Public Laboratory Services in Kerala: Organization, Classification, and Service Delivery Framework

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KERALA.HEALTH

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Foreword

Medical Science and its practice is based on evidence. And that brings us to one of the most critical areas of Health care delivery systems i.e. reliable and timely diagnostic services. These are fundamental to quality healthcare and effective public health action. Kerala has consistently recognized the central role of public laboratory systems in clinical care, disease surveillance, and outbreak response, and has made sustained investments to strengthen laboratory services across all levels of care.

Innovations such as the structured classification of laboratory services, expansion of advanced diagnostics, and the introduction of the Nirnaya hub-and-spoke diagnostic network has significantly improved access, equity, and efficiency in testing services; by enabling basic diagnostics closer to communities and centralising specialised testing at well-equipped hubs, Kerala has strengthened early detection and management of non-communicable diseases, supported antimicrobial resistance surveillance, and enhanced preparedness for public health emergencies.

The conversion of Primary Health Centre to Family Health Centre (FHC) and establishing laboratories in FHC was a major shift. This was supplemented by introducing hub-and-spoke model of sample transfer for doing high-end diagnostics. Aardram.1 focused at structural reforms and Aardram.2 brought the attention to the functional aspects of health service delivery. The chain of laboratory networks was also worked out for Antimicrobial Resistance and under ONE HEALTH initiatives, laboratory network was worked out with the mapping of all the line departments referral laboratories.

Other than such specific grids, the system also responds to any emergencies. During the COVID pandemic the Laboratory set up was put up by aggregating the RTPCR units from various research institutions, University laboratories. Some of the units were designated testing centres and they were the first set of laboratories to provide results to work out strategies to control the pandemic.

This document presents a comprehensive overview of Kerala’s public laboratory services, including organisation, service delivery models, quality systems, and future priorities. I am confident that it will serve as an important reference for policymakers and health administrators, supporting evidence-based planning and further strengthening diagnostics as a cornerstone of Kerala’s resilient health system.

The committed efforts of Dr Sunija Saikumar and her teams at Public Health Laboratories and all the others laboratories staff’s dedicated efforts is providing qualitative diagnostic services to lakhs of people every day and saving their crores of rupees annually. I appreciate the work of all the functionaries in diagnostic services and wish them success in their future endeavors.

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Chapter 1. Introduction and Scope

1.1Role of laboratory and diagnostic services in healthcare delivery and public health

The medical/clinical laboratory services are an integral part of the health care system which are essential for the prevention, screening, diagnosis, treatment and patient management. Limited availability and access to quality laboratory services are among the major challenges contributing to delayed or inappropriate responses to disease control and patient management.

Laboratories are essential pillars in public health surveillance, providing the critical data needed for early detection, pathogen identification, and monitoring of infectious diseases. They enable the tracking of disease spread, identification of emerging pathogens, and the guidance to public health interventions.

Kerala has a robust system of Laboratories comprising Inhouse Laboratories, standalone Public Health Laboratories & Referral Laboratories. The inhouse laboratories cater their services to the OP&IP patients & focus more on the patient management. Public Health Laboratories, apart from providing diagnostic services to the referred patients, focus more on the disease surveillance & outbreak samples. Referral laboratories include NIV Kerala unit, State Public Health Laboratory, VRDL Kozhikode, IRL Trivandrum etc.

1.2 Key roles of laboratories in disease surveillance include

1.2.1. Early Detection and Outbreak Confirmation

- Diagnostic confirmation: Labs provide definitive proof of a disease etiology.
- Pathogen Identification: Using techniques like PCR and culture, laboratories identify specific viruses, bacteria, or parasites.
- Surveillance of notifiable diseases.

1.2.2. Monitoring Trends and Patterns

● Antimicrobial Resistance (AMR): Laboratories track how pathogens respond to drugs, identifying emerging resistance patterns.

● Variant Tracking: Through Whole Genome Sequencing (WGS), labs monitor genetic mutations in pathogens to assess changes in transmission/ severity.

1.2.3. Outbreak Investigation and Source Tracking

● **Transmission Dynamics:** By analyzing the relatedness of isolates, laboratories help epidemiologists map how a disease is moving through a population or between animals and humans (One Health approach).

1.2.4. Public Health Response and Evaluation

● Interventions: Lab data guides decisions on where to allocate resources, such as targeted vaccination campaigns or specific quarantine measures.

●Assessing Impact: Post-intervention testing allows health officials to measure if a strategy (e.g., a new vaccine or a public health campaign) is successfully reducing the presence of the pathogen.

●Reference Services: National and international reference labs (like those at the NIV/CDC) provide specialized testing for rare or highly dangerous pathogens.

1.2.5. Data Management and Communication

● Integrated Reporting: Modern labs use Laboratory Information Management Systems (LIMS) to electronically transmit results in real-time to surveillance databases, significantly reducing response times compared to paper-based systems.

● Quality Assurance: Laboratories shall maintain strict standards to ensure the surveillance data is accurate and reliable.

1.3 Importance of diagnostics in clinical care, surveillance, and outbreak response

1.3.1. Diagnostic, Surveillance & Referral services in the public health sector of Kerala

Most of the tests mentioned under the 'Free Diagnostics' initiative as per the GoI guidelines are offered in-house through the public health system. Those tests which are not available in the center are being made available through the **Nirnaya Hub & spoke** system. The complete list of all tests being provided at various levels are given in **Annexure 1** For specialized, advanced and specific diagnostic tests, linkages with public health labs, Medical Colleges and National Reference Laboratories are established. In all cases, sample transport is managed carefully in order to maintain integrity of the sample, giving attention to temperature, preservation needs, special transport containers and time limitations. It is also important to ensure the safety of those handling the material before, during and after transport.

Under the PM ABHIM IPHL program, an integrated public health laboratory with comprehensive testing facilities for pathology, bio-chemistry, microbiology, serology and other samples in every district is being established. Linkages with the National

Reference Laboratory do exist for novel pathogens and illnesses of unknown etiology. Round the clock functionality is recommended at larger facilities to cater to the needs of the Emergency services and intensive care and high dependency areas. The turnaround time for test results shall also be standardized, adhered to and monitored.

1.4 Reagents& equipment

The availability of necessary reagents and equipment, laboratory personnel and their capacity building, mechanisms for internal and external quality assurance and follow-up with clinicians shall be strengthened. Internal Quality Control (IQC) to detect, evaluate and correct errors due to test system failure, environmental conditions, or operator performance, before patient results are reported is also an Essential measure.

Validation of procedures and equipment should be carried out by running samples in parallel using both old and new equipment and methods for a period of time to determine that the expected results can be obtained. These validation procedures should be completely recorded. The staff posted in diagnostic services can be trained under the EQAS programme run by AIIMS, New Delhi and CMC Vellore. List of equipment included in Annexure III

1.5 Key functions of IPHL

- 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.
- Carryout laboratory-based surveillance for infectious and non-infectious diseases and also to support in outbreak investigation.
- Carryout water culture for coliforms and rapid diagnostic tests (RDTs) e.g. cholera RDT to support outbreak investigation as and when needed.
- 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.
- It will also support the block and district surveillance units.
- Conduct training for peripheral laboratory staff as well as provide supervision and monitoring for implementation of Quality Management System.
- 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 utilize the resources without altering the program strategies and functions.

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

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 the ultimate aim to facilitate coordinated public health action.

1.6 Scope of the document -covering diagnostic, surveillance, and reference laboratory services in Kerala

The scope of laboratory services encompasses a vast range of testing and analysis of biological samples (blood, tissue, fluids) to aid in patient diagnosis, monitoring, and treatment, covering areas like hematology, chemistry, microbiology, immunology, molecular diagnostics, Histopathology and providing crucial data to healthcare providers.

Key Areas of Testing:

- Clinical Chemistry: Glucose, lipids, electrolytes, liver/kidney function, HbA1c, Hormone Assays etc.
- Hematology: Blood cell counts, peripheral smear study, coagulation (clotting) tests, anemia screening, bone marrow analysis etc.
- Microbiology: Identifying bacteria, viruses, fungi, and parasites causing infections, antibiotic sensitivity testing.
- Immunology/Serology: Testing for antibodies (e.g., Hepatitis, HIV), autoimmune conditions, blood typing.
- Molecular Diagnostics: Genetic testing, viral genome screening.
- Histopathology: Diagnosing diseases from tissue (biopsies, surgical specimens) and cytology (Pap smears, fine needle aspirations).
- Blood Bank/Transfusion Medicine: Blood component preparation and testing for transfusions etc.

Core Functions:

- Specimen Management: Sample collection, labeling, storing, and processing samples.
- Testing & Analysis: Performing tests using sophisticated equipment like Automated analyzers.
- Quality Assurance: Equipment calibration, quality control, and ensuring accurate results.
- Reporting-Providing timely, accurate results to clinicians which is important for
- Diagnosis: Detecting diseases early and accurately.
- Treatment Guidance: Monitoring disease progression and treatment effectiveness.
- Patient Care: Supporting physicians in managing patient health from screening to critical care.

Chapter 2. Classification of Public Laboratory Services in Kerala

2.1 Rationale for Laboratory Service Classification

- The primary rationale lies in organizing diagnostics to match specific medical needs, ranging from rapid point-of-care tests to highly complex specialized analyses, thereby directly improving patient care.
- Optimized Resource Allocation: Not all laboratories need to perform all tests. Classifying labs helps in directing simple tests to smaller labs and complex tests to specialized centers (hub-and-spoke).
- Risk Management: Classifying laboratories by bio-safety level or risk level (e.g., TB labs) helps in establishing appropriate safety measures for both staff and the community.
- Public Health Surveillance: Public health labs are distinct, focusing on disease surveillance, and tracking outbreaks apart from diagnosis of clinical samples.

2.2 Overview of the Functional Domains

Public laboratory services in Kerala are organised into different functional domains, including routine diagnostics, specialised testing, screening, surveillance, and emergency public health response. This framework serves as the backbone for the organisation and strengthening of laboratory services across all levels of care.

2.3 Details of functional Domains of Laboratory Services

2.3.1 Basic Laboratory Tests

Small laboratories in the PHC/FHC/UPHC are provided with basic laboratory test facilities. Those tests which are not available in the centre as per Free diagnostic services are provided through Hub & spoke system.

Annexure 1

2.3.2 Advanced Laboratory Tests

Advanced laboratory services are provided from District Hospital labs/Public Health Labs/Government medical colleges.

Annexure 2

Reference Laboratories, Research Laboratories and Specific Disease Reference Laboratories

Laboratories play a crucial role in addressing diseases of national significance. National and State/Intermediate Level Reference Laboratories (NRL, SRL, or IRL) offer scientific and technical support, including expert guidance on disease surveillance, standardization of diagnostic methods, and disease control measures. These laboratories may also conduct training for personnel and collaborate with other laboratories or institutions on scientific and technical research initiatives. Eg. NIV Pune, NIV Kerala unit Alappuzha, IAV Kerala, State public Health Lab, VRDL Kozhikode etc.

2.3.3 Antimicrobial Resistance (AMR) Surveillance

The AMR surveillance data generated by the network laboratories are compiled at the state level and forwarded to the National Centre for Disease Control (NCDC). In addition, the validated data are uploaded to the Global Antimicrobial Resistance Surveillance System (GLASS), thereby integrating Kerala's surveillance efforts with global AMR monitoring.

At the district level, a hub-and-spoke model has been established. In each district, one laboratory with culture and antimicrobial susceptibility testing facilities, and in some districts one or two such laboratories, are designated as hub laboratories. Peripheral primary and secondary healthcare facilities without culture facilities function as spokes.

Clinical samples requiring culture and sensitivity testing are promptly transported from spoke centres to the designated hub laboratory, where they are processed according to standard protocols. The test reports are communicated back accurately and timely to the spoke centres, enabling clinicians to practice evidence-based antimicrobial therapy. This system plays a crucial role in preventing the overuse and misuse of antimicrobials.

The hub-and-spoke model for AMR surveillance and diagnostics has been successfully implemented across all districts in the state, ensuring standardized testing, optimal antimicrobial use, and strengthened AMR containment efforts.

2.3.4 Metabolic Screening

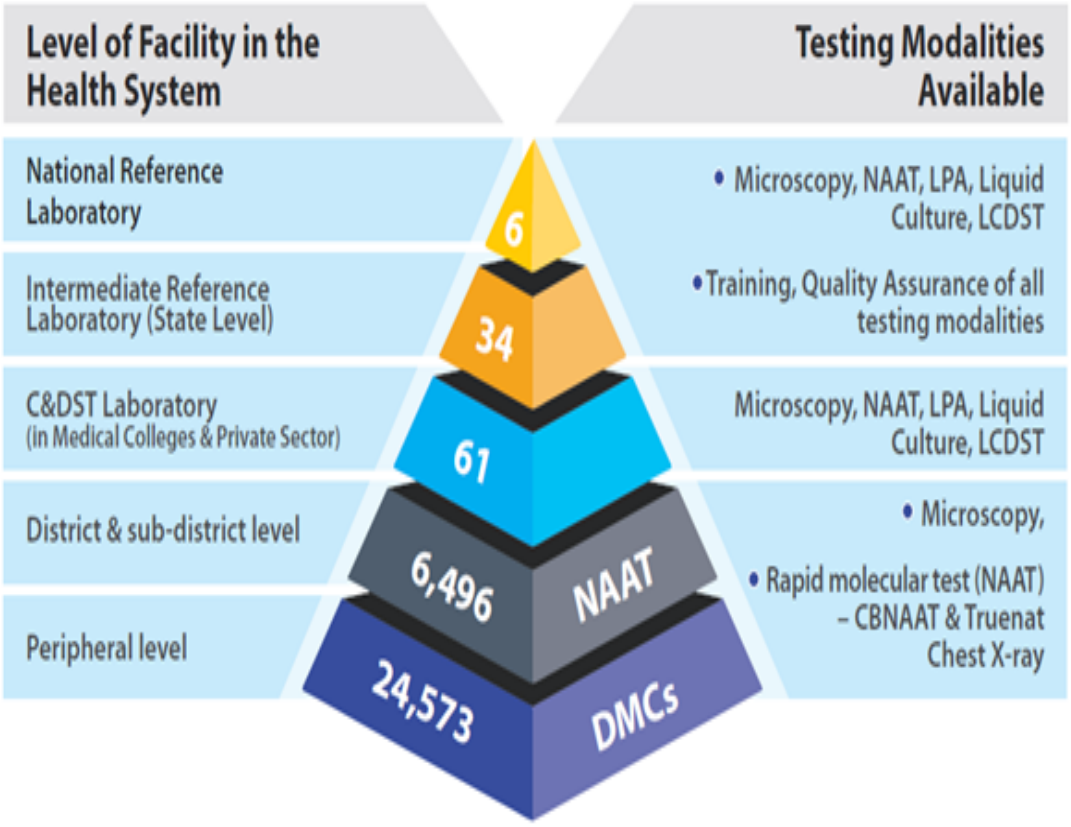
The newborn screening test aims at the early detection of disorders to prevent the most serious consequences by timely intervention. The first expanded New Born Screening Programme has been implemented in the state from March 2013 onwards. The heel prick sample of new born babies collected from Govt hospitals are being tested in the four designated Public Health Labs in the State (SPHCL TVM, RPHL KKD, KNR and EKM). The screening tests include tests for detection of congenital hypothyroidism, Congenital Adrenal Hyperplasia, G6PD deficiency and Phenylketonuria till July 2018 and after that PKU is replaced by Galactosemia since there were no PKU positive cases. The screening tests are based on ELISA and Immunofluorescence methods. The positive cases detected by screening tests are confirmed by other methods like Chemiluminescence/Radio Immuno Assay.

As such the programme has completed twelve years of New Born Screening. We haven't come across a single positive case of Phenyl Ketonuria till July 2018. After that Phenyl Ketonuria has been replaced by Galactosemia. Moreover, newborn screening has been spread to all the delivery conducting Government Hospitals. Now there are more than hundreds of hospitals participating in the New Born Screening programme. At present nearly thousand children detected

through metabolic screening are undergoing treatment for congenital hypothyroidism which is the most important cause of preventable mental retardation.

2.3.5 Tuberculosis and Cancer Screening

2.3.5.1 NTEP Diagnostic Network in Kerala



The above illustrated picture shows the **laboratory tier system in NTEP in India**.

The NTEP diagnostic network in Kerala is mentioned in the table below

NTEP diagnostic facility	Sites	Diagnostic tests	Number of centres
DMCs (Designated Microscopic centres; new terminology is TDC- Tuberculosis diagnostic centre)	• FHC, CHC, TH, THQH, DH, GH • Medical Colleges	**Microscopy**	**633 centres** (Govt - 530; Private- 103)
NAAT centers	•CHC, TH, THQH, DH, GH •All district tuberculosis centres •Medical Colleges •Mobile Medical unit (CBNAAT - 2)	**NAAT** tests- For detection of *Mycobacterium tuberculosis* and Rifampicin resistance. Now our State is initiating, Upfront NAAT, i.e. all presumptive TB cases' first diagnostic test offered must be NAAT test. • **CBNAAT** • **Truenat**	**178 machines** (Govt. sector only included) CBNAAT: 45 machines (38 sites) Truenat: 133 machines (123 sites)
Culture and drug sensitivity (C & DST) laboratory	Government Medical College, Kozhikode	• **Culture of MTB-** Liquid (MGIT) • **Line probe assay** – First line LPA (Rifampicin, Isoniazid, Ethionamide resisitance) and Second line LPA (Fluoroquinolone, Second line injectables)	1
Intermediate Reference laboratory (IRL) for Tuberculosis	State TB Cell, Thiruvananthapuram	• **Culture of MTB**- liquid-MGIT, solid-LJ • **Line probe assay** – First line LPA (Rifampicin, Isoniazid, Ethionamide resistance) and Second line LPA (Fluoroquinolone, Second line injectables) • **Phenotypic drug sensitivity testing (DST) of first, second line and newer drugs** • **Non tuberculous Mycobacteria:** culture, speciation and drug resistance testing using line probe assay (Macrolides & Aminoglycosides)	1

		• **Supportive supervision of all NTEP laboratories** • **External quality assurance (EQA)** of all NTEP laboratories • **Training regarding NTEP laboratory work**.	

The Intermediate Reference Laboratory (IRL) of Kerala State is monitored and supervised by the National Institute for Research in Tuberculosis (NIRT), Chennai, which functions as the Supra National Reference Laboratory (SNRL) for the South-East Asia region. The External Quality Assurance (EQA) for all government NAAT sites is coordinated and assured by the National Tuberculosis Centre, Bengaluru.

2.3.5.2 Cancer screening

Cancer screening involves testing healthy people for cancer before symptoms appear, using methods like blood tests, imaging (mammograms, CT scans), or physical exams to find it early, when treatment is often easier and more effective, saving lives by catching precancerous changes or early-stage disease. Common screenings target breast, cervical, colon, and lung cancers, with guidelines recommending tests based on age, risk, and lifestyle.

1. Common Screening Methods

Blood Tests: Detect tumor markers (e.g., PSA for prostate) or abnormalities in blood cells (CBC).

Imaging: Mammograms (breast), CT scans/X-rays (lung), Ultrasounds (various organs).

Physical Exams: Clinical breast exams, Pap smears (cervical), skin checks, testicular exams.

Genetic Testing: Checks for inherited mutations (like BRCA1/2)

Early Detection: There by increasing cure rates.

Prevention: Can detect precancerous cells, allowing for prevention before cancer develops.

Saves Lives: Routine screenings significantly reduce cancer deaths

2. Mass screening program conducted by Govt of Kerala

Government of Kerala in 2025 initiated a new programme (Arogyam anandham Akattam Arbudham) for screening the entire population above 30years of age for the common cancers like Breast cancer, Cervical cancer, Oral cancer and Colorectal cancers. The programme was initiated on World Cancer Day February 4th 2025 which was inaugurated by the Hon'ble Chief Minister of Kerala in presence of the Hon'ble Health Minister. The basic strategy for this screening was to promote and motivate the public to come voluntarily to the

screening camps. Hence, massive IEC campaigns and awareness sessions were conducted prior to the launch of the event and all groups across all sections of the society were involved in this campaign.

The community was mobilized by ASHA Volunteers, the field level health workers, the women Self Help Groups, the Political Organizations and the Non-Government Organizations. Screening camps were conducted in all the primary care centers and also in the Janakeeya Arogya Kendrams. All health staff including the doctors were all trained in basic screening practices. After the initial screening at the Janakeeya Arogya Kendrams the suspected persons were referred to the primary care centers where the basic investigations were done and those suspected of cancers were referred to the district level and sub district level hospitals for confirmation and other investigations. Once confirmed and diagnosed of the diseases, patients will be transferred to the cancer treating centers in accordance with the severity of the diseases. Investigations were arranged at the district level, Taluk level hospitals, Medical Colleges, Regional Cancer Centers and also in Private Laboratories and hospitals that cooperated with the programme and provided the services at a subsidized rate or at free of cost. So far 22 Lakhs people were subjected to screening in different centers across Kerala and more than 500 new cases of cancers were diagnosed.

2.3.6 Outbreak Investigation

Stages of an outbreak investigation

When a disease outbreak occurs, responding swiftly and effectively is critical to protect public health and minimize the spread of disease. The following steps outline a systematic approach to investigating an outbreak, from confirming its existence to communicating findings for future preparedness.

1. **Conduct initial investigation to confirm the existence of an outbreak and verify the diagnosis**

   - Implement immediate and generic control measures, if possible
   - Apply generic public health and social measures, to prevent further spread while the investigation is ongoing.
   - Immediate control measures are implemented as soon as the suspected routes of transmission are identified.

2. Develop a case definition for the outbreak

As soon as a suspected outbreak has been confirmed, an outbreak case definition must be agreed upon to enable the rapid identification.

3. Systemically find cases and contacts (when appropriate) and collect individual data using standardized case investigation forms and a line-list.

4. Conduct descriptive epidemiological analyses, describing time, place and person characteristics

- Create an epidemic curve (time distribution of cases).
- Map cases to identify geographic patterns.
- Analyse demographic characteristics (age, gender, occupation).

5. Develop hypotheses for the exposure, source and mode of transmission. Update the case definition, Conduct further investigations to evaluate these hypotheses, including further laboratory investigations, environmental sampling and epidemiological studies to further define the agent, its mode of transmission, risk and the effectiveness of control measures.

6. Implement agent-specific control measures.

7. Communicate **-** Develop public health messages with affected communities and the national public health authorities (or its equivalent), and other

2.3.7 Infectious Disease Diagnosis and Monitoring

Infectious diseases are caused by pathogenic microorganisms, such as bacteria, viruses, parasites or fungi; the diseases can be spread, directly or indirectly, from one person to another.

These diseases can be grouped in three categories: diseases which cause high levels of mortality; diseases which place on populations heavy burdens of disability; and diseases which owing to the rapid and unexpected nature of their spread can have serious global repercussions

The methods of detection include cultivation of bacteria and fungi on growth medium, isolation of viruses in cell culture, and identification of the agent biochemically, antigenically, or genetically.

Traditional methods are phenotypic identification of microbes using microscopy, culture and biochemical tests which is practiced even today for diagnosis of diseases.

Bacteria and fungi can grow in laboratory culture media and identified based on colony characteristics. It is observed microscopically using appropriate staining methods such as gram staining, acid fast staining, capsular staining, metachromatic granular staining, endospore staining, immune fluorescence stains, fluorochrome stains and lactophenol cotton blue staining. Physiological characteristics of bacteria and fungi can be studied by using biochemical tests such as fermentation of sugars, presence or absence of a particular enzyme, capacity to digest complex polymers and sensitivity to certain drugs. Serological tests are also used to detect the ability of the antibody to bind to specific antigen. These tests are reliable, sensitive and affordable.

Traditional methods are time consuming, since some microorganisms such as Mycobacterium species are slow-growing. Some bacteria like Treponema palladium cannot grow in artificial media. Some bacteria such as Chlamydia and Rickettsia are obligate intracellular parasites, grown by cell culture techniques.

Microorganisms including bacteria such as, Brucella species, Francisella tularensis etc., and viruses like Covid19 virus, Ebola virus, SARS virus, HIV, HBV etc., are highly infectious to grow in laboratories. Even the serological tests have some disadvantages because of the hosts delayed immune response or existence of antibodies even after the disappearance of infection. Thus, the use of genotypic methods of diagnosis has come into existence.

Molecular methods can be classified as hybridization methods, amplification methods and sequencing enzymatic digestion of nucleic acids10. Nucleic acid hybridization is used for the identification of specific DNA sequence of an organism, identified using a nucleic acid probe which is specific to that organism11. Amplification methods use the technique of enhancement of sensitivity of the DNA by manipulation of one of the three signals namely signal, probe and the target. The most important technique using this system is polymerase chain reaction (PCR) which is most widely used currently for identification of microorganisms. PCR uses sequence-specific primers for the detection of DNA or RNA. Specific primer is a design based on the selection of a sequence of DNA to Page | 348 be amplified. Different types of PCR are available but real-time PCR is the most

preferred one, because it distinguishes specific target sequence in the given sample from a complex mixture. This method is also more accurate and rapid comparing to other methods.

Advantages of molecular diagnostics over traditional methods

1. Usually, the physician decides the chemotherapy based on the laboratory report of culture and sensitivity result which takes around 48 to 72 hours depending upon the sample and organism. This makes the patient delay in starting the treatment and there is a chance of increase in mortality rate especially in invasive fungal infections15. The turnaround time for molecular methods is only 4 to 8 hours and makes the beginning of anti-microbial therapy quickly.

2. It will reduce the duration of staying of patients in the hospital and cost of ICU. By reducing the duration of staying of patient in the hospital, the infection caused by multidrug resistant bacteria can be prevented and reduces the usage of broad-spectrum antibiotics which has side effects such as antibiotic associated diarrhea

3. Since it is possible to identify DNA or RNA of a particular strain using nucleic acid probing, it is easy to identify the strain responsible for causing nosocomial infection at that period

4. Molecular methods are also used in the determination of drug-resistant genes and thus helpful in antimicrobial sensitivity assays.

5. PCR plays an important role in diagnosis during outbreaks such as SARS, MERS, EBOLA and the recent COVID19 for rapid and accurate diagnosis.

6. A molecular method detects the organism even when the load is very low as in forensic samples or intra ocular fluid. With the help of molecular methods, the viral load in infections caused by HIV, Cytomegalovirus, Hepatitis B Virus can be monitored. PCR of amniocentesis is used to detect the rubella, varicella zoster, and Cytomegalovirus in intrauterine infections of fetus.

Current trends in molecular diagnostics

1. Genomic microarrays or microchips were made which contains various nucleic acid probes arranged in a chip in a grid like pattern. These microarrays are also helpful in genotyping, gene sequencing and protein analysis

2. Proteomics identifies disease mechanisms of a patient based upon the pattern of disease specific protein mixtures in the body fluids or tissues and comparing it with the healthy control The most important application of proteomics to the laboratory diagnostics are mass spectrophotometers which are capable of rapid sequencing and analysis. The most advanced application of proteomics is "Matrix Assisted Laser Desorption/Ionization." (MALDI-TOF) which is used for analysis of peptides based on the mass/charge ratio, time of flight (TOF) and quantity with the help of an ion detector. MALDI-TOF is one of the most advanced methods in laboratory diagnosis for identification of microorganisms, drug resistance and detection of certain cancers.

Molecular techniques are advancing; the traditional methods have not been eradicated completely. Till now agar plates are considered as the backbone of the laboratories since we rely on them for microbial sub-culturing. Even now most of the laboratories in developing countries are using disc diffusion tests for antimicrobial susceptibility testing. Automated ID/AST machines like VITEK are using broth dilution breakpoint methodology. It is impossible to stop using basic instruments like microscopes, incubators, hot air oven etc., even though we have advanced sophisticated machines. Small laboratories are not able to afford advanced molecular machines because of financial constraints. So, some laboratories even now are using a combination of molecular techniques along with some reliable traditional methods for diagnosis.

Infectious disease diagnosis and monitoring involve a combination of clinical evaluation (symptoms, history), imaging, and laboratory tests—including molecular diagnostics (PCR), microbial culture, microscopy, and antibody/antigen detection—to identify pathogens, confirm infections, and guide treatment. Rapid, accurate diagnostics are critical for tracking disease spread, managing treatment efficacy, and, in some cases, detecting pathogen mutations.

Key Diagnostic Methods

PCR (polymerase chain reaction) tests detect specific DNA/RNA sequences of viral pathogens, offering high sensitivity.

- Immunological tests -These detect antibodies (indicating exposure/immune response) or antigens (indicating active infection) in blood, saliva, or other body fluids. Eg: Ig M Elisa test for Dengue Ig M, NS1 ELISA test for Dengue etc.
- Microbial Culture: The traditional "gold standard" method for growing pathogens in a medium for identification,
- Microscopy: Direct visualization of pathogens (bacteria, parasites) from samples.
- Clinical Investigation: Physical exams and patient history are essential first steps)

Monitoring and Tracking Infections

- Rapid Diagnostic Tests: allow for rapid, often point-of-care (POC) identification of pathogens.
- Multiplex PCR Panels: Used for simultaneously detecting multiple pathogens in syndromes like respiratory infections or meningitis.
- Genomic Surveillance: Sequencing is increasingly used for tracking variants.
- Antibody Titers: Used to monitor immune response over time.
- Common Sample Types, Blood, Urine, Stool, Throat/Nasal Swabs (especially for respiratory viruses), Cerebrospinal Fluid (CSF), Tissue Biopsies etc.
- Next-Generation Sequencing (NGS): Provides comprehensive data on pathogen identification and resistance patterns.

2.4 Service Availability Across Levels of Care

Mapping of the seven laboratory service domains across Family Health Centres, Community and Taluk Hospitals, District Hospitals, and Medical Colleges/Reference Laboratories, including defined referral linkages and escalation pathways.

In India, laboratory services are integrated into the three-tier public health system, encompassing the primary, secondary, and tertiary care levels. In addition to these, a network of Reference Laboratories, Research Laboratories, and Disease-Specific Reference Laboratories supports the delivery of specialized and complex diagnostic Tests.

a. Primary Level:

Ayushman Aarogya Mandir – Sub Health Centres (AAM-SCs) and Primary Health Centres (AAM-PHCs) are central to delivering primary healthcare services to the most remote and underserved populations. With more than 1.77 Lakh AAMs now operational, they serve as the first point of contact and a trusted source of care, ensuring continuity and comprehensiveness across the health system. These centres now deliver an expanded package of 12 services, addressing emerging health priorities such as non-communicable diseases (NCDs), mental health, palliative care, and others- marking a paradigm shift from illness-based care to wellness-oriented services.

b. Secondary level:

The secondary level of health care essentially includes Community Health Centres (CHCs) and Sub-District Hospitals (Taluk &Taluk headquarters) & District Hospitals. CHCs are part of the secondary level of healthcare and act as referral centres for Primary Health Centres (PHCs). They are designed to provide specialist healthcare services, including medicine, surgery, pediatrics, and obstetrics & Gynecology, to the population. CHCs serve as referral centres for 4-5 PHCs providing specialized care that PHCs may not be equipped to handle. CHCs have in-patient facilities (30 Beds) and are established as per the population norm. The Taluk, THQ hospitals and DHs have a greater number of Specialists and acts as hub Laboratories for the AAMs & CHCs.

c. Tertiary level:

Laboratories are equipped with advanced diagnostic and investigation facilities to provide tertiary level health care. These hospitals receive Hub & spoke samples from secondary levels. Tertiary level hospitals are usually District Hospitals, Medical college, State Government Medical colleges, Public Health Labs etc.

2.5 Implications of the Classification Framework

Infrastructure and equipment planning, Human resource deployment and capacity building, Quality assurance and accreditation systems, Digital integration and reporting, Surveillance strengthening and outbreak preparedness.

For efficient and effective functioning of the laboratory, it is important to have a 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 staff are clearly defined by GO/institution level orders.

Mapping of the existing HR under all the programs at the facility level is being 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 the 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 more 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, Capacity building. Capacity building in laboratories involves strengthening infrastructure, human resources, and systems to improve performance, diagnostic accuracy, and sustainability. Key initiatives include training staff in advanced techniques, implementing ISO quality upgrading equipment, and enhancing data management. It is critical for responding to public health emergencies.

Key Aspects of Lab Capacity Building

- Human Resource Development: Training personnel in molecular virology, microbiology, and quality assurance to reduce errors and improve diagnostic reliability.
- Infrastructure & Equipment: Investing in modern diagnostic tools (e.g., Aito analyzers, microscopes) and ensuring a sustainable supply chain for consumables.
- Systemic & Organizational Improvement: Establishing robust laboratory information management systems (LIMS), implementing accreditation standards (like ISO 15189), and strengthening leadership.
- Sustainability: Creating long-term strategies.

Steps for Effective Capacity Building

1. Assess Needs: Identify gaps in current capabilities, equipment, and staff skills.

2. Plan & Design: Develop tailored training programs and infrastructure upgrades.

3. Implement: Execute training, mentoring, and technical support.

4. Monitor & Evaluate: Evaluate the improvements

Surge Capacity Strategies To handle pandemics or emergencies, laboratories are building surge capacity by adopting flexible, open diagnostic platforms and fostering public-private partnerships, such as the initiative where India onboarded NABL-accredited labs for COVID-19 testing.

Chapter 3. Service Delivery Model and Network Integration

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 the aim to facilitate coordinated public health action.

3.1 Structure of the public laboratory network in Kerala

Apart from hospital inhouse labs, Kerala has a strong network of public health laboratories. The public health laboratory (PHL) is critical to the public health response capability of each state and, by extension, the nation. Kerala has a very good network of standalone public health labs. The State Public Health Lab at Trivandrum is the apex laboratory for national programmes like NRCP, NVBDCP, PPCL, Hepatitis Viral load testing etc. & also State level designated lab for Amoebic Meningoencephalitis.

The state has Regional public health laboratories at Ernakulam, Kozhikode, Kannur & Pathanamthitta. The district public health laboratories are functioning at Alappuzha, Kollam, Malappuram, Wayanad & Kasargod. Upcoming new public health labs include public health labs at Kottayam, Trissur, Palakkad& Malappuram. These Laboratories function under the technical guidance &material supply from State Ph Lab. In Kerala the Public Health Labs contribute to a greater extent regarding communicable disease surveillance & also diagnosis &management of noncommunicable diseases.

In this new model, the PHL leads a network of clinical and other agency (e.g., food testing, veterinary, and local public health) laboratories to support public health response. The development of a robust national network of laboratories is, however, dependent on the existence of such laboratory networks within each state. The development of these statewide laboratory networks is, in turn, dependent on state-specific leadership and resources. This article describes the process of laboratory network development in Wisconsin and the application of the laboratory network model to specific public health issues.

3.2 Service delivery across facility levels

Service Flow and Referral Pathway of Hub and Spoke

1. Test Ordering and Sample Collection at the Spoke Facilities:

The Tests ordered in the Sample Collection facility as per the Clinical Directions of the Clinician (in Health Care Facilities- Human and Non-Human), whereas the Designated Officer will order the tests (in the case of Environmental/Non-Human Specimens).

A Unique Sample Referral ID will be generated at the Spokes as per the Request (For Human Samples-the ID registration will be through the UHID linked Mobile Number of the Patient/Specimen) and in the case of environmental/non-human specimens , in the initial phase, the same SRF ID will be generated manually and will be integrated to the E-health backed LMIS system in the later phase. This SRF ID will be reflected in the E-Health HMS Portal which may be used by the Hub Labs while entering the test reports in the Portal.

This Unique SRF ID will be the unique identification Number for the Specimens for logistic purposes and for identification and report generation at the HUB lab.

2.Sample Transportation and Logistics to the Hub Laboratory:

All spoke laboratories (Primary and Secondary Spokes) send the concerned samples for testing to the concerned Hub Laboratories as per the type of the Specimen and the type of the Test Intended. The Spoke Laboratories shall ensure that the samples are booked for transportation only to their mapped concerned 'hubs' (primary and secondary hubs) only. If specimens of the same patient have to be sent to both primary and secondary hubs for performing different kinds of tests, the specimens have to be packed separately and bookings done as two different parcels to the concerned hubs. The Vendor for the Logistics Management shall be India Postal Services. All the concerned Spokes will set up an Advanced Deposit Account with the corresponding Local Post Offices and Bookings done as 'Speed Post Parcel' packages. In the case of the Utilisation of the Alternate vendors/ any existing Logistic vendor (if already in contract, for non-human / environmental samples, in place, the same shall be continued in the case of an already existing system).

3. Packing and Transportation of the Samples:

Standard Operating Procedures and technical guidelines to be followed at the Spokes during the collection, packaging and transportation of Patient Specimens. The samples to be sent only to the designated Hubs for the concerned tests (Primary and Secondary) from the Spokes. Cold chain to be maintained as per the technical guidelines. The adequately packed samples need to be handed over to the concerned vendor (personnel deputed from the Post Office/ authorized personnel of the logistic vendor designated), who will be reporting to the spokes at the designated time of sample collection, every day.

4. Result Validation at the Hub Laboratory:

The results generated at the Hub Laboratory may be updated in the Portal by the Hub Laboratory which will be reflected in the HMS/LMIS portal in real time. The intimation regarding the same may be sent to the registered Mobile Number of the Patient (in the case of the Human Specimens). For Non-Human Specimens also, the reports of the samples may be entered in the LMIS Portal and the results reported in real time. In the case of Nin Human specimens, the results may also be generated manually and the results disseminated to the Spokes via e-mail.

5.Escalation Pathways for Specified/Confirmatory Testing:

In the case of escalation for any specific tests and the specimens to be sent to the concerned Regional/State Level/National Level Laboratory, the same shall be communicated to the District Level Designated Officer for the Lab Systems and he/she shall facilitate the further escalation of the Testing to the concerned higher level Hub Laboratory in consultation with the State Team. The transport of the samples from the Secondary hubs to the tertiary hub/Referral laboratories may also be facilitated using the same Logistic network. In those cases, the booking of the samples which are to be transported to the tertiary hubs may be done by the Secondary Hubs so that tracking of the specimens may be done effectively.

3.2.1 Referral mechanisms and sample transportation systems

Referral laboratory networking

1. NIV Pune - is the National reference laboratory for testing and confirmation of various dangerous pathogens like Nipah, Mpox, Crimean-Congo hemorrhagic fever (CCHF), Chandipura virus etc.

2. NIV Kerala unit Alappuzha, Regional VRDL Kozhikode GMC, VRDL Malappuram GMC and Kannur GMC, these laboratories have PCR facility for diagnosis of Nipah, which will be confirmed by NIV Pune.

3. Designated laboratories for diagnosis of Mpox – Regional VRDL Kozhikode, VRDL Thrissur, VRDL Trivandrum & STATE PUBLIC HEALTH AND CLINICAL LABORATORY Trivandrum. Final confirmation is from NIV Pune.

4. Designated laboratories for diagnosis of Lepto PCR tests in Kerala –

Leptospirosis is the most frequently encountered zoonotic disease in Kerala, which has a high mortality rate also. Lepto PCR test is required for diagnosis of the disease in the first week of onset. Hence the Govt of Kerala has established 12 Lepto PCR testing laboratories in the State. With State Public Health Lab being the nodal lab which supplies in house synthesized PCR reagent to all the 12 labs.

- NIV Alappuzha
- State Public Health and Clinical Laboratory
- VRDL Thrissur
- Regional VRDL Kozhikode
- VRDL Trivandrum
- GMC Palakkad
- GMC Kottayam
- RPHL Kozhikode
- RPHL Ernakulam
- RPHL Kannur
- RPHL Pathanamthitta
- DPHL Wayanad

5. Institute of Advanced Virology Thonnakkal Trivandrum has the facility for preliminary diagnosis of the following organisms (which has to be confirmed from NIV Pune).

- Nipah virus
- Hanta virus
- Mpox virus
- Kyasanur Forest Disease (KFD)
- Crimean-Congo hemorrhagic fever (CCHF)
- Chandipura virus
- Ebola virus

- Eastern Equine Encephalitis virus
- Western Equine Encephalitis virus
- Rift valley fever virus
- Marburg virus
- Yellow fever

6. State Public Health and Clinical Laboratory (SPHCL)
    - Designated laboratory for diagnosis of Human rabies
    - Nodal laboratory for diagnosis of Amoebic Meningo Encephalitis
    - PCR facility for diagnosis of viral infections like Covid influenza, respiratory panel, Meningitis panel etc
    - Lepto PCR facility
    - Scrub typhus PCR facility

3.2.3 Integration between diagnostic and surveillance laboratories

Integration between diagnostic and surveillance labs, such as through the Integrated Disease Surveillance Programme (IDSP), creates a unified network for rapid disease detection, data analysis, and response to outbreaks. This approach connects clinical testing with public health monitoring, enabling early detection of trends and improving outbreak response through shared data and resources.

- Decentralized Testing: Strengthening district and block-level labs ensures faster, more accurate diagnosis of epidemic-prone diseases, reducing reliance on central labs.
- Data Sharing & Technology: Utilizing web-enabled portals for weekly data reporting (S-suspected, P-presumptive, L-laboratory confirmed) ensures real-time monitoring and analysis of disease trends.
- Response Mechanisms: Integrated labs, supported by Trained Rapid Response Teams (RRTs), facilitate immediate investigation of unusual disease trends.
- Infrastructure & Capacity: Involves upgrading lab equipment, training staff in microbiology, and implementing IT-enabled reporting systems.
- Scope: Integrates surveillance across human and sometimes animal health sectors (One Health) to detect zoonotic threats.
- Benefits of Integration
- Improved Early Detection: Rapid identification of disease clusters before they become large-scale outbreaks.

- Better Resource Allocation: Efficient use of equipment and staff, reducing redundant testing and costs.
- Enhanced Evidence-Based Action: Enables policymakers to make data-driven decisions based on real-time surveillance data.
- Challenges & Future Directions
- Interoperability: Ensuring different lab information systems and instruments can communicate, as described by Roche Diagnostics.
- Data Security: Managing privacy and confidentiality when sharing sensitive health information.
- Systemic Strengthening: Addressing resource constraints in developing settings.

3.2.4 Role of the Nirnaya Diagnostic Network: Hub-and-Spoke Laboratory Model

Introductory section outlining the rationale for laboratory centralization under Nirnaya and the objectives of the hub-and-spoke diagnostic model.

3.2.4.1. Overview of the Hub-and-Spoke Structure

- Definition of hub laboratories and spoke facilities
- Levels of hubs (district / regional / reference)
- Role of spokes (Family Health Centres, CHCs, Taluk and District Hospitals)

3.2.4.2 Service Flow and Referral Pathways (Flow charts and description can be used)

- Test ordering and sample collection at spoke facilities
- Sample transportation and logistics to hub laboratories
- Result validation and reporting back to spokes
- Escalation pathways for specialized and confirmatory testing

3.3 Scope of Diagnostic Services

Basic tests at spoke level, Advanced, specialised, and molecular tests at hubs, Integration of surveillance, AMR, screening, and outbreak diagnostics.

3.3.1 Sample transportation policy

As proper transportation of clinical samples is very crucial to obtain good quality laboratory results, various aspects related to specimen transportation and handling have to be given due importance. This document outlines briefly about the guidelines and Standard Operating Procedure adopted from National guidelines and State

specific guidelines which includes all types of clinical specimen apart from samples for zoonotic disease diagnosis.

Proper transportation of clinical specimens involves safety aspects like secure leak proof containers, biohazard labels, personal protective equipment and correct handling to prevent exposure, maintaining integrity of the sample quality like maintaining temperature/stability of the sample and timeliness for the prompt delivery of the sample to the testing laboratory.

3.3.2 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 HWCs, FHCs, PHCs, UPHCs, BFHCs, CHCs, TH/THQHs, GH, DH to the concerned Primary hub/Secondary hub/Tertiary hub laboratory respectively. Generally, the samples collected are of two types- blood and body fluids (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.
2. Samples which do not require a 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/containers in upright position.

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

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

e. The spokes at different levels should be set up in such a manner that cumulative sample transportation time from multiple health facilities to the receiving hub laboratory should not exceed 2 hours with in the district (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 at least once a day from the spokes.

h. Pick-up of emergency samples (as per the clinical judgement of a Medical Officer) should be carried out immediately without waiting for the routine channel (eg: - by hand delivery).

i. The sample dispatch time should be recorded manually/electronically and monitored till the report is generated and delivered to patients.

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 (By email delivery if there is no LIMS facility). This service will be in-addition to the right of the patient to receive the hard copy of reports where the sample was submitted.

3.3.3 Mode of transportation of samples

In our state the main mode of transportation at present is the **"Nirnaya" hub and spoke facility** in collaboration with India Post Department. The program was officially launched in the State in October 2025.

3.3.4 The Work Flow of the Model

Designated Spokes and Hub Laboratories have been set up with a three-tiered Structure with Primary Spokes set up in all the Primary Health Centres and Family Health Centers. Secondary Spokes are set up in the Community Health Centres and the Taluk Hospitals and Taluk Headquarters Hospitals.

The Primary Hub Labs are set up in the Community Health Centres and the Taluk/Taluk Headquarters Hospitals with the Laboratories in the District /General Hospitals acting as the Secondary Hubs. The Referral State Level and National Level Laboratories function as the Tertiary Hub Laboratories. (refer fig 3.i)

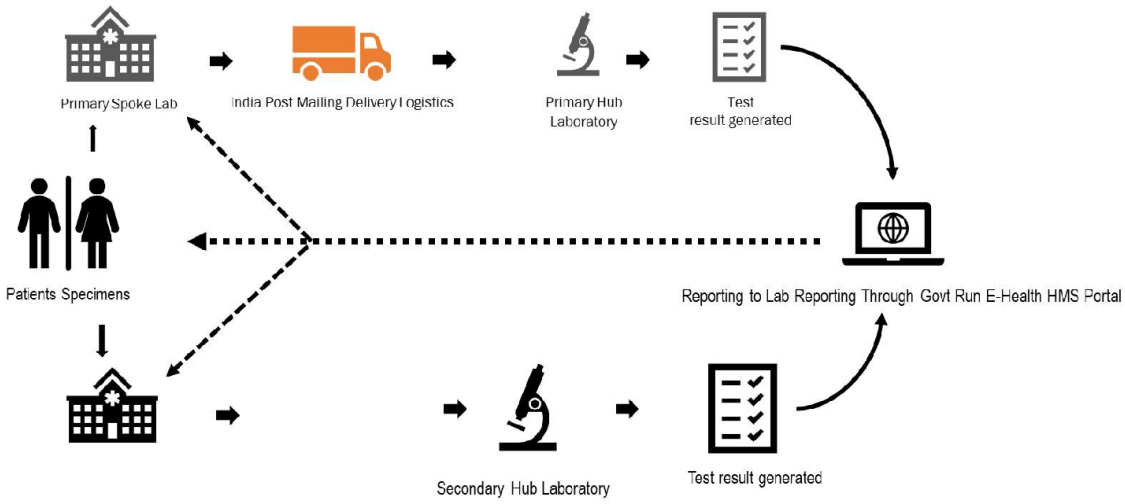


Fig 3.i

3.3.5 The Work Flow of the Logistics System

All spoke laboratories (Primary and Secondary Spokes) send the concerned samples for testing to their respective mapped Hub Laboratories (depending on the type of specimen and the tests mentioned) as 'Speed Post Parcel'. If specimens of the same patient are sent to both primary and secondary hubs for performing different kinds of tests, the specimens are packed separately and bookings done as two different parcels to the concerned hubs. The transport of the samples from the Secondary hubs to the tertiary hub laboratories are also facilitated using this network. In those cases, the booking of the samples which are to be transported to the tertiary hubs are done by the Secondary Hubs so that tracking of the specimens is done effectively.

3.3.6 Packing and Transportation of the Samples

Standard Operating Procedures and technical guidelines are followed at the Spokes during the collection, packaging, and transportation of Patient Specimens. The samples are sent only to the designated Hubs for the concerned tests (Primary and Secondary) from the Spokes. The cold chain is maintained as per the technical guidelines. The adequately packed samples are handed over to the concerned personnel deputed from the Post Office, who report to the spokes at the designated time of sample collection, every day.

3.3.7 Customization of the Sample Delivery System

For the Delivery of the Biological Specimens using the Mailing Delivery System of the India Post, additional modifications were made to the mailing delivery system which included the introduction of the Direct Bagging Facility.

3.3.8 Designated Time of Sample Collection & Booking Procedure

The designated time of sample collection (DTSC) from the Spokes by India Post is fixed as 1.30 P.M every day and the spokes ensure that all the samples which need to be transported to the Hubs are packed and made ready before this. Other modes of transportation include Private couriers and by hand delivery whenever the situation demands.

3.4 Digital Integration, Quality Assurance, and System Impact

Digital integration in the laboratory involves connecting instruments, software, and workflows into a cohesive digital ecosystem to automate processes, enhance

data integrity, and accelerate research. It transforms manual, paper-based operations into streamlined, automated, and electronic systems using tools like Laboratory Information Management Systems (LIMS) (LIMS), Electronic Laboratory Notebooks (ELN) (ELN), and artificial intelligence. Key benefits include improved accuracy, increased productivity, better regulatory compliance, and faster turnaround times.

- Data Management: Replacing paper with ELNs for unstructured, experimental data and LIMS for structured, routine data.
- Instrument Connectivity: Connecting laboratory devices (both new and legacy) to a centralized network for automated data collection and transfer, minimizing manual transcription errors.
- Workflow Automation: Utilizing Laboratory Execution Systems (LES) to guide scientists through procedures and automate compliance, with solutions like simplifying this process.
- Digital Twins & AI: Using digital representations of physical assets for real-time monitoring and applying algorithms to interpret complex data, improving predictive maintenance and operational efficiency.
- Digital Pathology: Integrating high-resolution imaging and molecular data, allowing for more accurate, collaborative, and, in some cases, faster diagnostic workflows.

Chapter 4. Infrastructure, Human Resources, and Quality Systems

This chapter covers laboratory infrastructure and equipment standards, human resource structure and training, quality assurance mechanisms (IQC, EQAS, SOPs, NABL), and biosafety, biosecurity, and infection control practices, presented as individual subheadings.

4.1 Biosafety, Biosecurity, Standard Precautions

Biosafety is the safe working practices associated with handling of biological materials, particularly infectious agents. It addresses containment principles, technologies and practices that are implemented to prevent the unintentional exposure to pathogens and toxins, or their accidental release.

Biosecurity describes the protection, control, and accountability for Valuable Biological Materials agents and toxins within laboratories, in order to prevent their loss, theft, misuse, diversion of, unauthorized access, or intentional unauthorized release"

Key components include primary barriers (e.g., PPE, biosafety cabinets) and secondary barriers (e.g., facility design) tailored to the risk level (BSL-1 to BSL-4).

Biosafety Level	**Agent Type**
BSL-1	Low-risk microbes, minimal, specialized precautions.
BSL-2	Moderate-risk pathogens, requires restricted access and biohazard signage
BSL-3	Serious or lethal airborne pathogens, aerosol transmission risk; requires specialized ventilation.
BSL-4	High-risk, life-threatening pathogens, High-risk, dangerous agents with no vaccines or treatments

4.1.1 Biosafety Level -1

It deals with the microbes there are not known to consistently cause disease in healthy adults and present minimal potential hazard to laboratorians and the environment. An example of a microbe that is typically worked with at a BSL-1 is a nonpathogenic strain of *E. coli*.

Specific considerations for a BSL-1 laboratory include the following:

1. Laboratory practices

- Standard microbiological practices are followed.
- Work can be performed on an open lab bench or table.

2. Safety equipment

- Personal protective equipment, (lab coats, gloves, eye protection) are worn as needed.

3. Facility construction

- A sink must be available for hand washing.
- The lab should have doors to separate the working space with the rest of the facility.

4.1.2 Biosafety level- 2

It deals with the microbes there pose moderate hazards to laboratorians and the environment. The microbes are typically indigenous and associated with diseases of varying severity. An example of a microbe that is typically worked with at a BSL-2 laboratory is *Staphylococcus aureus*.

In addition to BSL-1 considerations, BSL-2 laboratories have the following containment requirements:

1.Laboratory practices

- Access to the laboratory is restricted when work is being conducted.

2.Safety equipment

- Appropriate personal protective equipment (PPE) is worn, including lab coats and gloves. Eye protection and face shields can also be worn, as needed.
- All procedures that can cause infection from aerosols or splashes are performed within a biological safety cabinet (BSC).

- An autoclave or an alternative method of decontamination is available for proper disposal.

4.1.3 Biosafety level 3

BSL-3 builds upon the containment requirements of BSL-2. If you work in a lab that is designated BSL-3, the microbes there can be either indigenous or exotic, and they can cause serious or potentially lethal disease through respiratory transmission. Respiratory transmission is the inhalation route of exposure. One example of a microbe that is typically worked with in a BSL-3 laboratory is *Mycobacterium tuberculosis*, the bacteria that causes tuberculosis.

In addition to BSL-2 considerations, BSL-3 laboratories have the following containment requirements:

1. Laboratory practices

- Laboratorians are under medical surveillance and might receive immunizations for microbes they work with.
- Access to the laboratory is restricted and controlled at all times.

2. Safety equipment

- Appropriate PPE must be worn, and respirators might be required.
- All work with microbes must be performed within an appropriate BSC.

3. Facility construction

- A hands-free sink and eyewash are available near the exit.
- Exhaust air cannot be recirculated, and the laboratory must have sustained directional airflow by drawing air into the laboratory from clean areas towards potentially contaminated areas.
- Entrance to the lab is through two sets of self-closing and locking doors

4.1.4 Biosafety level 4

BSL-4 builds upon the containment requirements of BSL-3 and is the highest level of biological safety. There are a small number of BSL-4 labs around the world. The microbes in a BSL-4 lab are dangerous and exotic, posing a high risk of aerosol-transmitted infections. Infections caused by these microbes are frequently fatal and without treatment or vaccines.

Two examples of microbes worked with in a BSL-4 laboratory include Ebola and Marburg viruses.

In addition to BSL-3 considerations, BSL-4 laboratories have the following containment requirements:

1.Laboratory practices

- Change clothing before entering.
- Shower upon exiting.
- Decontaminate all materials before exiting.

2. Safety equipment

- All work with the microbe must be performed within an appropriate Class III BSC , or by wearing a full body, air-supplied, positive pressure suit.

3.Facility construction

- The laboratory is in a separate building or in an isolated and restricted zone of the building.
- The laboratory has dedicated supply and exhaust air, as well as vacuum lines and decontamination systems.

4.2 Infection control practices

The use of standard precautions is the primary strategy for minimizing the risk of transmission of microorganisms in HCFs. Standard precautions are to be followed for all patients, irrespective of their infection status. These are to be used to avoid contact with blood, body fluids, secretions and excretions regardless of whether contaminated grossly with blood or not; non-intact skin; and mucous membrane. The key components of standard precautions are:

1. Hand hygiene- Handwashing with soap and water is preferred when the hands are visibly dirty or soiled with blood or other body fluids or after using the toilet.

- Hand rubbing with an alcohol-based preparation is the preferred method for routine hygienic antisepsis if the hands are not visibly soiled.
- Surgical hand scrub

2. Personal protective equipment (PPE) -PPE includes gloves, aprons and gowns, facial protection, footwear and hair cover or cap.

3. Respiratory hygiene and cough etiquette-Cover the mouth and nose with a tissue when coughing or sneezing.

- Dispose of the tissue after use in the nearest waste container.
- Perform hand hygiene after contact with respiratory secretions and contaminated objects or materials.

4. Prevention of injuries from sharps -Used needles must not be recapped by hand; if necessary, use the single hand “scoop” method.

- Used needles should not be bent or broken after use.
- Used sharps should be disposed of immediately in designated puncture-proof containers

5. Safe handling of patient-care equipment -Equipment that has been in contact with a patient should be disinfected or sterilized as appropriate before use on another patient. Equipment that has been soiled with blood or body fluids should be decontaminated and cleaned to prevent transfer of microorganisms to other patients and the environment.

• Cleaning of patient-care areas and equipment should be carried out by a team of dedicated personnel trained in the appropriate cleaning procedures. A hospital disinfection policy should be prepared for appropriate cleaning, disinfection and sterilization of patient-care devices that come in contact with mucous membranes and access sterile tissues. The policy should be strictly followed and monitored. Accountability and responsibility should be assigned.

6. Principles of asepsis -Injection safety is an important component of standard precautions. Whenever possible, use a single-dose vial for each patient to reduce cross contamination between patients.

• Open only one vial of a particular medication at a time in each patient-care area.

• If possible, keep one multi-dose vial for each patient, and store it with the patient’s name on the vial in a separate treatment or medication room.

• Do not store multi-dose vials in the open ward or general patient-care area, where they could be inadvertently contaminated.

• Before use, examine the vial for turbidity, particulate matter or discoloration, and discard if any of these is present.

7. Environmental infection control:

a. Patient placement

b. Environmental cleaning

c. Linen and laundry

d. Waste disposal.

Bio waste management

Fig 4.i

4.3 Biosecurity

Key Components of Laboratory Biosecurity:

- Physical Security: Restricts access to the laboratory and secure areas through measures like locked doors, key card systems, surveillance, and alarms.
- Personnel Reliability: Ensures that staff working with high-consequence pathogens are authorized, trained, and monitored to prevent insider threats.
- Accountability for Materials (Inventory): Maintains a detailed, up-to-date inventory of all biological agents, toxins, and samples to track their location and usage.
- Transport Security: Manages the secure transfer of biological materials within and between facilities, including proper packaging and documentation.
- Information Security: Protects sensitive information regarding pathogen inventory, security systems, and research, preventing unauthorized access.
- Emergency Response: Develops plans for incidents like theft, accidental release, or intentional misuse of materials.
- Risk Assessment: Identifies, evaluates, and prioritizes assets (agents, equipment) based on the risk of misuse.

Chapter 5. Surveillance, Data Systems, and Reporting

Role of laboratories in disease surveillance and outbreak response

5.1 The role of the laboratory in disease surveillance

Laboratory information is critical for disease surveillance and control programmes. Before an outbreak, laboratory-supported surveillance allows early detection of cases. During an outbreak a sample of cases should be laboratory confirmed to assess changes in the etiological agent and to guide decisions about the allocation of resources. Support is provided by laboratories of differing capabilities. Field laboratories are useful in areas where resources are limited or nonexistent. More complete testing is usually done in regional laboratories. International reference laboratories may identify rare or dangerous pathogens, identify newly described organisms, and provide uncommon diagnostic reagents. Laboratory information must be accurate, timely and subjected to quality assurance procedures.

- **Laboratory support: a key to disease surveillance**

Accurate laboratory-based information is a critical component of disease surveillance and is among the highest goals of disease control programmes. Pathogen-specific surveillance information, based on factors such as geographic range, vectors, antibiotic resistance and biotype/serotype of the etiologic agent, is critical for predicting outbreaks and for differentiating background events from true outbreaks. Early detection of disease outbreaks with confirmation of etiology allows the institution of proper treatment, control and prevention practices. Likewise, during a disease outbreak a sample of cases should be laboratory confirmed in order to monitor the characteristics of the epidemic strain of the organism. Significant changes in key phenotypic or genotypic characteristics (antibiotic resistances, serotype, biotype, antigenic shifts, etc.) may warrant changes in treatment or control practices.

- Adequate epidemiological support can often be provided by laboratory facilities of differing levels of sophistication and capabilities. Field laboratories, either portable, mobile or fixed, can provide screening tests and simple diagnostic procedures in areas where more extensive resources are limited or non-existent. Field facilities, however, may be limited to collection and processing of specimens or the performance of simple, rapid diagnostic procedures that do not require significant environmental controls, containment capabilities or support facilities. Field laboratories, however, require

significant logistical support and are best suited to providing limited services for brief periods of time.

- Larger laboratories, such as those found at the district, regional and national levels require significant infrastructure and support. These larger facilities, however, are often the only ones with the resources to perform complex or lengthy testing procedures, such as viral cultures and molecular biological assays. These facilities often operate in concert with smaller facilities and field laboratories in order to expand the availability of regional diagnostic capabilities. Tests offered may include the isolation, identification and characterization of the spectrum of pathogenic microorganisms.

- International reference laboratories, such as WHO collaborating centres, are often asked to confirm the identification of rarely encountered organisms as well as to identify extremely dangerous pathogens. These laboratories may also be able to identify newly described pathogens and may represent the only source for infrequently used diagnostic reagents and materials. It is important that these unique facilities be empowered to maintain not only their expertise, but also supplies of reagents for which there may be no commercial supplier.

- **Integration with IDSP, AMR, TB, and cancer surveillance programmes**

Integration between diagnostic and surveillance labs, such as through the Integrated Disease Surveillance Programme (IDSP), creates a unified network for rapid disease detection, data analysis, and response to outbreaks. This approach connects clinical testing with public health monitoring, enabling early detection of trends and improving outbreak response through shared data and resources.

Key Aspects of Integration

- Decentralized Testing: Strengthening district and block-level labs ensures faster, more accurate diagnosis of epidemic-prone diseases, reducing reliance on central labs.
- Data Sharing & Technology: Utilizing web-enabled portals for weekly data reporting (S-suspected, P-presumptive, L-laboratory confirmed) ensures real-time monitoring and analysis of disease trends.
- Response Mechanisms: Integrated labs, supported by Trained Rapid Response Teams (RRTs), facilitate immediate investigation of unusual disease trends.

- Infrastructure & Capacity: Involves upgrading lab equipment, training staff in microbiology, and implementing IT-enabled reporting systems.
- Scope: Integrates surveillance across human and sometimes animal health sectors (One Health) to detect zoonotic threats.

Benefits of Integration

- Improved Early Detection: Rapid identification of disease clusters before they become large-scale outbreaks.
- Better Resource Allocation: Efficient use of equipment and staff, reducing redundant testing and costs.
- Enhanced Evidence-Based Action: Enables policymakers to make data-driven decisions based on, real-time surveillance data.

Challenges & Future Directions

- Interoperability: Ensuring different lab information systems and instruments can communicate, as described by Roche Diagnostics.
- Data Security: Managing privacy and confidentiality when sharing sensitive health information.
- Systemic Strengthening: Addressing resource constraints in developing settings.

a) Laboratory Information Management Systems (LIMS) (Both central and institutional level), Data governance, confidentiality, and analytics
b) In Kerala, the majority of our laboratories are enabled with the e Health lab module for Laboratory information management system. The patient gets a software SMS & link to access their lab result.
c) All communicable diseases are reported through the national IHIP portal. Designated laboratories & officials at the state & district level have access to this portal.
d) During the covid pandemic Kerala was using a dedicated portal for reporting lab data from both public & private sector (LDMS portal)
e) One Health Approach in Public Laboratory Services the One Health approach, emphasizing integrated surveillance and laboratory collaboration across human, animal, and environmental health sectors, is addressed within the chapter on surveillance and data systems. It is used to improve detection, surveillance, and response to zoonotic diseases and environmental threats. By bridging laboratory silos, it enables rapid sharing of diagnostic data, enhances pandemic preparedness, and optimizes resources through shared, standardized testing techniques.

Key components of this approach include:

- Integrated Surveillance: Utilizing shared databases and networking across medical, veterinary and environmental labs for real-time monitoring of pathogens like Influenza or Antimicrobial Resistance (AMR).
- Joint Investigations: Coordinated sampling and analysis of human clinical specimens, animal tissues, and environmental samples (e.g., water, soil).
- Enhanced Diagnostics: Adopting molecular, serological, and genomic sequencing technologies, such as the IAEA Zodiac initiative, to identify and characterize diseases at the source.
- Collaborative Capacity Building: Training laboratory professionals across sectors in shared protocols, biosafety, and data management.
- This collaborative framework enables faster identification of potential outbreaks and more effective, evidence-based public health interventions.

One Health approach refers to an integrated, unifying approach that aims to achieve optimal and sustainable health outcomes for people, animals and ecosystems. Historically, the human, animal, and environmental health sectors have often operated in isolation, leading to fragmented approaches in combating diseases and addressing health risks. One Health seeks to bridge this gap by promoting interdisciplinary collaboration, data sharing, and communication across various sectors, including human and veterinary medicine, public health, agriculture, ecology, and environmental conservation.

This approach is often used to coordinate multi-sectoral prevention, preparedness and response efforts of zoonotic diseases – those that can transmit from animals to humans (spillover), or humans to animals (spillback) – such as rabies, avian flu or viral hemorrhagic fevers such as Ebola and also covid 19.

Additionally, climate change influences the distribution of disease vectors, such as mosquitoes, impacting the spread of diseases like malaria and dengue fever. By considering these interconnections, the One Health approach provides a framework to mitigate these risks and safeguard human, animal, and environmental wellbeing.

Benefits of the One Health Approach

1. Disease Prevention and Control: One Health approach emphasizes early detection, surveillance, and rapid response to disease outbreaks. Collaborative efforts between human and veterinary health sectors enable better monitoring and control of zoonotic diseases, reducing the likelihood of pandemics and improving public health outcomes.

2. Antimicrobial Resistance: One Health recognizes the overuse and misuse of antibiotics in both human and veterinary medicine as a significant concern. By fostering collaboration, One Health advocates for responsible antimicrobial stewardship, promoting the judicious use of antibiotics in both human and animal health settings, thus combating the growing threat of antimicrobial resistance.

3. Environmental Sustainability: The One Health approach underscores the importance of sustainable environmental practices. By addressing the root causes of environmental degradation, such as deforestation, pollution, and climate change, we can mitigate the emergence and spread of infectious diseases, preserve biodiversity, and ensure the long-term health of our planet

4. Research and Innovation: One Health encourages interdisciplinary research collaborations, leading to new insights and innovations. By integrating knowledge from various fields, we can develop novel diagnostics, vaccines, and treatments for both human and animal health, improving health outcomes for all species.

One Health programme initiatives in India

1. National Programme for AMR

2. National Programme for Climate Change and Health was launched by MoHFW under National Health Mission in 2019

3. National One Health Mission was set up upon approval of The Prime Minister's Science, Technology and Innovation Advisory Council (PM-STIAC) to coordinate, support and integrate all the existing One Health activities in the country and fill any existing gaps

4. National One Health Programme for Prevention and Control of Zoonoses: The goal of the programme is protecting communities and minimizing socioeconomic losses due to emerging and re-emerging zoonotic threats.

One health programme initiatives in INDIA are mainly to create an integrated web/digital portal for zoonotic pathogens which would be a joint IT platform for data sharing on agreed parameters between concerned sectors such as health (IDSP), veterinary (NLM/NADRS) and Climate data (IMD). This will enable the development of a Real-time alert mechanism for zoonotic diseases and timely detection, effective prevention, and public health response for impending outbreaks.

Challenges

Firstly, the divergent priorities across different sectors pose a significant hurdle. Each sector, be it human health, animal health, or environmental sector, operates with its own set of priorities and objectives, often leading to fragmented efforts.

There is a need to integrate and strengthen legislation for development of a comprehensive One Health regulatory framework that integrates laws across human health, animal health, and environmental protection to enforce robust surveillance systems and timely reporting that is imperative for effective One Health practices.

Another critical issue is the minimal data sharing between sectors, hindering comprehensive and effective response to health challenges.

Public awareness about the interconnectedness of human, animal, and environmental health remains low, further exacerbating the problem. Insufficient technical capabilities, especially in rural areas, and logistical constraints pose additional barriers.

Conclusion

One health is well conceptualized in the above national programme but realization of the concept seems impractical at times due to many challenges such as lack of policy framework, sectoral silos and disparate human and animal disease reporting and surveillance systems.

Inadequate resource allocation, lack of SOPs for systematic communication, inherent differences in disciplinary training, knowledge deficits and inter and Intra hierarchical coordination challenges further complicate the situation.

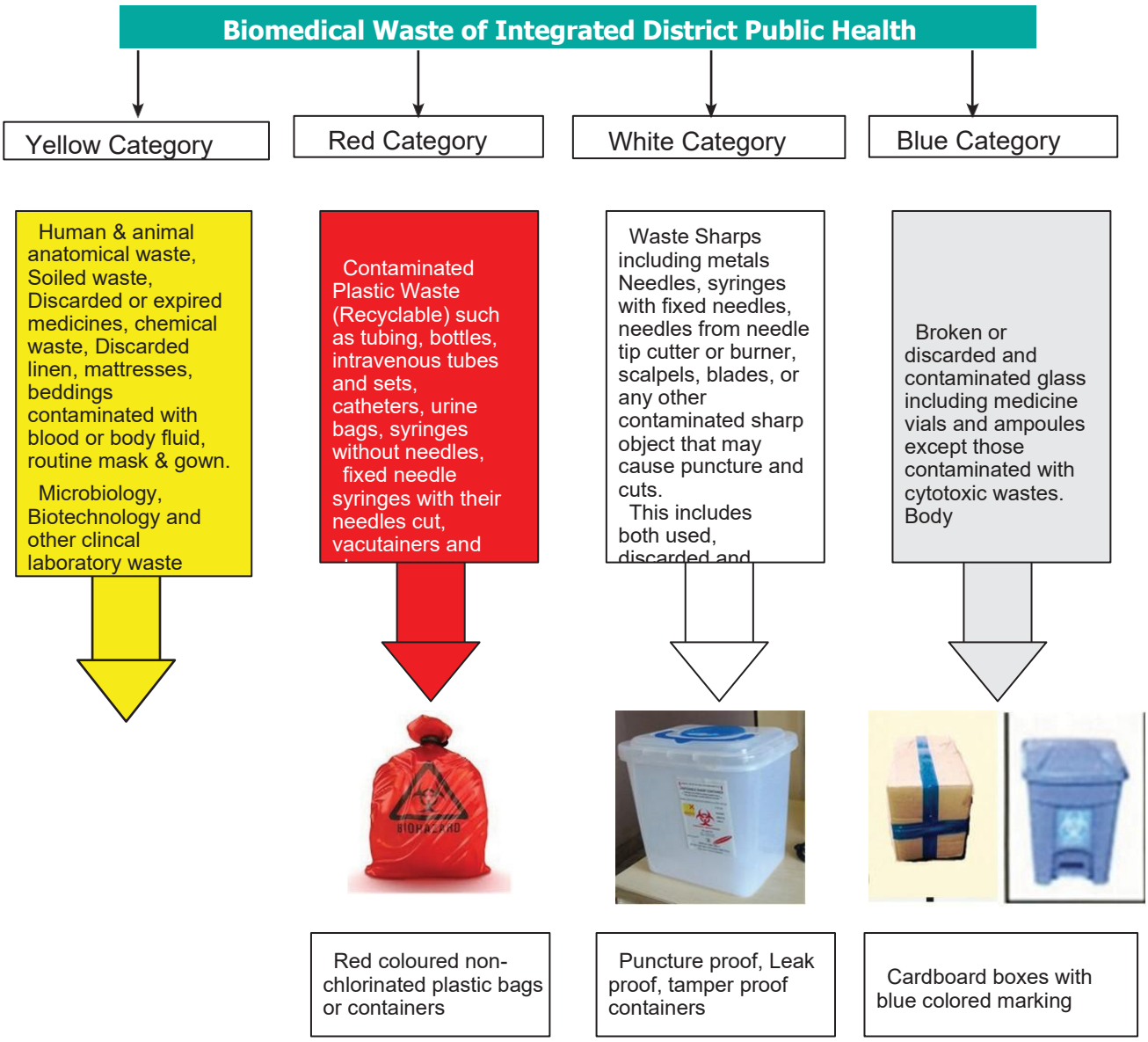
Quality assurance and quality control

Effective quality control and quality assurance programmes help to ensure the accuracy of laboratory results and heighten their utility in programmes for disease control. Good laboratory practices require that appropriate quality control and quality assurance procedures be regularly used at all levels. The quest for maximum efficiency and effectiveness coupled with a reduction in errors and reduction in risk to the worker are essential components of quality assurance and laboratory management. Quality assurance should include internal quality controls and external quality assessment. A comprehensive programme of quality assurance should include the elements of test selection, patient and sample preparation, documentation, transport, handling and storage, sample analysis, reports, and analysis of data. Laboratory elements to be considered when evaluating the quality of laboratory activities and test results are presented

In Kerala majority of the clinical labs use Internal quality control reagents from AIM, Delhi / reputed manufacturers for Haematology tests. EQAS is done through reputed agencies. For Biochemistry IQC reagents are procured from reputed manufacturers. EQAS biochemistry is mainly through CMC Vellore. Microbiology EQAS is also mainly from CMC Vellore.

Chapter 6. Supply Chain, Logistics, and Sample Management

- Procurement and inventory management
- Procurement of all major equipment including Automated analysers are being done by Kerala medical services corporation. Rate contract for the reagent is also fixed for a prescribed period as per tender conditions. (sample quality evaluated through major institutions like medical colleges & public health labs before finalising the item). For public health laboratories reagent supply based on the rate contract is done through state public health lab. For inhouse laboratories reagent procurement based on the rate contract is done by the institution head. Some of the test kits related to communicable diseases like Hepatitis B&C IgM ELISA, Leptospira Ig M ELISA, Dengue IgM & NS1 ELISA kit etc are also supplied centrally from KMSC. A wide range of consumables are also being supplied centrally through KMSCL.
- Reagent and consumable forecasting
- All public laboratories including medical colleges & Public health labs prepare their annual indent based on the previous years'consumption. (Usually, a ten percent hike in intended quantity is given to tackle unforeseen public health events.
- Sample collection, transport, and cold chain systems
- Biomedical waste management (Refer fig 6.i)



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 an effluent treatment system.

Fig 6.i

Chapter 7. Financing, Performance Monitoring, and Governance

- **Cost of diagnostics and free diagnostics initiatives**

The Cost of the Diagnostics met from the Finance Commission Grants, under the concerned Heads for the Laboratory Infrastructure. The additional Funds from the revenue generated through the Nirnaya Hub and Spoke Laboratory System and the additional funds through the other initiatives like CSR funds and National Programmes shall also be utilised for the Same.

- **Key performance indicators and monitoring mechanisms**

Laboratory Key Performance Indicators (KPIs) are essential, measurable metrics—such as turnaround time, error rates, and instrument utilization—used to evaluate, manage, and optimize the efficiency, quality, and productivity of laboratory operations. They cover pre-analytical, analytical, and post-analytical phases to ensure data accuracy, regulatory compliance, and cost-effective workflows.

In Kerala, since the hub and spoke system is implemented smoothly, the following indicators are also considered for monitoring mechanisms.

The Potential Indicators for Review shall include

- The Number of Spokes actively sending samples to the primary and secondary hubs in the District in the Previous Month
- The number of Primary and secondary Hubs in the District which are actively receiving and processing samples in the previous Month
- No of tests performed by each Hub, the previous month
- The Number of Primary Spoke-Primary Hub Units actively functioning in the districts
- Sample Rejection Rate by each Hub
- Repeat Sampling Rate by Each Hub
- No of Tests Outside Biological Interval reported by each Hub
- The Average Specimen Wise Turn Around Time reported by Each Hub
- Inter Lab Comparison reports of each Hub
- No of Hubs performing e-reporting
- Sample Loss Rate of each Hub

The Following Proforma may be used for Data Monitoring: (Data to be compiled from all Spokes and Hubs in the District)

Monitoring Tool for Districts- Indicators							
Name of the Primary Spoke	**Name of the Primary Hub**	**No of Samples Received by Primary Hub - Hub and Spoke (*Previous Month*)**	**No of samples received by the secondary Hub (Previous Month)**	**No of samples rejected by the Primary Hub**	**No of Repeat samples sought by the primary Hub**	**No of test reports released outside the accepted TAT (If any)**	**No of samples lost (Previous Month, if any)**

District level monitoring team for the monitoring of the programme set up by the districts. The Members of the team shall include: Senior Medical Officer of the Regional Public Health Lab/ District Public Health Lab, Pathologist/Clinical Microbiologist (from the district for Districts without RPHL/DPHL), District Lab Officer and a Lab Technician (Grade 1), designated from the district. The team shall submit the report pertaining to the monthly monitoring of the programme to the concerned District Surveillance Officer. The monitoring can also be performed using the State wide and Data Wise collected from the LMS system.

The State Level Monitoring Committee of the Network shall be the State Level Executive Committee of the State Public Health Laboratory and the members of the same shall be the members of the State Level Monitoring Committee. The Committee shall convene and consolidate the data received from the Districts on a Periodic Basis and to guide the districts towards the optimum utilisation of resources.

- **Governance and Accountability Structures:**

The State Level Executive Committee of the State Public Health Lab with the following members may act as the Governing Body of at the State Level-

Chairperson: Principal Secretary, Principal Secretary, Health & Family Welfare Department

Member Secretary & Convenor: Director, State Public Health and Clinical Laboratory (SPHL)

Official Members:

1. State Mission Director, National Health Mission

2. State Mission Director, National Ayush Mission

3. Director of Health Services

4. Director, Ayush Department

5. Director, Homeopathy Department

6. Director, Indian Systems of Medicine

7. Additional Director of Health Services (Public Health)

8. Additional Director of Health Services (Planning)

9. Additional Director of Health Services (Medical)

10. Senior Finance Officer

11. Senior Consultant- State Public Health and Clinical Laboratory

12. Senior Administrative Officer

At the District Level, it shall be as follows

Chairperson: District Collector

Vice Chairperson: District Medical Officer (Health)

Member Secretary & Convenor: Senior Medical Officer/Medical Officer Regional Public Health Laboratory/District Public Health Laboratory

Official Members:

1. District Programme Manager, National Health Mission

2. Consultant- Regional Public Health Laboratory/District Public Health Laboratory

3. District Surveillance Officer

4. Bio Medical Engineer (National Health Mission)

5. District Medical Officer- Ayush

6. District Medical Officer - ISM

7. District Medical Officer -Homeo

Chapter 8. Innovations, Challenges, Best Practices, and Future Roadmap

This chapter outlines the challenges and highlights best practices and innovations within Kerala, and presents strategic priorities and recommendations

BEST PRACTICES

1) <u>NEW BORN SCREENING PROGRAM</u>

- One of the most prestigious initiatives of the health department, the New born metabolic screening programme, started in march 2013 for the early detection of inborn errors of metabolism and early intervention to prevent serious consequences like mental retardation. The program has completed 12 years now.
- Screening tests are done for four selected disorders namely congenital hypothyroidism, congenital adrenal hyperplasia, phenyl ketonuria, and g6pd deficiency. phenyl ketonuria has been replaced by galactosemia in 2017 as there were no positives detected during the initial 3 years.
- The blood samples of newborns from more than 100 delivery points under the government sector are tested through four public health laboratories-

State Public Health & clinical Laboratory is the apex laboratory for newborn metabolic screening programmes. Since it was a state initiative, guidelines pertaining to sample collection, transportation, testing, reporting & monitoring etc were prepared by the state public health lab & approved by the government. Regional public health laboratories.

The newborn screening test aims at the early detection of disorders to prevent the most serious consequences by timely intervention. The first expanded New Born Screening Programme has been implemented in the state from March 2013 onwards. The heel prick sample of new born babies collected from Govt hospitals are being tested in the four designated Public Health Labs in the State (SPHCL TVM, RPHL KKD, KNR and EKM). The screening tests include tests for detection of congenital hypothyroidism, Congenital Adrenal Hyperplasia, G6PD deficiency and Phenylketonuria till July 2018 and after that PKU is replaced by Galactosemia. The screening tests are based on ELISA and Immunofluorescence methods. The positive cases detected by screening tests are confirmed by other methods like Chemiluminescence/Radio Immuno Assay.

As such the programme has completed ten years of New Born Screening. We haven't come across a single positive case of Phenyl Ketonuria till July 2018. After that Phenyl Ketonuria has been replaced by Galactosemia. Moreover, newborn screening has been spread to all the delivery conducting Government Hospitals. Now there are more than hundreds of hospitals participating in the New Born Screening programme.

Fig 7.i – Award winning poster in National submit

2) HUB AND SPOKE MODEL (NIRNAYA LAB SERVICES)

Operational frame work

- Primary Spokes-PHC/FHC: Collection centers and Laboratories for basic laboratory tests
- Primary Hub Laboratories: Block Public Health Labs/CHCs/Taluk Hospital labs designated by the district
- Secondary Hub Labs: Taluk HQ hospitals/GH-DH Labs, RPHLs, District AMR Labs, Designated District Lab for Cancer Diagnosis
- Tertiary Hub Labs: State Level Labs (SPHL, ICMR-NIV Alleppey, designated tertiary institutes), National level Laboratories (NIV Pune and similar referral labs)
- Involves Sample Collection, transportation, Testing and reporting

3) DIGITAL PATHOLOGY LAB NETWORKING FOR CANCER DIAGNOSIS

- Activities are undergoing for the networking of 4 regional public health laboratories to the regional cancer center and Malabar cancer center.
- 2 PH labs in the southern region will be connected to RCC and 2 PH labs in the northern region will be connected to Malabar cancer center this will enable the spoke laboratories (PH labs) to provide cancer diagnosis without delay

▪ PPCL Leptospira PCR facility is available. SPHCL supplies Lepto PCR kits synthesized in house to all the 12 Lepto PCR labs in the state (GMC's and PH Labs).

▪ SPHCL provides Amoebic Meningoencephalitis (Accanthamoeba spp, Naegleria fowleri, Paravahlkampfia francinae, Vermamoeba vermiformis, Balamuthia madrillaris) State wide testing facility to all the districts.

4)High end equipment present in SPHCL

Automated Extraction system

Automated Biochemistry Analyser

AUTOMATED TISSUE EMBEDDING STATION

Automated Histokinete

Automated Identification System

Automated immuno Analyser


Hematology 5 part Analyser


ELISA Workstation

8.2 Challenges

1. Shortage of human resources.
2. Post creation is not affected for upcoming new public health labs (Kottayam, Thrissur, Palakkad).
3. Lack of uninterrupted supply of kits and reagents due to shortage of funds.

Annexure I

Basic Laboratory Tests

Sl No	Name of the Test	Requirements at Spoke	Packing Materials
1	Hemoglobin	K3 EDTA Tubes/EDTA Vacutainer, Syringe, Needles,	Ice Pack, Thermocol box, micropore tape, adhesives, marker, labelling stickers, zip lock cover, brown adhesive tapes, secondary container for triple layer packing
2	Total leucocyte count	K3 EDTA Tubes/EDTA Vacutainer, Syringe, Needles,	
3	Differential leucocyte count	K3 EDTA Tubes/EDTA Vacutainer, Syringe, Needles,	
4	Platelet count	K3 EDTA Tubes/EDTA Vacutainer, Syringe, Needles,	
5	Complete blood count	K3 EDTA Tubes/EDTA Vacutainer, Syringe, Needles,	
6	Erythrocyte sedimentation rate	3.8% Trisodium Citrate Tube, Syringe, needle	
7	Blood group and Rh typing	K3 EDTA Tubes/EDTA Vacutainer, Syringe, Needles,	
8	Peripheral blood film	K3 EDTA Tubes/EDTA Vacutainer, Syringe, Needles,	
9	Reticulocyte count	K3 EDTA Tubes/EDTA Vacutainer, Syringe, Needles,	
10	Absolute eosinophil count	K3 EDTA Tubes/EDTA Vacutainer, Syringe, Needles,	
11	Bleeding time & clotting time	Bed side at Spoke- Glass slide, Filter Paper, Capillary Tube, Lancet	
12	Sickling Test	K3 EDTA Tubes/EDTA Vacutainer, Syringe, Needles,	
13	Quantitative test for G6PD enzyme deficiency	K3 EDTA Tubes/EDTA Vacutainer, Syringe, Needles,	
14	a. MP slide method and	K3 EDTA Tubes/EDTA Vacutainer, Syringe, Needles,	
	b. Malaria rapid test	RDT Card- can be done at Spoke	
15	Prothrombin time (PT)	3.2% Trisodium Citrate Tubes, Needle, Syringe,	
16	Activated partial thromboplastin time (APTT)	3.2% Trisodium Citrate Tubes, Needle, Syringe,	

17	Human chorionic gonadotropin (HCG) (Urine test for pregnancy)	Sterile Urine Container,	
18	Urine test for ph., specific gravity, leucocyte esterase, glucose, bilirubin, urobilinogen, ketone, protein, nitrite	Sterile Urine Container,	
19	Urine microscopy	Sterile Urine Container,	
20	Urine protein (24 hr)	5 Litre Can, preservative- Boric Acid/Acetic Acid	
21	Urine for microalbumin	Sterile Urine Container,	
22	Urine for creatinine & Albumin to Creatinine Ratio (ACR)		
23	Stool for ova and cyst	Container with Spatula (Red, Screw CAAPPED)	
24	Stool for Occult Blood	Container with Spatula (Red, Screw CAAPPED)	
25	Test for Dengue PHC		
	a. Rapid card test for combined NS1 antigen & IgM antibody	Rapid Card can be done at Spokes. Clot Activator Tube (Red Capped Vacutainer, dropper	
	b. ELISA	Red Capped vacutainer- Clot activator Tube	
26	RPR/VDRL test for syphilis	Red Capped vacutainer- Clot activator Tube, syringe, needle	
27	HIV test (Antibodies 1/2 and HIV 1/2)	Red Capped vacutainer- Clot activator Tube, syringe, needle	
28	Hepatitis B surface antigen test	Red Capped vacutainer- Clot activator Tube, syringe, needle	
29	PHC ANM/Lab tech Rapid card test	Red Capped vacutainer- Clot activator Tube, syringe, needle	
30	HCV Antibody Test (Anti HCV)	Red Capped vacutainer- Clot activator Tube, syringe, needle	
31	31 Sputum for AFB PHC	Sterile Sputum screw cap cup/container	
32	Typhoid test (IgM)	Red Capped vacutainer- Clot activator Tube, syringe, needle	
33	Blood sugar	glucometer strip	
34	Glucose Tolerance Test (GTT)		
35	S. Bilirubin	Red Capped vacutainer- Clot activator Tube, syringe, needle	

36	S. Bilirubin direct and indirect	Red Capped vacutainer- Clot activator Tube, syringe, needle	
37	Serum creatinine	Red Capped vacutainer- Clot activator Tube, syringe, needle	
38	Blood Urea	Red Capped vacutainer- Clot activator Tube, syringe, needle	
39	Uric acids	Red Capped vacutainer- Clot activator Tube, syringe, needle	
40	SGPT	Red Capped vacutainer- Clot activator Tube, syringe, needle	
41	SGOT	Red Capped vacutainer- Clot activator Tube, syringe, needle	
42	S. Alkaline Phosphatase	Red Capped vacutainer- Clot activator Tube, syringe, needle	
43	S. Total Protein	Red Capped vacutainer- Clot activator Tube, syringe, needle	
44	S. Albumin & AG ratio	Red Capped vacutainer- Clot activator Tube, syringe, needle	
45	S. Total Cholesterol	Red Capped vacutainer- Clot activator Tube, syringe, needle	
46	S. Triglycerides	Red Capped vacutainer- Clot activator Tube, syringe, needle	
47	S. VLDL	Red Capped vacutainer- Clot activator Tube, syringe, needle	
48	S.HDL	Red Capped vacutainer- Clot activator Tube, syringe, needle	
49	S. LDL Hub lab	Red Capped vacutainer- Clot activator Tube, syringe, needle	
50	Serum Sodium	Red Capped vacutainer- Clot activator Tube, syringe, needle	
51	S. Potassium	Red Capped vacutainer- Clot activator Tube, syringe, needle	
52	Serum Calcium	Red Capped vacutainer- Clot activator Tube, syringe, needle	
53	Gram Smear for RTI/STD	cotton swab, sterile containers, test tube, sterile centrifuge tube	
54	Gram staining for clinical specimen	cotton swab, sterile containers, test tube, sterile centrifuge tube	
55	Throat swab for Diphtheria	cotton swab, amies transport media, Loeffler's serum slope	
56	Visual Inspection Acetic Acid (VIA)	5% acetic acid , pap smear spatula, sterile gloves	
57	rK39 for Kala Azar*	n/a	Field
58	Smear for Filaria*	n/a	Field
59	TB – Mantoux		
60	RA factor (Quantitative)	clot activator tube	

61	CRP (including new born) (Quantitative)	clot activator tube	
62	TSH	clot activator tube	

Annexure II

Advanced Laboratory Tests

Sl No	Name of The Spoke	Name of the Test	Requirements at Spoke
II.	Advanced Diagnostic Tests	Other Tests including Culture & Sensitivity	No Primary Hub
		CBNAAT for TB	Block Public Health Unit/Block CHC if facility available
		Antimicrobial Resistance Surveillance	No Primary Hub
		TrueNAT for TB	Block Public Health Unit/Block CHC if facility available
		Other Disease Diagnosis with Truenat compatibility (National programmes)	Block Public Health Unit/Block CHC if facility available
	Communicable Disease Confirmation	Elisa for Communicable Disease Confirmation	Block Public Health Unit/Block CHC if facility available
		Dengue ELISA	Block Public Health Unit/Block CHC if facility available
		Lepto ELISA	Block Public Health Unit/Block CHC if facility available
		Hepatitis A, E, B- ELISA	Block Public Health Unit/Block CHC if facility available
	Cancer Care Programme	Cytopathology	
		Histopathology	No Primary Hub
	Environmental Surveillance	Water Quality Testing	
		Air Quality Testing	No Primary Hub
		Surface Swabs for testing	No Primary Hub
		OT /Hospital swabs for Sterility Testing	No Primary Hub
	Molecular Tests-RT-PCR tests	COVID-19	No Primary Hub
		Leptospirosis- PCR	No Primary Hub
		Hepatitis-PCR	No Primary Hub
		Others-PCR	No Primary Hub

Annexure III

Sl 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)
5	(Desirable)
6	Semi-automated Biochemistry analyser (Essential)
7	Automated Hormone Analyser (CLIA Based)
8	Centrifuge (fixed head) table-top 16 tubes. Up to 6000 RPM
9	Centrifuge tabletop (swing out) with 8 tubes. Up to 6000 RPM
10	Automated Coagulometer
11	ISE based Electrolyte analyser
12	VDRL rotator/shaker
13	Binocular Microscopes
14	Fluorescent Microscope (Desirable)
15	ELISA reader with washer
16	Refrigerator 400 litres
17	Deep freezer (-20 deg C)
18	Deep freezer (-80 deg C) (Desirable)
19	Vertical Autoclave (for sterilisation) 100L
20	Vertical Autoclave (for disinfection) 100L
21	Vortex mixer
22	Urine analyser
23	Electronic balance up to 3 decimal places
24	Hot Air oven (medium size)
25	Hot Plate for culture media preparation
26	Computer with scanner, printer, UPS
27	Incubator (2 medium-sized)
28	Digital Thermometer
29	Needle destroyer
30	ESR Tubes with stand
31	Neubauer’s Counting Chamber
32	Manual Cell Counter
33	HPLC machine/automated system for haemoglobinopathies/HbA1C (Desirable)
34	Micropipette 0.1- 2µl
35	Micropipette 1- 10µl
36	Micropipette 5- 50µl
37	Micropipette 50- 200µl
38	Micropipette 200- 1000µl
39	Multi-Channel pipette (Octa pipette) 200-1000µl
40	pH meter
41	Automated ESR analyser
42	Electrophoresis unit (horizontal)

43	Gas supply
44	Bunsen burner
45	Glassware, Kits and Consumables (as needed)
46	Real Time PCR machine
47	Microcentrifuge machine (up to 16,000 rpm)
48	PCR workstation
49	Automated system for Blood culture (Desirable)
50	Automated system for Bacterial Identification and sensitivity (Desirable)
51	Blood gas analyser
52	Flow cytometer (for CD4/CD8 counts) (Desirable)
53	Alcohol thermometer
54	Alarm clock
55	Binocular Microscope LED with camera (Desirable)
56	Slide staining racks
57	NAAT machine
58	Histopathology equipment (Desirable)
59	Tissue Homogenizer (Desirable)
60	Micro-incinerator for inoculating loops and needles

IV 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
- BSL-3- Biosafety Level 3
- BSL-4- Biosafety Level 4
- 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
- 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
- FRU First Referral Unit
- G6PD Glucose 6 Phosphate Dehydrogenase
- 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
- HDL - High Density Lipoprotein
- HIS - Hospital Information System
- HIV - Human Immunodeficiency Virus
- HMIS - Health Management Information System
- 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

- 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
- MoHFW - Ministry of Health & Family Welfare
- NABL - National Accreditation Board for Testing & Calibration Laboratories
- 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 &
- NQAS - National Quality Assurance Standards
- NTEP - National Tuberculosis Elimination Programme
- NVBDCP - National Vector Borne Disease Control Programme
- NVHCP - National Viral Hepatitis Control Programme
- 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
- PHC - Primary Health Centre
- 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
- RDT - Rapid Diagnostic Tests
- RPM - Rotations Per Minute
- RRT - Rapid Response Team
- SC - Subcentre
- SGOT - Serum Glutamic Oxaloacetic Transaminase
- SGPT - Serum Glutamic Pyruvic Transaminase
- SOP -Standard Operating Procedures
- TAG -Technical Advisory Group
- TRF -Test Requisition Form
- TSH - Thyroid Stimulating Hormone

- TWG - Technical Working Group
- UPHC - Urban Primary Health Centre
- VDRL - Venereal Disease Research Laboratory
- VLDL - Very Low-Density Lipoprotein

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