for the same needs to be maintained both at hub and spoke. Patients can collect printed reports from the institution where the sample was taken. The intimation that the reports are ready will be sent through SMS to the patient along with the link for downloading the soft copy of the reports, wherever possible. This service will be in-addition to the right of the patient to receive the hard copy of reports where the sample was submitted.

CHAPTER 5

Infrastructure

5.1 Structural Components and Design of IPHL

Presently, various program laboratories are functional in the district like for TB, HIV, IDSP, etc., either within the DH or outside its premises, besides the clinical laboratories for routine testing. In order to establish an integrated laboratory, the existing clinical laboratories, public health laboratories or any other program laboratory need to be mapped and restructured to provide comprehensive services as envisaged under IPHL guidelines.

- An ideal IPHL design should have two components- a central sample collection facility and an integrated diagnostic testing facility. Both these components can be established as a combined unit on the same floor or in parts at different floors.
- If the existing hospital design permits vertical extension, then the central sample collection facility should be located near or coincide with the main OPD area of the hospital. The waiting, registration, report dissemination, toilets, drinking water facility and other amenities available in the OPD area can be common and preferably located at the ground floor.
- The integrated diagnostic testing facility can be established in a separate location or floor and a dumb waiter can be used to transport samples from the collection area to the testing area.
- The samples received from IPD, and Emergency department will be sent directly to the testing area. An alert (alarm) system can be used to indicate sample drop. The diagnostic facilities should be available 24 X7.
- The access to laboratory's testing area should be restricted to the laboratory staff only.
- A counselling area to be included in the layout for pre and post testing counselling and for taking consents for testing.

5.2 Details of the Components

i) Central sample collection facility

In the design, a common sample collection area for specimens must be conveniently located, especially for pregnant women, elderly, and differently abled patients. It should have sufficient space for patient

reception, registration and waiting area. There should be adequate space provided for setting up at least 3 sample collection counters/stations (with adequate provisions for privacy like curtains, etc) and a separate negative-pressure room for collection of Microbiology samples with potential for airborne transmission (e.g. oro/naso-pharyngeal swabs, pus aspirates, skin scrapings) and performing Fine Needle Aspiration Cytology (FNAC). For FNAC, a separate room to be provisioned with a bed and adequate privacy. The pathologist doing FNAC needs to ensure smears are made there itself. The sample collection area must have a well-designated biomedical waste management corner indicated with signage and protocol posters.

The interaction of patients with the laboratory needs to be limited to central sample collection area. The registration for laboratory, in DHs lacking digitalized registration system will be done by a DEO into the Laboratory Information Management System (LIMS) directly. Since most of the equipment are automated and linked with computerized system so the same DEO can be utilized for compiling the reports.

i) Integrated Diagnostic Testing Facility

This has facility for testing routine and public health related diagnostic facilities located at one place. The following areas should be clearly marked i) Sample receiving and reporting area ii) Clinical pathology iii) Hematology iv) Cytology v) Biochemistry vi) Bacteriology vii) Mycobacteriology viii) Serology ix) Molecular Diagnostic/Virology x) Media preparation room xi) Washing and sterilization area (linked with Effluent Treatment Plant, ETP) with auxiliary areas. The Microbiology laboratory, Mycobacteriology (TB) and Molecular diagnostic (PCR) laboratories are separated from rest of the laboratories through an access-controlled entry to ensure safety of the laboratory staff. TB and PCR laboratories will be negatively pressurized within the same facility.

The integrated laboratory testing area will be accessible to staff only and includes space for office, cubicles for four specialists, staff room, change rooms (including for donning and doffing) and rest rooms. The staff room will also be utilized as training hall for the capacity building of the block laboratory staff.

In addition to the above structures, the lab will have auxiliary/accessory areas like i) Small storeroom ii) Cold room iii) Server and electrical room, which will have entry from the emergency exit gate and restricted entry will be ensured by the store manager.

This is only a sample design and individual labs may need to improvise according to the space available to them. For example, a laboratory may set up the collection and testing facilities at different locations. It is however advised that the core concept of the design as pertaining to central sample collection, streamlined specimen flow, access restriction and biosafety controls be adhered to as closely as possible.

5.3 Principles of Laboratory Design

1. The laboratory shall have adequate space allocated designed to ensure the Quality, safety and efficacy of the service provided to the users and the health and safety of laboratory personnel, patients, and visitors. The proposed infrastructure of the laboratory is based on the range of services to be provided at that facility. However, planning should be prospective and take into account expected burden of disease and seasonal variation. New structures should be planned, designed and constructed considering the scope for future expansion.
2. The laboratory needs to be compliant with mandatory regulations like Biomedical Waste Management Rules, 2016, Liquid waste management, Fire Safety, potable water, HIV/AIDS prevention and control Act (with mandatory provision of pre and post-testing counselling), Occupational Health and Safety Management System (OHSMS) and other such regulatory requirements for running a laboratory.

3. Clean electric power supply: Electrical installation must be done carefully to ensure proper distribution of electric load along with load balancing to various equipment and installations in a laboratory. Automatic voltage regulators which regulate fluctuating input power voltage and maintain constant output voltage should be provided. Adequate electric points on the various walls (at < 1.5 m height from the floor) needs to be ensured for easy connection. Use of explosion proof plugs, plug connector and socket is essential to ensure safety against explosion. All equipment must have separate connections with electrical points for safety of the equipment. New electrical appliances should have a minimum 3-star rating from Bureau of Energy Efficiency or equivalent recognized organization to minimize the energy input.

4. The laboratory should have round the clock power back-up option, a UPS connection should be provided with critical equipment to ensure uninterrupted testing in case of power cut.

5. The laboratory should have arrangement for round the clock potable piped water supply with a provision to store at least three days of water requirement. Installation of water purifiers can be done as per the requirement to ensure availability of water-free of microbes, ions and organic compounds for conducting tests. Cleaning of all water tanks should be ensured on a regular basis (at an interval of maximum three months) and records should be maintained accordingly.

6. There should be separate Air Handling Units (AHUs) for Mycobacteriology and Virology laboratories. AHUs are required to maintain negative pressure in these highly infectious areas. However, a positive pressure needs to be maintained for other areas to prevent spread of infectious spore/viruses to rest of the laboratory. Thus, installation of Heating Ventilation and Air conditioning (HVAC) system is sufficient in other areas of core testing facility. The category of HEPA filter H13-14/99.7% efficiency with air flow speed 25-35 FPM can be used for ventilation. Ductless AHU can be preferred since it reduces the maintenance cost, growth of microbes and frequency of cleaning.

7. Also, air changes are critical for controlling airborne organisms. It is suggested that the air changes of critical areas like Mycobacteriology and Virology will be like that of an ICU that is ideally 12-15 air exchange and out of these, six should be fresh air exchanges per hour. The specifications to be maintained will be-humidity 45-65%, temperature 23±2, positive and negative pressure -2.5Pa (particularly for TB containment Laboratory -12.5 Pa).

8. Flooring: Floor in the lab should be of vitrified anti-skid titles with seamless joints which are easy to clean.

9. Since this laboratory is an integrated laboratory including Bacteriology, Mycobacteriology and Virology/Molecular Diagnostic sections, entry to the laboratory needs to be regulated through access control to ensure Biosafety and Biosecurity. The high containment areas (bacteriology, mycobacteriology and virology) will be set-up in the farthest corner of the facility *(These areas are demarcated in the sample layout)*. There shall be adequate provision for waste segregation and disposal in the IPHL and disposal for highly infectious materials shall be in accordance with latest biomedical waste disposal guidelines of the Central Pollution Control Board (CPCB) of Government of India. Liquid waste generated in the laboratory needs to be connected to an effluent treatment plant (ETP) of the hospital through a dedicated outlet.

10. The following specific design requirements for a BSL-2 Lab need to be in-built in the design of the laboratory.

    a. Doors should have access control (lockable door if housing restricted agents) and a sink must be located near the exit door

    b. Handwashing sink should be present

    c. Bench tops should be impervious to water and resistant to moderate heat and organic solvents, acids, alkalis, and chemicals used for surface decontamination

d. No fabrics or carpeting allowed in the lab

e. BSCs should be positioned such that fluctuations in air supply and exhaust or the operations of equipment do not alter the performance standard of the cabinet

f. Eyewash station should be readily available.

g. Autoclave should be available in the facility

h. Negatively pressurized sections of the laboratory (e.g. Mycobacteriology, Virology lab) should have 100% exhaust.

i. The laboratory should be equipped with fire/emergency exits along with provisions for appropriate storage of inflammable materials and appropriate class of extinguisher (class BC or ABC).

5.4 Sample Layout of IPHL

Sample layout of IPHL are given in **Annexure- IV**. There can be two models- one with separate central sample collection facility and integrated core testing facility or an integrated laboratory with co-located central sample collection and core testing area. The layout design should take into consideration the liquid waste generated in the laboratory which needs to be connected to an effluent treatment plant (ETP) of the hospital through a dedicated outlet.

The area of the laboratory shown in the sample layout is around 4000-5000 square feet which is adequate to carry out the desired functions without compromising quality and safety. However, this is not binding requirement and the size of IPHLs may vary depending on the availability of the space as long as the basic principles of workflow, quality, safety and waste management are followed.

CHAPTER

6

Human Resource

For efficient and effective functioning of the laboratory, it is important to have motivated, empowered, trained and skilled workforce. The number and type of staff in terms of specialists, paramedical and support staff will be as per IPHS, any additional requirement of workforce will be guided by the services and the performance parameters. The roles and responsibility of each category of IPHL staff should be clearly specified in the Terms of Reference (TORs).

Mapping of the existing HR under all the programs at the facility level should be done, and accordingly the HR components under different programs can be clustered into essential and desirable as mentioned in the Indian Public Health Standards (IPHS). This will help to prevent hiring of additional staff as existing staff can be roped in to perform the functions. The details of workforce required are given below.

To ensure delivery of assured services, the laboratory technicians and support staff will work together under the guidance of specialists i.e. Microbiologists, Pathologists and Biochemists. While maximum Human Resource can be utilized during the core shift (morning), all the emergency services/tests can be performed in other shifts utilizing staff. Human Resource will depend on the case load of the facility, for example,

i. For instance, a facility with approximately 1000 OPD per day, will conduct roughly amount to 1200 tests. In addition to above, samples from around the district will also be received at this laboratory through hub and spoke model. These will roughly be additional 1000 tests per day.

ii. For the above load, the following laboratory staff will be required for a 24 x 7 running laboratory with the minimum performance standard for LTs as 200 tests per day. (as per IPHS 2021, for a 300-bedded DH)

Specialists:

- Essential- 03 Specialists (01 Pathologist, 01 Microbiologist & 01 Biochemist)
- Desirable (Additional)- 02 Specialists (01 Pathologist, 01 Microbiologist)

Lab Technicians (Shift Wise*):

- Essential- 11 Lab Technicians
    i. Morning: 08

ii. Evening: 02

iii. Night: 01

- Desirable (Additional)- 04 Lab Technicians

**The shift-wise deployment of the HR is only indicative; the number will depend upon the case load of the facility.*

Table No.: Minimum Human Resource Required for Integrated District Hospital Laboratory functioning round the clock (24 x 7) as per IPHS

Human Resource	Morning	Evening	Night	Total Number	Remarks
Specialist	1 Pathologist, 1 Microbiologist, 1 Biochemist	-	-	03	
Laboratory Technician	08	02	01	11	One of the Senior Lab Technicians will be trained in quality to perform the functions of Quality Manager for the lab.
Data Entry Operator/ Data Analyst	01	-	-	01	Normal Duty Hours – 9 to 5:30 pm
Cleaning Staff	01	01	-	02	
Housekeeping/Ward-boy/ Ward-girl	01	01	01	03	Report Dispatch, Decontamination, and other activities.
Guard	01	01	01	03	
Total				23	
Sanitary Inspector/Infection Control Nurse of the hospital will work in close association with laboratory/IPHL for implementation of infection control practices.					

Developing IPHL as a Training Hub

District Hospitals having more than 200 beds with integrated lab services as per the GoI guideline can initiate training courses for lab technicians and post-MBBS doctors. The IPHL can also offer internships/ short-term trainings to the students pursuing courses related to lab. However, any pre-service courses need to follow the protocols and norms of the respective University giving affiliation for such courses. The pre-services/in-service postgraduate training courses for MBBS doctors in Pathology, Microbiology and Biochemistry can be initiated if the facility meets the accreditation criteria of the NBE. This will also help to get additional HR for the IPHL.

CHAPTER 7

Quality Assurance (QA)

To ensure that the testing at the IPHL is reliable and accurate, a stepwise approach is followed towards ensuring implementation of Quality procedures and Quality Management System (QMS). This stepwise procedure will begin at the gap analysis to document the present Quality status of an IPHL and to identify training needs.

The process of QA of IPHL should be in accordance with QA programme and with other specific requirements of the GoI. This will also include regular quality audits both, external and internal. The upward and downward linkages with block and zonal/state/regional laboratories should be clearly defined and documented. A detailed Quality Manual for the laboratories will be prepared in addition to this guidelines and include the protocols for testing under specific programmes. Under the overall ambit of the QA Programme of GoI, the Quality initiatives and accreditations shall be undertaken to define mechanism of National Quality Assurance Standards (NQAS) and External Quality Assurance Scheme (EQAS) for IPHL.

Presently, the labs are generally being accredited under NABL, but in phases this will be taken up under GoI guided QA programme. The existing QA team at district and state level will conduct the process of gap assessment and gap filling, report, monitor and review the progress periodically as per the protocols defined under QA programme.

To ensure quality practices in laboratories, the IPHL should implement Laboratory Quality Management System (LQMS) with the following components.

7.1 Scope of Services

The laboratory should ensure that full range of tests should be available as per IPHS.

7.2 Documentation requirements

Quality Manual: The laboratory shall establish and maintain a Quality Manual that includes;

- **Organogram** or Hierarchical structure of laboratory mentioning responsibilities, authorities, and interrelationships of the staff
- **List of documents** along with brief description and unique number used in QMS as described below:
  - Specimen handling manual (including patient preparation, sample collection, storage and transport)

- Test Requisition Form (TRF)
- Specimen logbook
- Specimen acceptance/rejection criteria
- Standard Operating Procedures (SOP) for each test*
- Result reporting format
- Critical alert criteria
- Laboratory safety manual
- Temperature records (equipment and environment)

- **Documented policies** established by the laboratory (e.g. policy for waste management, critical alert, turnaround time, verbal reporting, amended reports, lab safety and occupational hazards, etc.) along with activities to implement those policies.
- **Quality Control Plan** prepared by each section of the laboratory

***Format for Standard Operating Procedures (SOP):** SOP for each test shall be written in a language commonly understood by the staff in the laboratory and be available in appropriate locations. Each SOP should have the following components;

- Purpose of the examination/test
- Principle and method of the procedure used for examinations
- Performance characteristics (sensitivity, specificity, detection/quantitation limit/ range etc)
- Type of sample (e.g. plasma, serum, urine)
- Patient preparation (pre-collection)
- Type of container and additives
- Required equipment and reagents
- Environmental and safety controls
- Calibration procedures
- Procedural steps
- Quality control procedures
- Interferences (e.g. lipaemia, haemolysis, bilirubinaemia, drugs) and cross reactions
- Principle of procedure for calculating results
- Biological reference intervals or clinical decision values
- Alert/critical values, where appropriate
- Laboratory clinical interpretation
- References

7.3 Testing by referral laboratories

Each district/sub-district laboratory shall identify and document the referral laboratories they will send samples to.

7.4 External services and supplies

The laboratory shall have a documented procedure for the selection and purchasing of equipment, reagents and consumable supplies along with the list of approved suppliers.

The laboratory shall monitor the performance of supplies (through internal quality control) to ensure that purchased items consistently meet appropriate quality standards.

7.5 Resolution of complaints

The laboratory shall have a documented procedure for the management of complaints or other feedback received from clinicians, patients, laboratory staff or others. It should be linked with integrated (104) Grievance Redressal System (website and call centre) of the state to ensure time-bound redressal at the appropriate level. Records shall be maintained of all complaints and their investigation and the action taken within the facility itself.

7.6 Identification of Errors & Corrective/Preventive action

The laboratory shall document corrective and preventive action (CAPA) to eliminate the cause(s)/potential causes of errors and deviations.

Errors and deviations can be identified in many different ways, including clinician feedback, internal quality control indications, instrument calibrations, checking of consumable materials, inter-laboratory comparisons, staff comments and internal and external audits

7.7 Maintenance of documents

The laboratory shall have a documented procedure to ensure that following conditions are met.

- All documents, including those maintained in a computerized system, are reviewed and approved by authorized personnel before issue.
- All documents are identified to include:
    a) A title
    b) A unique identifier on each page
    c) The date of the current edition and/or edition number where applicable (e.g. SOPs, Quality Manual
    d) Page number to total number of pages (e.g. "Page 1 of 5," "Page 2 of 5,")
    e) Authority for issue
- Only current, authorized editions of applicable documents are available at points of use.
- Documents are periodically reviewed and updated at a frequency that ensures that they remain fit for purpose.
- Obsolete controlled documents are dated and marked as obsolete

7.8 Control and Archival of records

The laboratory shall have a documented procedure for storage and amendment of records which include at least the following:

a) List of approved suppliers

b) Staff qualifications, training and competency records

c) Test requisition forms

d) Specimen logbook and worksheets

e) Information on reagents and materials used for testing (e.g. lot documentation, certificates of supplies, package inserts)

g) Instrument printouts (e.g. calibration prints, LJ charts, ELISA readings etc)

h) Test results and reports

i) Instrument maintenance records, including internal and external calibration records

k) Quality control records

l) Incident/accident records and action taken

n) Corrective Actions and Preventive Actions (CAPA) taken

p) Complaints and action taken

q) Records of internal and external audits

s) Inter-laboratory comparisons (ILC) /EQAS results

t) Records of quality improvement activities

u) Minutes of meetings that record decisions made about the laboratory's quality management activities

7.9 Quality indicators

The laboratory shall establish quality indicators to monitor and evaluate performance throughout critical aspects of pre-analytical, analytical and post- analytical processes e.g.

Pre-analytic Indicators:

- Percentage of unacceptable samples (samples rejected)
- Percentage of contaminated blood cultures

Analytic indicators:

- EQAS score*/ILC
- Number of IQC failures
- Results of competency assessment of the staff
- Average downtime for hematology analyzer (3 part/5 part) and biochemistry analyser (semi/fully automatic)

*Participation in EQAS is mandatory for most of the areas of testing. For those tests not covered by EQAS, Inter-Laboratory Comparison (ILC) should be done.

Post-analytic indicators:

- Turnaround times compliance (Percentage of results meeting turn-around-time)*
- Number of missed critical alerts

*The laboratory shall establish turnaround times for each of its examinations that reflect clinical needs. The laboratory shall periodically evaluate whether or not it is meeting the established turnaround times.

Indicators for Public Health Functions:

- Number of IPHS recommended parameters included in the scope of testing
- Number of Tests being done by Labs
- Percentage of outbreaks detected by IPHL through routine lab-based surveillance
- Percentage of outbreaks investigated by IPHL in the district

7.10 Human Resource and Training

- A **Quality Manager** should be identified, and their responsibilities should be defined
- **TOR/Job Descriptions:** The laboratory to provide (by the state) job descriptions that describe responsibilities, authorities and tasks for all personnel.
- **Training:** The laboratory shall develop an annual calendar and provide induction and yearly refresher training for all personnel at least in the following areas:
  - Documentation (specimen handling manual, specimen request form, specimen logbook, acceptance/rejection criteria, critical alerts, inventory management, result reporting format, IQC records, patient information confidentiality etc.): 2 days
  - Training on SOP development: 2 days
  - Training on sample collection, packaging and transport: 1 day
  - Training on laboratory safety, infection prevention and biosafety cabinet certification: 2 days
  - Applicable laboratory information system: 1 day
  - Comprehensive practical training on laboratory testing, including Internal Quality Control (IQC): 3 days
  - Orientation Training for clinicians and rapid response teams on laboratory-based surveillance of infectious disease, including syndrome-based approach for detection and response: 3 days

District IPHL should be responsible for training and mentorship of Block Public Health Laboratory staff. The laboratory in-charge will be responsible for training and competency assessment of laboratory staff.

7.11 Laboratory equipment, reagents, and consumables

- Equipment acceptance testing and maintenance: The laboratory shall verify upon installation and before use that the equipment is capable of achieving the necessary performance. The laboratory shall have a documented system for preventive maintenance which, at a minimum, follows the manufacturer's instructions.
- Equipment calibration: The laboratory shall have a documented procedure for the calibration of equipment. Laboratories must calibrate a test system when it is first placed in service and perform recalibration at least every six months thereafter. Recalibration is also required (regardless of when it was done last) immediately if any of the following occurs:
    i. A change of reagent lots
    ii. If QC results are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fails to identify and correct the problem
    iii. After major maintenance or service.
    iv. When recommended by the manufacturer
- Equipment records: These equipment records shall include, but not be limited to, the following:
    i. Identity of the equipment with manufacturer's name, model and serial number or other unique identification
    ii. Contact information for the supplier or the manufacturer
    iii. Date of receipt and date of entering into service
    iv. Location
    v. Condition when received (e.g. New, used or reconditioned)
    vi. Manufacturer's instructions
    vii. Records that confirmed the equipment's initial acceptability for use when equipment is incorporated in the laboratory
    viii. Maintenance carried out and the schedule for preventive maintenance
    ix. Equipment performance records
    x. Malfunction, modification, or repair of the equipment

7.12 Reagents and consumables

- Acceptance testing: Each new lot or shipment, shall be verified for performance before use in tests. For example: Evaluation of serological testing of kits for quality (HIV, HCV and HBsAg) before they are made available in the field.
- Inventory management: The laboratory shall establish an inventory control system for reagents and consumables.
- Records: Records shall be maintained for each reagent and consumable that are used for the tests. This will include batch number, lot number, date of receipt, date of expiry, date of entering into service and manufacturers' instructions.

7.13 Pre-analysis processes

- Information for patients and users: The laboratory shall have information available for patients and users of the laboratory services regarding lab opening hours, tests offered, patient preparation, instructions for patient-collected samples and transport of such samples
- Test request form information: The request form or an electronic equivalent shall include, but not be limited to, the following;
    i. Patient identification, including gender, date of birth, and the location/contact details of the patient, and a unique identifier;
    ii. Name or other unique identifier of clinician, healthcare provider, or other person legally authorized to request tests or use medical information, together with the destination for the report and contact details;
    iii. Type of primary sample and, where relevant, the anatomic site of origin;
    iv. Tests requested;
    v. Clinical history of the patient, for test performance and result interpretation purposes
    vi. Date and, where relevant, time of primary sample collection
    vii. Date and time of sample receipt
- Primary sample collection and handling: The laboratory's instructions for collection activities shall be described in detail in the sample handling manual and will include process for assigning patient identifiers, pre-test requirements, method of collection and storage of samples and safety practices.
- Sample reception: The laboratory's procedure for sample reception shall ensure that laboratory-developed and documented criteria for acceptance or rejection of samples are applied, all samples received are recorded in a specimen logbook, or computer.

7.14 Analysis processes and Quality Control (QC)

- All test methods will be documented in Standard Operating Procedures (SOP)
- Test procedures shall be verified through appropriate QC methods by the laboratory before being introduced into routine use. For this, the laboratory shall use appropriate QC materials at recommended frequencies and the data reviewed by authorized personnel. When the QC rules are violated, the results shall be rejected, and relevant patient samples re-examined after the error condition has been corrected
- External Quality Assessment Scheme (EQAS): The laboratory shall participate in an External Quality Assessment Scheme appropriate for the whole range of testing (scope of testing) and shall monitor the results of the EQAS and participate in the implementation of corrective actions as and when required.
- Whenever EQAS is not available for any test parameter, the laboratory shall develop an alternative system for the same purpose (e.g. exchange of sample with other laboratories i.e. inter-laboratory comparisons)

7.15 Post-analysis processes

- The laboratory shall have a documented procedure to ensure that the confidentiality of patient information is maintained at all times.
- Review of results: The laboratory shall have procedures to ensure that authorized personnel review the results of tests before release and evaluate them.
- Storage, retention and disposal of clinical samples: The laboratory shall have a documented procedure for retention, storage and safe disposal of clinical samples and shall define the length of time clinical samples are to be retained.
- Reporting of results:
  - Report content: The report shall include, but not be limited to, the following:
    i. Name of the test including, where appropriate, the test procedure
    ii. The identification of the laboratory that issued the report
    iii. Identification of all tests that have been performed by a referral laboratory
    iv. Patient identification and patient location on each page
    v. Name of the requesting doctor
    vi. Date of primary sample collection (and time, when available and relevant to patient care)
    vii. Type of primary sample
    viii. Test results reported in SI units or other applicable units
    ix. Biological reference intervals (normal ranges)
    x. Interpretation of results and comments where appropriate
    xi. Identification of the person(s) reviewing the results and authorizing the release of the report
    xii. Date of release of report
    xiii. Page number to total number of pages (e.g. "Page 1 of 5", "Page 2 of 5", etc.)
  - Critical/Alert result reporting:

    When examination results fall within established "alert" or "critical" intervals (e.g. very low platelet count, low or high serum potassium levels, growth in blood culture etc.):

    i. A physician (or other authorized health professional) should be notified immediately
    ii. Records should be maintained of such notification that document date, time, examination results conveyed, responsible laboratory staff member and person notified.

7.16 Monitoring and Supervision

State Health Unit needs to develop a team of experts for regular troubleshooting and mentorship of IPHL staff using online platforms. The team will include experts on Microbiology, Pathology and Biochemistry along with state health representatives. The platform will promote discussions through shared digital images, relevant national and international standards to uplift the knowledge on diagnostic and

quality needs to ensure effective functioning of the laboratories. The involvement of the state health representatives can help achieve the following goals through this platform: i) monitor public health activities on a regular basis, ii) drive target-based performance indicators for DPHLs, and iii) resolve certain administrative challenges. In addition, the state team may conduct onsite visits to laboratories as deemed necessary.

Also, a system should be developed for regular monitoring and periodic (quarterly/six-monthly) review of IPHLs by state health unit based on indicators to assess performance of IPHLs and identify scope of improvement (**List of monitoring indicators for the State are given in Annexure-V)**

To motivate IPHL staff for continuous Quality improvement, well-performing IPHLs should be recognised for their efforts in the following ways:

i) Non-monetary team awards to the facility and laboratory staff.

ii) Felicitation of IPHL team at State and National level.

iii) IPHL Staff can be nominated for higher education/training in reputable institutions at state expense.

The Central and State lab QA teams are expected to develop a laboratory safety manual which will include adequate engineering controls and biosafety measures to ensure safe working environment. The staff to be informed/trained to practice protocols for needle prick injury, splashes, spill management, etc. The staff should be immunized regularly as per the schedule. The labs can also apply for certification on Occupational Health Safety Management System.

All laboratory practices must adhere to the process for disinfection, liquid waste management, segregation of medical wastes as per the protocol and processes defined under BMW rules 2016 (***as per Annexure-VI)*** and amended from time to time along with guidelines and directions issued by GoI and the respective States. The labs will also adopt standard procedures for chemical, electrical, mechanical and fire safety. Biohazard signs need to be used for infectious materials as required.

Basic practices for BSL-II containment laboratories

- Access to the laboratory should be restricted when work is being conducted.
- Use of appropriate personal protective equipment (PPE) including lab coats and gloves, eye protection and face shields, as needed.
- Perform all procedures that can cause infection from aerosols or splashes within NSF-certified Class II type A1/A2 biological safety cabinet
- Segregation and disposed of waste generated as per Biomedical Waste Management Rules, 2016 and guidelines.
- Use autoclave or an alternative method for decontamination for proper disposals.
- Annual inspection of fire extinguishers and replacement as per need.
- Annual trainings of laboratory staff to use fire extinguisher and on hazardous waste management.

CHAPTER 8

Laboratory Information Management System (LIMS)

All the laboratory information data need to be digitalized to support surveillance and managing outbreaks using geospatial information. The system for digitalization of the laboratory information data ideally be a part of Integrated Health Information Platform (IHIP). In case, it is not there any laboratory information system/ data necessarily needs to be linked with the IHIP. The computer-based information management system i.e. LIMS for IPHLs needs to deliver correct and complete information to the laboratory staff, clinicians, patients and programme managers as efficiently as possible. LIMS plays a key role in laboratories meeting Quality standards, decreasing transcription errors, reducing turnaround time from specimen receipt to reporting of results, and improving patient outcomes. There are two common types of LIMS: (1) a module within a hospital information system (HIS) and (2) a stand-alone LIMS. A LIMS within HIS serves mostly as a means to capture results and a few key elements of data. The second system—a dedicated LIMS—shares most of the components listed above and can support all the laboratory functions.

A good LIMS should be able to:

i. Track samples from collection to reporting

ii. Report test results for patient care (via HIS, email, SMS, etc.)

iii. Collect, store, archive and analyze laboratory data

iv. Report analyzed data to district and state administration, Ministry of Health & Family Welfare (MOHFW)

v. Inventory management (kits and reagents etc.)

As a backup, laboratories may choose to keep paper-based records (in case computerized information system not available) to manage workflow, quality and audit trail for the samples processed in the laboratory. Also, laboratories shall have a documented procedure to ensure that the confidentiality of patient information is maintained at all times.

Annexures

Annexure-I: Services

(Lab test as per IPHS + other essential tests+ Public health functions)

S.No.	Areas	Tests
1	Clinical pathology	➢ Human chorionic gonadotropin (HCG) (Urine test for pregnancy) ➢ Urine test for pH, specific gravity, leucocyte esterase, glucose, bilirubin, urobilinogen, ketone, protein, nitrite ➢ Urine Microscopy ➢ Stool for ova and cyst ➢ Stool for Occult Blood ➢ Semen analysis
2	Hematology (including malaria/filaria microscopy)	➢ Haemoglobin ➢ Total leucocyte count ➢ Differential leucocyte count ➢ Platelet count ➢ Complete blood count ➢ Erythrocyte sedimentation rate ➢ Blood group and Rh typing ➢ Blood cross matching ➢ Peripheral blood film ➢ Reticulocyte count ➢ Absolute eosinophil count ➢ Fibrinogen degradation products (FDP) ➢ D-Dimer ➢ Coombs test direct with titre ➢ Coombs test indirect with titre ➢ Sickling Test for screening of Sickle cell anemia

S.No.	Areas	Tests
		➢ Sickle cell test rapid for screening of Sickle cell anemia ➢ DCIP test for screening HbE hemoglobinopathy ➢ Screening test for G6PD enzyme deficiency ➢ Testing for sickle cell anemia and thalassemia through automated system (desirable) ➢ Test for Malaria (microscopy & rapid test) ➢ Test for Filariasis (microscopy) ➢ Prothrombin Time (PT) and International Normalised Ratio (INR) ➢ Activated partial thromboplastin time ➢ Mixing study for Factor Deficiency and inhibitors Haemophilia ➢ Haemoglobin electrophoresis/ ➢ HPLC ➢ CD4 / CD8 count ➢ Serum Electrophoresis and free light chain assay ➢ Plasma fibrinogen and fibrinogen inhibitors serum electrophoresis
3	Cytopathology & Histopathology	➢ FNAC ➢ Pap smear ➢ CSF and body fluid counts cytology ➢ Histopathology (Desirable) ➢ Immunohistochemistry (Desirable)
4	Biochemistry/Special Chemistry	➢ Blood sugar ➢ Glucose Tolerance test (GTT) ➢ S. Bilirubin (T) ➢ S. Bilirubin direct and indirect ➢ Serum creatinine ➢ Blood Urea ➢ SGPT /Alanine Aminotransferase (ALT) ➢ SGOT/ Aspartate Aminotransferase (AST) ➢ S. Alkaline Phosphatase ➢ S. Total Protein ➢ S. Albumin & AG ratio ➢ S. Globulin ➢ S. Total Cholesterol ➢ S. Triglycerides ➢ S.VLDL ➢ S.HDL ➢ S. LDL ➢ S. GGT ➢ S. Uric acid

S.No.	Areas	Tests
		➢ S. Amylase ➢ S. Iron ➢ S. Total Iron binding capacity ➢ S.LDH ➢ Glycosylated haemoglobin (HbA1C) ➢ Testing for HbA1C through automated system (Desirable) ➢ CRP (including newborn) (Quantitative) ➢ S. Sodium ➢ S. Potassium ➢ S. Calcium ➢ S. Ionised Calcium ➢ S. Chloride ➢ S. Magnesium ➢ Arterial blood gas test ➢ 24-hours urinary protein ➢ Urine for microalbumin, creatinine and urea protein ➢ S.TSH (including for new-born screening) ➢ S.Free T3 ➢ S.Free T4 ➢ Ferritin ➢ Troponin - I / Troponin – T ➢ S. PSA ➢ CSF and body fluid analysis (Glucose, CSF protein, ADA, LDH)
5	Microbiology (including Bacteriology, Mycobacteriology, Serology & Molecular diagnostics/Virology)	➢ Wet mount and Gram stain for RTI/STD ➢ KOH Mount for fungal microscopy ➢ Sputum, pus etc. for AFB by smear microscopy ➢ Slit skin smear for leprosy ➢ Gram staining for clinical specimen ➢ Throat swab (Albert stain) for Diphtheria ➢ Stool hanging drop for Vibrio Cholera ➢ Blood/ body fluid culture (manual/automated) ➢ Urine culture ➢ Other cultures (pus, throat swab etc.) ➢ Culture for Diphtheria ➢ Culture of stool specimen for Vibrio cholera and other common bacterial enteropathogens ➢ Bacterial identification and Antimicrobial Susceptibility Testing (AST) for all the above cultures (manual/automated)

S.No.	Areas	Tests
		➢ Microbiological analysis of Water (H2S test for screening, Coliform presence-absence (PA) test for confirmation) ➢ RPR/VDRL for syphilis (rapid card tests) ➢ HIV 1 & 2 (rapid card test) ➢ Hepatitis B surface antigen (rapid card test) ➢ HCV Antibody (Anti HCV) (rapid card test) ➢ rK39 for Kala Azar (rapid card test) ➢ Rapid test for Cholera ➢ Rapid antigen detection test for Bacterial meningitis ➢ Tube Widal/ Typhoid test (IgM) ➢ Japanese Encephalitis IgM (ELISA/Rapid) ➢ Scrub typhus Test (ELISA/Weil Felix) ➢ Test for Leptospirosis (ELISA/Rapid) ➢ Test for Chikungunya (ELISA) ➢ IgM for Measles (ELISA) ➢ Rapid test for Leishmaniasis ➢ IgM for Hepatitis A (ELISA/Rapid) ➢ IgM for Hepatitis E (ELISA/Rapid) ➢ Dengue NS1 & IgM (ELISA) ➢ Real Time PCR & Rapid platforms for Influenza, COVID-19 and other emerging infectious diseases ➢ Viral load for HCV ➢ Viral load for HBV ➢ Rapid molecular testing for TB (CB-NAAT)

Annexure-II: List of Equipment

S. No.	Equipment Name
1	Biosafety Cabinet Class II A2 with thimble ducting
2	Cell counter automatic (5 part) for haematology (Desirable)
3	Cell counter semi-automatic (3 part) for haematology (Essential)
4	Fully automated biochemistry analyser with ISE module (Minimum through put of 60 samples/hour) (Desirable)
5	Semi-automated Biochemistry analyser (Essential)
6	Automated Hormone Analyser (CLIA Based)
7	Centrifuge (fixed head) table-top 16 tubes. Up to 6000 RPM
8	Centrifuge tabletop (swing out) with 8 tubes. Up to 6000 RPM
9	Automated Coagulometer
10	ISE based Electrolyte analyser
11	VDRL rotator/shaker
12	Binocular Microscopes
13	Fluorescent Microscope (Desirable)
14	ELISA reader with washer
15	Refrigerator 400 litres
16	Deep freezer (-20 deg C)
17	Deep freezer (-80 deg C) (Desirable)
18	Vertical Autoclave (for sterilisation) 100L
19	Vertical Autoclave (for disinfection) 100L
20	Vortex mixer
21	Urine analyser
22	Electronic balance up to 3 decimal places
23	Hot Air oven (medium size)
24	Hot Plate for culture media preparation
25	Computer with scanner, printer, UPS
26	Incubator (2 medium-sized)
27	Digital Thermometer
28	Needle destroyer
29	ESR Tubes with stand
30	Neubauer's Counting Chamber
31	Manual Cell Counter
32	HPLC machine/automated system for haemoglobinopathies/HbA1C (Desirable)
33	Micropipette 0.1- 2µl

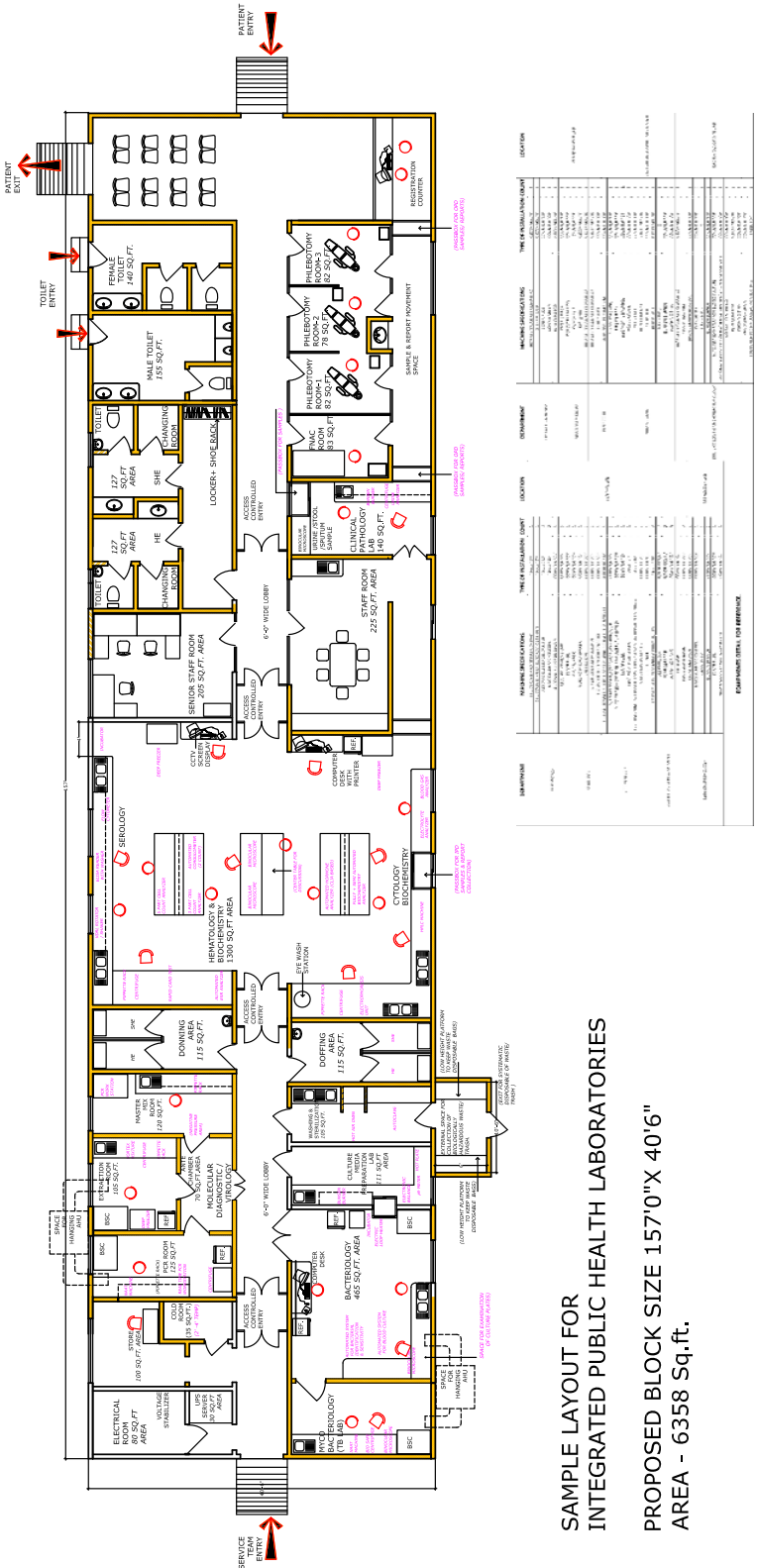
S. No.	Equipment Name
34	Micropipette 1- 10µl
35	Micropipette 5- 50µl
36	Micropipette 50- 200µl
37	Micropipette 200- 1000µl
38	Multi-Channel pipette (Octapipette) 200-1000µl
39	pH meter
40	Automated ESR analyser
41	Electrophoresis unit (horizontal)
42	Gas supply
43	Bunsen burner
44	Glassware, Kits and Consumables (as needed)
45	Real Time PCR machine
46	Microcentrifuge machine (up to 16,000 rpm)
47	PCR workstation
48	Automated system for Blood culture (Desirable)
49	Automated system for Bacterial Identification and sensitivity (Desirable)
50	Blood gas analyser
51	Flow cytometer (for CD4/CD8 counts) (Desirable)
52	Alcohol thermometer
53	Alarm clock
54	Binocular Microscope LED with camera (Desirable)
55	Slide staining racks
56	NAAT machine
57	Histopathology equipment (Desirable)
58	Tissue Homogenizer (Desirable)
59	Micro-incinerator for inoculating loops and needles

Annexure-III: List of Equipment available under Various Programs

S.No.	Name of Equipment	
1. National Vector Borne Diseases Control Programme		
1.	Autoclave (Vertical)	Autoclave (Horizontal)
2.	Biosafety cabinet	Computer with printer and UPS
3.	Hot Air Oven	Weighing scale
4.	Incubators Binocular	Needle Destroyer
5.	Microscopes	Centrifuge
6.	ELISA Reader & Washer	Mixer/Rotator
7.	Micropipette Water bath	Refrigerator Deep freezer (-20 °C)/ any other.
2. National AIDS Control Programme		
1.	Pipettes	Torniquets
2.	Centrifuge	Disposable Gloves
3.	Needle Destroyer	Disposable Masks
4.	Room Thermometer	Plastic/ Water- Resistant
5.	HIV Test Kits	Spillage Kit
6.	Test Tube Racks	Soap/ Handwash
7.	Discarding Jar	Eyewash Kit
8.	Color coded bags & bins	PEP Kit
9.	Sodium Hypochlorite Solution	First Aid Kit
10.	Disposable Syringes	Refrigerator
11.	Needle Spirit	Cotton swabs
3. Integrated Disease Surveillance Programme		
1.	Water Bath	Mixer/Rotator
2.	Incubator	Autoclave (Horizontal)
3.	BOD Incubator	Autoclave (vertical)
4.	Binocular Microscope	Biological Safety Cabinet Class 2A
5.	ELISA Reader & Washer	Hot Air Oven
6.	Micropipettes	Weighing scale
7.	Deep Freezer (-20 °C)	Needle destroyer
8.	Centrifuge machine	Computer with printer and UPS Others
9.	Lab Refrigerator (350-450 Ltrs)	
4. National Tuberculosis Elimination Programme		
1.	Autoclave (Horizontal)	Air Conditioner (Split AC with Voltage Stabilizer, Capacity: 1 ton, 1.5 ton and 2 ton)
2.	Autoclave (Vertical)	Microscope Binocular -Bright Field
3.	Balance- Analytical Balance	PCR Thermocycler:
4.	Balance- Precision Balance	PCR Workstation
5.	Bottle Washer	PH Meter
6.	Biological Safety Cabinet Class 2A with thimble ducting and with UPS	Refrigerated Centrifuge with UPS
7.	Electric micro-incinerator for loops	Hot Air Oven (32L)
8.	Hot plate	Microliter Centrifuge
9.	Incubator	Microliter Pipette

Annexure-IV: Sample Layout of IPHL

MODEL – 1

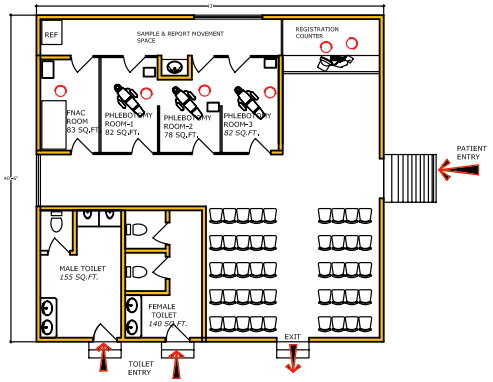


SAMPLE LAYOUT FOR
INTEGRATED PUBLIC HEALTH LABORATORIES

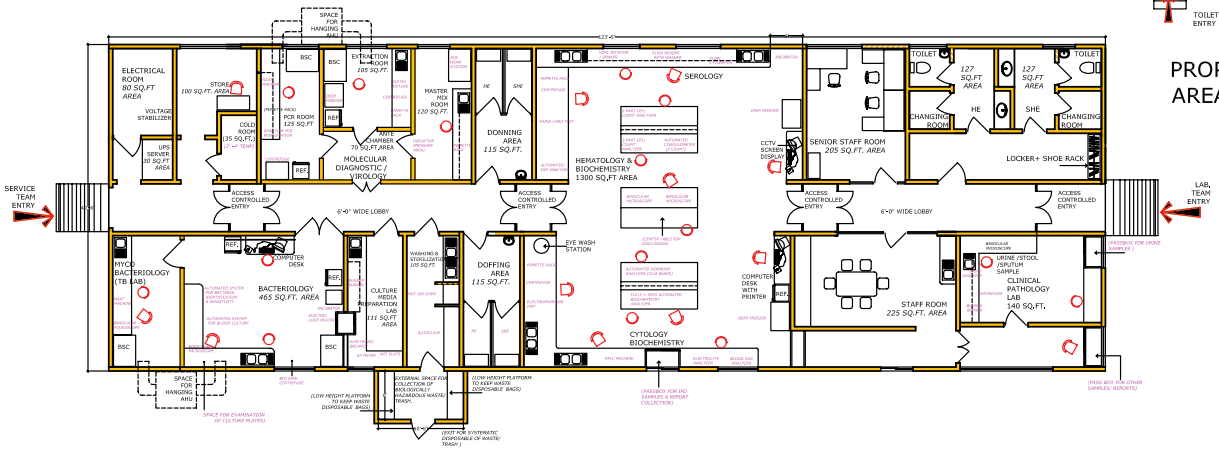
PROPOSED BLOCK SIZE 157'0"X 40'6"
AREA - 6358 Sq.ft.

SAMPLE LAYOUT FOR
INTEGRATED PUBLIC HEALTH LABORATORIES

CENTRAL SAMPLE
COLLECTION FACILITY



INTEGRATED DIAGNOSTIC TESTING FACILITY
BIO SAFETY LEVEL-2



PROPOSED BLOCK SIZE 43'0"X 40'6"
AREA - 1742 Sq.ft.

MODEL – 2

Annexure- V: List of Monitoring Indicators

a. No. of District with functional IPHLs conforming to norms

b. % of District PH Labs meeting turnaround time for critical tests as per MOHFW protocols

c. % of District PH Labs reporting through LIMS/IHIP as per protocols

d. Real time data uploading on IHIP portal

e. No. of outbreaks reported through IHIP

f. Number of Districts Saturated with trained HR for Surveillance activity

g. No. of Outbreaks detection within 48hours

h. No. of outbreaks with accessibility for lab testing

i. No. of BSL-II operational

j. Training conducted on biosafety and biosecurity

k. No. of outbreaks responded by RRTs

l. No. of outbreaks of emerging & remerging/ detected and responded to at district level and referred to State laboratories.

m. Nos. of training conducted

n. Number of District with integrated DHAP including plan for Epidemiological Emergencies

o. Number of diagnostic tests – (source: HMIS)

p. Reduction in OOPE (Source: National Health Accounts)

Annexure-VI: Biomedical Waste Management at Integrated District Public Health laboratory

Biomedical Waste of Integrated District Public Health Laboratory (IPHL)

Yellow Category Waste	Red Category Waste	White Category Waste	Blue Category Waste
Human & animal anatomical waste, Soiled waste, Discarded or expired medicines, chemical waste, Discarded linen, mattresses, beddings contaminated with blood or body fluid, routine mask & gown. Microbiology, Biotechnology and other clinical laboratory waste (Pre-treated)	Contaminated Plastic Waste (Recyclable) such as tubing, bottles, intravenous tubes and sets, catheters, urine bags, syringes without needles, fixed needle syringes with their needles cut, vacutainers and gloves	Waste Sharps including metals Needles, syringes with fixed needles, needles from needle tip cutter or burner, scalpels, blades, or any other contaminated sharp object that may cause puncture and cuts. This includes both used, discarded and contaminated metal sharps	Broken or discarded and contaminated glass including medicine vials and ampoules except those contaminated with cytotoxic wastes. Body
			
Yellow coloured non-chlorinated plastic bags	Red coloured non-chlorinated plastic bags or containers	Puncture proof, Leak proof, tamper proof containers	Cardboard boxes with blue colored marking

Note: Liquid waste generated from IPHL such as chemical Liquid Waste after pre-treatment, used or discarded disinfectants, liquid from laboratories after pre-treatment, Floor washing etc. should be treated in effluent treatment system.

Annexure-VII: Cleaning protocol of the equipment/items available in the IPHL

S.No.	Equipment	Type of Cleaning
1.	All equipment for laboratory diagnosis (Haematology analyser, ESR analyser, Biochemistry analyser, Urine analyser, Electrolyte analyser, Coagulation analyser, Turbidometer, Colorimeter, Flurometer, Flow cytometer, Rotor/shaker, Electrophoresis machine, High pressure liquid chromatography (HPLC), Blood Gas Analyser, ELISA, Chemiluminescence Immunoassay, Nucleic Acid Amplification Machine, Histopathology equipment)	Cleaning and disinfection
2.	Microscope	Cleaning and disinfection
3.	Centrifuge	Cleaning and disinfection
4.	Refrigerator	Cleaning and disinfection
5.	Water bath	Cleaning and disinfection
6.	Computer, UPS, Scanner, Printer & Bar Code Reader	Cleaning and disinfection
7.	Hot air oven	Cleaning and disinfection
8.	Incubator	Cleaning and disinfection
9.	Autoclave	Cleaning and disinfection
10.	UV steriliser	Cleaning and disinfection
11.	Needle syringe destroyer	Cleaning and disinfection
12.	Monopan analytic weighing scale	Cleaning and disinfection
13.	Alcohol thermometer	Cleaning and disinfection
14.	Bio-Safety Cabinets (Level- II)	Cleaning and disinfection
	A. Reusable Items	
1.	Test-tubes	Dry-heat sterilization (Hot-air oven)
2.	Petri-dishes	Dry-heat sterilization (Hot-air oven)
3.	Racks	Cleaning & disinfection
4.	Glass slides	Dry-heat sterilization (Hot-air oven)
5.	Micropipettes	Dry-heat sterilization (Hot-air oven)
6.	Head caps (non-disposable)	Steam sterilization (autoclave)
7.	Eye covers/goggles	Cleaning & disinfection or germicidal irradiation
8.	Apron/gowns	Steam sterilization (autoclave)
9.	Gum boots	Cleaning & disinfection
10.	Linen	Steam sterilization (autoclave)
11.	Bowls (washing)	Dry-heat sterilization (Hot-air oven)
12.	Reagent and other containers	Cleaning
13.	Mop heads and cleaning cloths	Heat disinfection with detergent and drying at 80 °C
14.	Plastic bins	Cleaning & disinfection

S.No.	Equipment	Type of Cleaning
15.	Respirators (half-or full-face elastomeric respirators, and powered air-purifying respirators (PAPRs)	Cleaning & disinfection
	B. Disposable items	
16.	Gloves (examination and sterile gloves)	Disposable; single use
17.	Masks	
18.	Head caps	
19.	Shoe cover	
20.	Apron/gowns	
21.	N-95 Respirators	
22.	Lancets	
23.	Sterile swabs	
24.	Containers/ blood collection tubes	
25.	Needles	
26.	Syringes	
	C. Other Non-disposable Items/Equipment	
A.	**Minimal hand-contact**	
27.	Floors	Cleaning (Wet mopping, and vacuum cleaning with filters)
28.	Walls, Blinds & Window Curtains	Cleaning
B.	**High Touch Surfaces**	
29.	Door and cabinet handles	Cleaning and disinfection
30.	Appliances & Light switches	Cleaning (dry)
31.	Furniture (Bench-tops, Desks, Chairs/seats)	Cleaning and disinfection
32.	Telephones	Cleaning and disinfection
33.	Hand-washing sinks and handles	Cleaning and disinfection

Note: For cleaning and disinfection following materials can be used:

a. Instruments – decontaminate before cleaning

b. Equipment – use 70% isopropyl alcohol for disinfection

c. Floor – damp mop with detergent and water followed by disinfection with 0.5% chlorine

d. Mops – soak in 0.5% chlorine solution for 30 minutes followed by washing with detergent and water

The details like frequency and process of the cleaning shall be given in a separate manual and the CSSD department to monitor the cleaning of equipment.

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