स्वास्थ्य एवं
परिवार कल्याण मंत्रालय
MINISTRY OF
HEALTH AND
FAMILY WELFARE

सत्यमेव जयते

NATIONAL HEALTH MISSION
राष्ट्रीय स्वास्थ्य मिशन

OPERATIONAL GUIDELINES FOR
STRENGTHENING LABORATORY SERVICES
UNDER
FREE DIAGNOSTIC SERVICES INITIATIVE

Ministry of Health & Family Welfare
Government of India

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STRENGTHENING LABORATORY SERVICES
UNDER
FREE DIAGNOSTIC SERVICES INITIATIVE

पुण्य सलिला श्रीवास्तव, भा.प्र.से.
सचिव
PUNYA SALILA SRIVASTAVA, IAS
Secretary

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

MESSAGE

Diagnostics serve a key role in improving health & quality of life. Equitable, accessible, affordable and appropriate use of good quality diagnostics are integral to quality health care.

2. This operational guidance document is designed to support States/UTs in effectively implementing the revised Free Diagnostic Service Guidelines released in 2019. It places strong emphasis on establishing and strengthening the laboratory sample transport system, monitoring mechanisms, quality assurance protocols, laboratory safety, and rational diagnostic testing across the country. These interventions are intended to reduce out-of-pocket expenditure for patients, minimize delays in diagnosis, and enhance clinical decision-making at all levels of care. For health leaders, providers, and policymakers committed to advancing equitable access and improving population health outcomes, these guidelines offer a crucial roadmap for action.

3. I commend all stakeholders involved in the development of these guidelines and urge all States/UTs to effectively leverage this operational framework to move closer to the shared vision of universal access to free, high-quality diagnostic services across the country.

Punya Salila

Date : 25.11.2025
Place: New Delhi

(Punya Salila Srivastava)

#StopObesity
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Additional Secretary & Mission Director (NHM)

सत्यमेव जयते

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MESSAGE

Availability of quality and free diagnostic services at public health facilities is a cornerstone of reducing Out-of-Pocket Expenditure (OOPE) and advancing the vision of Universal Health Coverage (UHC), as outlined in the National Health Policy (NHP) 2017. In line with this mandate, the Ministry of Health & Family Welfare (MoHFW), Government of India, launched the *Free Diagnostics Service Initiative (FDSI)* under the National Health Mission (NHM) in July 2015. The initiative was conceptualized to ensure that essential diagnostic services are made available to all beneficiaries at no cost.

Building on the progress achieved, the Ministry, in 2019, recommended a significant expansion of the diagnostic test-menu offered at public health facilities. The objective was to further strengthen access to timely, affordable, and high-quality diagnostics particularly at peripheral health centres so that communities can receive the care they need closer to their homes, ultimately contributing to a substantial reduction in OOPE.

The newly developed *Operational Guidelines* present a comprehensive overview of key learnings emerging from States and Union Territories, capturing the enablers that facilitated effective implementation as well as barriers that constrained progress. The document emphasizes the importance of rational diagnostic prescription, cautioning against over-testing and underscoring the need for clinical appropriateness in ordering investigations.

In addition, the guidelines detail the standard essential laboratory equipment required for public health laboratories and provide a consolidated list of approved equipment kits for various cadres including Medical Officers, Community Health Officers, Auxiliary Nurse Midwives (ANMs), and ASHA workers approved by MoHFW. These standardized kits are designed to strengthen diagnostic capacity across all levels of the health system.

I hope that the States/UTs will be able to use this guideline effectively and provide accessible and affordable diagnostics to the last mile.

Dated: 20th Nov, 2025

(Aradhana Patnaik)

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सत्यमेव जयते

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FOREWORD

Access to quality diagnostic services is fundamental to achieving improved health outcomes and ensuring timely, accurate clinical decision-making. Recognizing this, the *Free Diagnostic Services Initiative (FDSI)* was launched to bridge existing equity gaps and provide free-of-cost, reliable diagnostic services across public health facilities. By expanding access to essential diagnostics, the initiative plays a pivotal role in reducing Out-of-Pocket Expenditure (OOPE) for individuals and families, while simultaneously strengthening the public health system.

The *Operational Guidelines for Strengthening Laboratory Services* seek to address the systemic and operational gaps that hinder the availability of comprehensive diagnostic services. The guidelines outline a robust framework for establishing an efficient and scalable laboratory network, anchored in a 'Hub & Spoke' model. This model leverages an organized sample transportation system to enable optimal resource utilization, minimize duplication of infrastructure, and ensure that even remote communities have access to high-quality diagnostic testing.

Beyond detailing the diagnostic services required at various tiers of public health facilities, the document offers a holistic perspective on strengthening the diagnostic ecosystem. It includes recommended test for non-communicable disease screening, protocols for quality control and external quality assurance, and guidance on promoting rational diagnostic practices. The guidelines also provide curated lists of high-volume diagnostics that should be developed as in-house capacities within the public system, along with low-volume or specialized tests that may be efficiently outsourced through Public–Private Partnership (PPP) arrangements.

I am confident that this document will serve as a valuable reference for States/UTs to strengthen diagnostic services and contribute meaningfully to India's journey toward Universal Health Coverage.

(Saurabh Jain)

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Ministry of Health and Family Welfare
Government of India

MESSAGE

Accessible and affordable diagnostic services are the cornerstone of effective healthcare delivery, enabling timely and accurate diagnosis. Ministry of Health and Family Welfare, Government of India, had launched the National Free Diagnostic Services Initiative (FDSI) under the National Health Mission in 2015 and later a revised version in 2019 with an expanded basket of test menu.

This 'Operational Guideline' provides a comprehensive framework to support States/UTs in implementing the 'Free Diagnostic Services initiative' effectively. The guidelines also outline monitoring mechanism, quality assurance protocol, lab safety and rational diagnostic testing for early diagnosis and improved clinical decision making.

The operational guideline focusses on the implementation of the revised guidelines released in 2019 with the objective to establish and strengthen the lab sample transport system in the country for further reduction of out-of-pocket expenditure borne by the patient.

I am sure that the operational guidelines will help States/UTs to strengthen the lab processes effectively and establish sample transport system, thus achieve excellence in laboratory services at all level of healthcare.

Date 24th November 2025

Dr. (Prof) Pragya Sharma

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LIST OF ABBREVIATIONS

AAM-SCs	Ayushman Aarogya Mandirs - Sub-Health Centres
AAM-PHCs	Ayushman Aarogya Mandirs – Primary Health Centres
BPHL	Block Public Health Laboratories
BPHUs	Block Public Health Units
CGHS	Central Government Health Scheme
EQAS	External Quality Assurance Scheme
FEFO system	First-To-Expire, First-Out System
FIFO system	First-In, First-Out System
FRUs	First Referral Units
HA	Hospital Administrator
HIS	Hospital Information System
IPHL	Integrated Public Health Laboratory
IQAS	Internal Quality Assurance
IQC	Internal Quality Control Scheme
IRL	Intermediate Level Reference Laboratories
ISO	International Organization for Standardization
LIMS	Laboratory Information Management System
LJ charts	Levey-Jennings Chart
NCDC	National Centre for Disease Control
NCDs	Non-Communicable Diseases
NEDL	National Essential Diagnostics List
NQAS	National Quality Assurance Standards

NRL	National Reference Laboratories
OEM	Original Equipment Manufacturer
OOPE	Out-Of-Pocket Expenditure
PDCA	Plan-Do-Check-Act
PMSMA	Pradhan Mantri Surakshit Matritva Abhiyan
POCT	Point-Of-Care Test
RDTs	Rapid Test Kits
SDI	Standard Deviation Index
SLA	Service-Level Agreement
SRL	State Level Reference Laboratories
STGs	Standard Treatment Guidelines
STS	Special Transport Service
WHO	World Health Organization

Chapter 01

Introduction

Diagnostics are an essential pillar of the healthcare system, enabling timely and accurate clinical decision-making across prevention, screening, diagnosis, treatment, and disease management. The use of reliable diagnostic tests ensures appropriate case management, reduces complications, and improves health outcomes. However, despite their critical role, access to quality diagnostic services remains a challenge in achieving universal healthcare coverage.

The importance of quality laboratory services is indisputable. Laboratory services support clinical practice by providing information for differential diagnosis, for clinicians to choose appropriate treatment regimens, and for monitoring treatment. Monitoring tests enable clinicians to determine whether treatment is efficacious or adversely affecting the patient, allowing them to take appropriate action. In public health, laboratory tests are necessary to identify the causal agent of an epidemic; early identification of the causative agent and provide rapid treatment and containment of the disease to prevent further spread.

Figure 1. Public Health Laboratory

Out-of-pocket expenditure (OOPE) on diagnostics has emerged as a significant burden to the patients, often exceeding the cost of medications. This disproportionately affects economically disadvantaged populations, many of whom rely on public healthcare facilities where diagnostic services are often unavailable, under-equipped, or under-resourced. Factors such as shortage of trained personnel, inadequate supply of reagents and consumables, and lack of appropriate diagnostic infrastructure, further

compound the problem.

To address these challenges, the **Ministry of Health and Family Welfare (MoHFW), Government of India,** launched the **National Free Diagnostic Service Initiative (FDSI)** in 2015 and later revised the guidelines in **2019** to accommodate an expanded basket of test menu, appropriate to the level of the health facility after expert consultations.

Anchored in the principles of the National Health Policy 2017, this initiative aims to ensure the availability of essential, high-quality diagnostic services **free of cost** at all levels of public healthcare facilities, from Ayushman Aarogya Mandirs - Sub-Health Centres (AAM-SCs) to District Hospitals. The FDSI guidelines have recommended a **'Hub-and-Spoke mode'** for service delivery and optimal utilisation of the resources available with the States/UTs in the country. States/UTs have adopted FDSI with varying service delivery models like in-house, PPP model or a mixed model.

Under **revised FDSI guidelines-2019,** an expanded basket of diagnostic tests has been defined and scaled. This aligns with the National Essential Diagnostic List (NEDL) developed by ICMR. The details of tests under revised FDSI guideline are as follows:

- **Sub Health Centres:** 14 tests
- **Primary Health Centres (PHCs):** 63 tests
- **Community Health Centres (CHCs):** 97 tests (in addition with X-ray, ECG, and Ultrasound)
- **District Hospitals (DHs):** 134 tests (in addition with CT scan, X-ray, Ultrasound, and ECG)

In modern medicine, diagnostic tests, including laboratory tests, imaging and more invasive procedures, figure prominently in clinical decision making surrounding a new diagnosis. Overuse of diagnostic testing substantially contributes to healthcare expenses and potentially exposes patients to unnecessary harm. Patient satisfaction and outcome is generally based on efficient treatment in hospital-based settings. Overutilization of diagnostic tests have resulted in adverse effects, poor patient satisfaction and incorrect diagnoses.

Ordering the correct test, at an appropriate time, for the right purpose can lower costs, eliminate waste, and enhance patient quality, results, and satisfaction in this era of precision healthcare. The ultimate aim is to create a healthcare landscape where lab orders are performed judiciously so that every test adds measurable value to patient care, resulting in better health outcomes, and is aligned with the principles of cost-effective and patient-centred healthcare delivery.

Despite these efforts, ensuring consistent availability and rational use of diagnostic tests across public health facilities remains a challenge. This necessitates robust planning, infrastructure, skilled human resources, quality assurance mechanisms, and standardization of laboratory services.

This document is intended as a technical resource for program managers, public health administrators, and laboratory professionals working to improve diagnostic access and efficiency under the Free Diagnostic Services Initiative (FDSI) programme.

Chapter 02

FUNCTION AND ORGANIZATION OF LABORATORY SERVICES

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.

Levels of Public health care

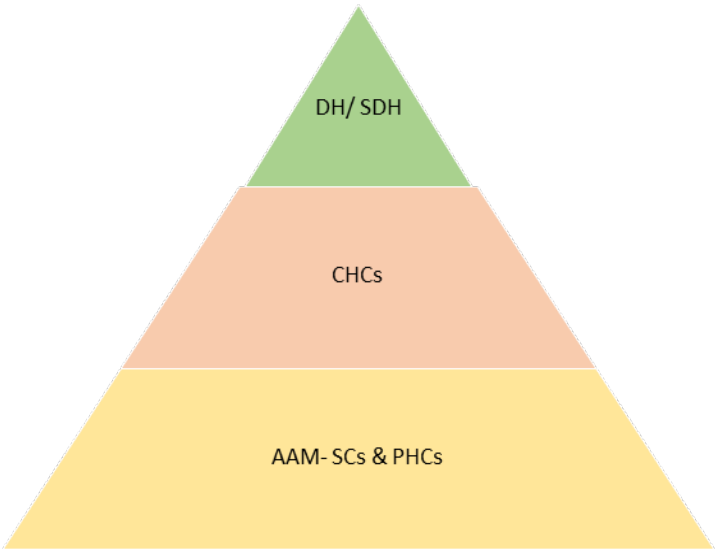


Figure 2. Level of Public Health Care

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 & 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, paediatrics, and obstetrics & Gynaecology, to the population. CHCs serve as referral centres for 4-5 PHCs providing specialised care that PHCs may not be equipped to handle. CHCs have in-patient facility (30 Beds) and are established as per the population norms. CHCs are also called as First Referral Units (FRUs) which is 24 X 7 days operational and non-FRUs which only provide day care facility. The Sub-district hospitals and DHs have more number of Specialists and also 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 referrals from the primary as well as the secondary levels. Tertiary level hospitals are usually District Hospitals converted to Medical college, State Government Medical Colleges, AIIMS, INIs and Super-specialised multi-speciality hospitals etc.

Reference Laboratories, Research Laboratories and Specific Disease Reference Laboratories

Reference Laboratories, Research Laboratories, and Specific Disease Reference 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.

IPHL AND BPHL

India's public health system has undergone significant transformation to strengthen diagnostic services and disease surveillance, particularly through the introduction of Integrated Public Health Laboratories (IPHL) at the district level and Block Public Health Laboratories (BPHL) at the block level under Pradhan Mantri Ayushman Bharat Health Infrastructure Mission (PM-ABHIM). The establishment of IPHLs at district level and Block Public Health Units (BPHUs) at block levels ensures timely diagnosis and effective outbreak response mechanisms. Institutes of National Importance (INIs) like National Institute of Virology (NIV), National Centre for Disease Control (NCDC) and the well-established centres for Infectious Disease Surveillance Units (IDSP) focusses on disease outbreak investigation and improve lab capacity. These institutions aims to better equip the country to tackle public health emergencies in the future.

Role and Function of IPHL

IPHLs are established at district hospitals as comprehensive diagnostic centres, integrating various laboratory services under one roof, including microbiology, hematology, biochemistry, pathology, and molecular biology.

- They serve as hubs for public health surveillance, outbreak investigations, and

provide technical support to block-level laboratories (BPHL) and peripheral facilities.

- IPHLs are equipped to conduct a wide range of tests (134 tests) and are staffed by a multidisciplinary team including lab technicians, microbiologists, biochemists, and pathologists.
- These labs also act as training hubs for peripheral laboratory staff and supervise the implementation of quality management systems

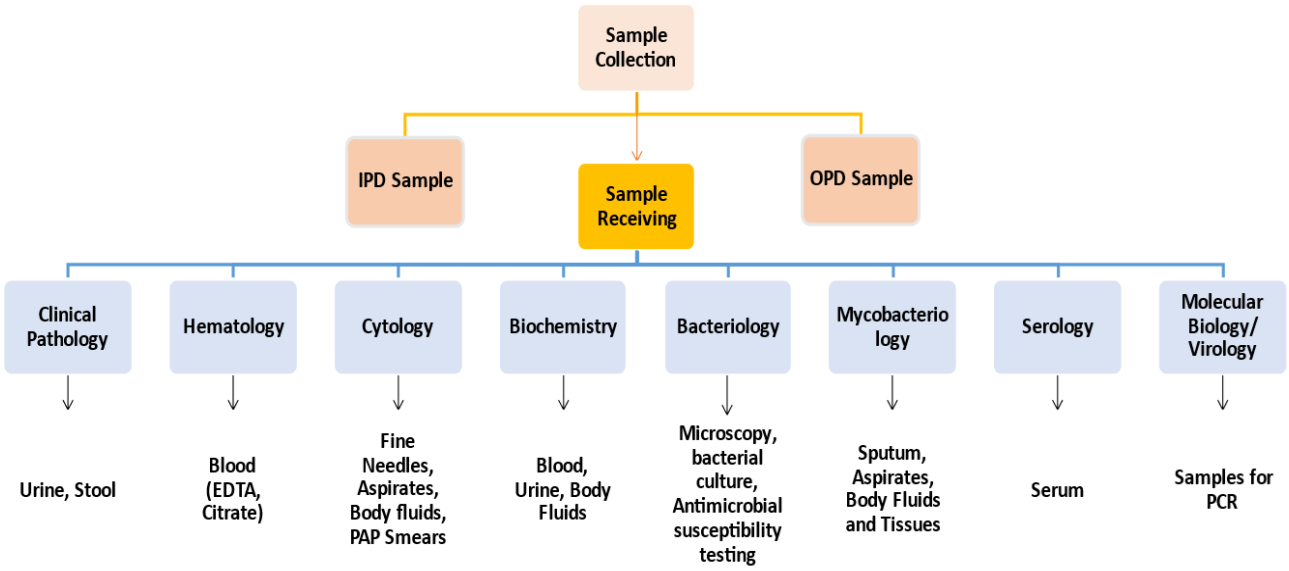


Figure 3. Workflow Diagram in IPHL

Integration and Linkages of IPHL:

- **Downward linkages:** IPHLs follow a hub-and-spoke model, acting as the central hub for BPHLs at the block level and ensuring upward and downward referral linkages for sample testing, technical support, and data integration (Figure 4).
- **Upward linkages:** IPHLs are linked upward with the State and National reference laboratories for specialized testing and surveillance (Figure 5).

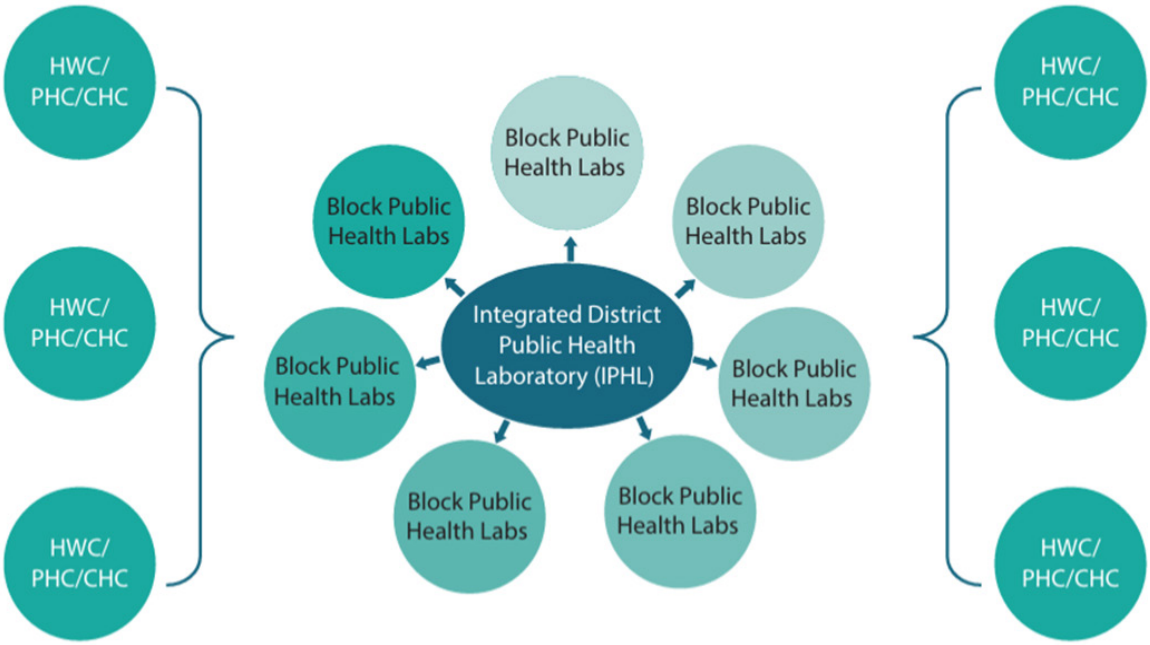


Figure 4. Downward Linkages of IPHL (Hub and Spoke Model)

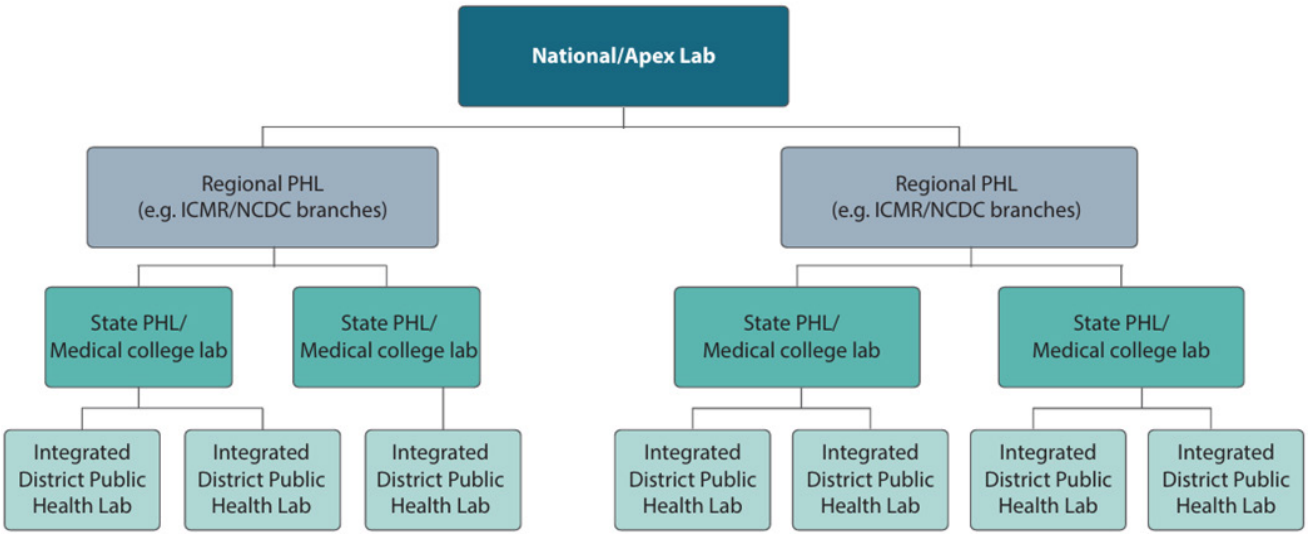


Figure 5. Upward Linkages of IPHL Network

Role and Functions of BPHL

- BPHLs are established at the block level to extend diagnostic services closer to remote and underserved populations.
- They function as referral hubs for peripheral facilities, such as Ayushman Arogya Mandir (AAMs), PHCs, and CHCs (non-hubs), supporting them in sample collection, basic testing, and referral of complex cases to the district IPHL.

- BPHLs are equipped to handle essential diagnostic tests (97 tests) and are linked with IPHLs for more advanced investigations and technical guidance.

Role of Hub Labs (District Hospital/SDH/CHC)

IPHS-2022 has laid down the infrastructural requirements of a DH/SDH/CHC laboratory. The hub labs are expected to have highest level of quality of services for overall patient satisfaction. Treatment of all patients depends to a great extent on the report generated by the Laboratory. The following aspects needs focussed approach:

- Hub lab services play a vital role in diagnosis and instituting correct treatment
- Provide baseline data for further clinical monitoring and follow-up
- Provision of measurable values/criteria for analysis of the reports generated.
- Month end summary of lab results for surveillance and early indications for disease outbreak.
- Develop SOPs for testing services and providing support to the peripheral labs.
- Undertake quality assurance and quality protocols for the tests by subscribing to External Quality Assurance Schemes (EQAS), Internal quality assurance (IQAS) and inter-lab comparisons (ILC)
- Space in the lab should be segregated into sample collection area, pre-analytical (procedure) area, analytical & testing, reagents & consumables storage areas.
- Facility for uninterrupted piped water supply with storage facility, deionised water, electric supply back-up and adequate lighting/ventilation should be ensured.
- Equipment should include autoclaves, balances, binocular microscope (bright field microscope), centrifuges, pH meter, hot air oven, incubators, refrigerator, rotor shaker, micro-pipettes, colorimeters, water bath and other essential equipment as required for analysis of lab samples. The list of medical equipment for IPHL and BPHL is attached as **annexure I.**
- Should maintain electronic record of the tests undertaken for future analysis.

- Equipment in the Lab should be tagged and mapped for linking it with the BEMMP programme post warranty period.
- Should contact the biomedical maintenance team/vendor for equipment calibration, testing, and report all breakdown through the established Toll-Free Number /Complaint management system.
- Should ensure availability of Laboratory Information Management System (LIMS) and all the major diagnostic equipment should be interfaced with the LIMS (e-Hospital / e-Shurust software have the LIMS facility)
- Universal work precautions – Lab technicians should be appropriately equipped with apron, gloves, googles and face masks while undertaking sample collection and during the pre-analytical & analytical stages.
- Biomedical Waste Management particularly sharp management should be ensured as per the guidelines given in BMW handling rules 2016 and subsequent revisions.

Role of Peripheral Labs (Spokes – PHC/CHC)

Peripheral labs are located as the patient's first point of contact with the health system. These laboratories should be equipped with adequate workspace, sample collection area, refrigerator for storing of the collected samples, storage area for lab reagents & consumables, and should have adequate supply of uninterrupted piped water supply with storage facility, electricity and Biomedical waste disposal facilities. The peripheral labs should be equipped with:

- Appropriate lab equipment as per the essential tests recommended by FDSI-2019 guidelines.
- Vacutainers, Urine & sputum collection bottles
- Bar code generator and reader with printer facility.
- Cold Boxes for sample transportation.

Lab Technician and Staffing norms

For effective and well-functioning laboratory, it is essential to have motivated, empowered and trained Lab technicians and Lab Assistants. IPHS 2022 has recommended a total of 11 Lab Technicians at IPHL and 07 Lab technicians at BPHL. However, the requirement of LTs should be based

on the workload and can be calculated by World Health Organisation's WISN (Workload Indicator for Staffing Needs) methodology. (https://iris.who.int/server/api/core/bitstreams/8b880867-a0a8-43e4-83b7-cc35f36809a9/content)

Staffing recommended for IPHL

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

Table 1

Staffing recommended for Block Public Health Lab (BPHL) 30 Bed FRU CHC

Block Public Health Laboratory	
Pathologist/ Microbiologist/ Biochemist	1
Lab Technicians	7
Support Staff	As per need

Table 2

Diagnostic kits for MOs, CHOs, ANMs, AND ASHAs at public health facilities

In healthcare systems, especially at primary healthcare facilities, Medical officers (MO), Community Health Officers (CHO), Auxiliary Nurse Midwives (ANMs), and Accredited Social Health Activists (ASHA) play a crucial role in screening and early diagnosis of diseases. They act as a crucial link between communities and healthcare services.

To support their effort and equip them with proper screening and diagnostic devices, MoHFW has developed a standard set of equipment and Diagnostic kits for MOs, CHOs, ANMs, and ASHA workers suiting the service delivery for 12 CP-CPHC packages. These kits are designed in alignment with the test and equipment listed in IPHS 2022. The details of diagnostic Kits along with D.O. Letter issued by MoHFW is placed as **Annexure II.**

Chapter 03

RESPONSIBLE DIAGNOSTICS

Responsible diagnostics means utilizing diagnostic tests in a thoughtful and evidence-based manner, prioritizing only those tests that are clinically necessary to accurately diagnose a patient's condition, considering cost- effectiveness, and minimizing unnecessary testing within the constraints of available resources in public healthcare settings.

Doctors at Ayushman Aarogya Mandirs play a critical role in diagnosing and managing common ailments such as cough, cold, fever, and diarrhoea. They must carefully assess the patient's signs and symptoms, align them with possible differential diagnoses, and prescribe basic diagnostic tests judiciously. Responsible prescription involves a systematic approach to ensure that diagnostic tests are medically appropriate, and evidence based. This includes selecting tests that confirm or rule out specific conditions while avoiding unnecessary investigations that may lead to false positives, incidental findings, or financial burdens for the patient4.

A lack of standardization and uniform protocols across health facilities often leads to inconsistent diagnostic practices. There is a need to strengthen systems to ensure that diagnostics are guided by standard operating procedures and clinical algorithms that support healthcare workers at all levels. This will help optimize test utilization and ensure equity in access to diagnostics.

For example, in cases of fever with suspected bacterial infections, simple tests like Complete blood count, or urine routine analysis may be prescribed. In case of follow up of diabetes, point-of-care tests such as blood glucose monitoring or HbA1c analysis are commonly utilized to provide rapid and actionable results. At the AAM- SC/PHC level, the focus remains on point-of-care tests, and Rapid Diagnostic Test Kits (RDTs) that are cost-effective and provide rapid results. In contrast, specialists at Community Health Centres (CHCs) and higher facilities can prescribe more advanced diagnostic tests based on their expertise and the complexity of the case4.

This patient-centered approach ensures that diagnostic testing is not only clinically relevant but also aligned with the patient's values and preferences. It minimizes harm while maximizing the benefits of early and accurate diagnosis, forming the cornerstone of effective primary healthcare delivery.

The Antimicrobial Stewardship (AMS) programme and the Antibiotic (AB) policy play a crucial role in reinforcing responsible diagnostic practices at all levels of care. These initiatives aim to curb the growing threat of antimicrobial resistance (AMR), which is often fuelled by the inappropriate use of antibiotics—frequently triggered by unnecessary or misinterpreted diagnostic tests. By encouraging evidence-based diagnostic approaches, the AB policy ensures that antibiotics are prescribed only

when clinically indicated and supported by diagnostic confirmation.

At the AAM-SC and AAM-PHCs level, this translates into the judicious use of point-of-care tests to accurately identify bacterial infections, thereby reducing empirical and indiscriminate antibiotic use. This approach complements the objectives of the Free Diagnostics Service Initiative (FDSI), which focuses on providing cost-effective and clinically relevant diagnostics to guide treatment. Integrating AMR strategies within primary healthcare systems not only strengthens rational therapy but also contributes to better patient outcomes and helps contain resistance development.

Key aspects of rational diagnostic prescription in India:

- **Clinical Need-Based Ordering**: Only ordering tests that are directly relevant to the patient's presenting symptoms and clinical history, avoiding unnecessary "routine" testing.
- **Evidence-Based Guidelines:** Adhering to established national guidelines for diagnostic test selection based on clinical practice and research evidence, including WHO recommendations.
- **Cost-Effectiveness Analysis:** Considering the cost of each diagnostic test relative to its diagnostic yield and clinical impact, prioritizing tests with high value for money.
- **Prioritization of Essential Diagnostics:** Focusing on readily available and affordable basic diagnostic tools for common diseases prevalent in the Indian population.
- **Appropriate Test Interpretation:** Ensuring healthcare providers are adequately trained to interpret test results accurately, considering potential limitations and confounding factors.

Key principles to promote rational diagnostic prescription:

1. Minimum Testing Intervals - Establish and enforce appropriate minimum intervals between repeat testing to prevent unnecessary duplication. This includes:

- Implementing specific waiting periods before repeating common tests (e.g., HbA1c every 3 months for diabetics, lipid profiles every 6 months for stable patients).
- Using ABHA ID for line listing of patients and having automated alerts in Lab Information Management System (LIMS) that flag when a test is being reordered before the recommended interval has passed.
- Setting condition-specific intervals for monitoring tests (e.g., TSH every 6-12 months for stable hypothyroid patients, vitamin D testing if required once a year).
- Developing clear guidelines for appropriate monitoring frequencies based on clinical evidence rather than arbitrary timeframes.

- Requiring prescription with justification for repeated test orders.

2. Strong Clinical Indication Before Ordering Tests - Require specific, documented clinical indications that justify each test ordered, ensuring tests serve a clear diagnostic or management purpose:

- Implementing prescription-based ordering of lab tests for the specific clinical question being addressed by each test.
- Establishing clear criteria for when certain tests are clinically indicated versus when they provide little value.
- Creating decision support tools that prompt providers to document relevant symptoms, signs, or risk factors that justify the test.
- Developing condition-specific testing algorithms that guide appropriate test selection based on clinical presentation.
- Instituting a review process to evaluate whether documented indications meet established criteria for necessity.

3. Targeted testing vs. Panel testing - Order only specific tests needed to answer the clinical question rather than default to comprehensive panels:

- Unbundling comprehensive metabolic panels into smaller, focused test groups
- Creating order sets that encourage selection of individual tests rather than entire panels
- Establishing a “choose tests individually” rather than “order panel” default in ordering systems

4. Need-based Ordering - Ensure all laboratory testing is ordered by qualified clinicians based on clinical assessment:

- Prohibiting self-ordered laboratory testing without appropriate clinical oversight.
- Creating protocols for how to handle patient-requested tests that lack clinical indication
- Developing educational materials explaining the importance of clinician-directed testing
- Setting up consultation pathways for patients seeking specific tests without clear indications

Suggested measures for responsible diagnostic test prescription

In clinical settings, lab tests are ordered by both general practitioners (MBBS doctors) and specialists, with the specific tests ordered depending on the patient’s condition and the doctor’s area of expertise. Doctors and specialists may order a wide range of

tests, including blood tests, urine tests, and imaging scans, to diagnose and monitor various health conditions.

General Practitioners

a) **Routine screenings –** Doctors often order basic blood test like complete blood count (CBC), basic metabolic panels (BMP) and lipid panels to assess overall health, screened for common conditions like diabetes and heart disease, and monitor treatment effectiveness.

b) **Initial Diagnosis –** For symptoms or conditions that are not immediately clear, doctors may order a variety of tests to help narrow down the diagnosis, such as Liver Function Tests, Thyroid Function tests, or tests for Sexually transmitted infections.

c) **Monitoring treatment –** Doctors may order follow-up tests to track the progress of a patient treatment or monitor for any potential side effects.

Specialists

a) **Targeted Testing –** Specialist such as Cardiologist, Endocrinologist, or Neurologist order tests specific to their area of expertise.

b) **Advanced Diagnostics –** They may utilise more specialised imaging like MRI or Echocardiograms to assess heart function or detect neurological issues.

c) **Specialised blood tests –** Specialist may order specific blood tests to further evaluate a condition, such as cardiac biomarkers for heart ailments or specialised antibody tests for auto-immune conditions.

MoHFW has approved training guidelines (Emergency Module) for Medical Officers in Ayushman Bharat Ayushman Aarogya Mandirs (AAM-SHCs & AAM-PHCs)[5]. Emergency care services are defined as acute medical/ surgical/ trauma care that is delivered within the first few hours of the onset of a condition which threatens the life or well-being of a patient5. The patient's level of consciousness is first assessed using the AVPU (Alert, Verbal, Pain and Unresponsive) method, followed by the ABCDE (Airway, Breathing, Circulation, Disability and Exposure) approach and the appropriate management is initiated accordingly.

States/UTs are advised to prepare SOPs based on Standard Treatment Guidelines (STGs) approved by MoHFW for the specific diagnostic protocol for emergency cases including comatose patients. The basic vital functions, routine clinical diagnostic tests (CBC & Urine RE/ME & RBS) should be the first line of tests ordered. Specialised tests can be ordered after consultation with the specialist available at the CHC/DH level. X-Ray & USG scan should be preferred before prescribing CT/MRI as discussed above.

Timely and appropriate diagnostic testing in emergencies enables early diagnosis, helps prevent complications, reduces morbidity and mortality, and supports optimal patient

outcomes. Therefore, integrating well-equipped laboratories, point-of-care testing (POCT), and streamlined sample collection processes into emergency departments is vital for efficient emergency care delivery.

Monitoring indicator for over-testing

Monitoring indicators for over-testing are crucial to ensure the rational and judicious use of diagnostic services across public health facilities. Excessive testing not only leads to unnecessary healthcare expenditure and strain on laboratory resources but also poses potential clinical risks such as false positives and patient anxiety. To assess over-testing, a simple yet informative indicator is used.

The **Patient to Test Ratio** evaluates the intensity of diagnostic test utilization within a healthcare facility. It is calculated by dividing the total number of laboratory tests conducted (OPD + IPD) in a given period by the total number of patients (OPD + IPD) who visited the facility during the same period. This ratio reflects the average number of tests conducted per patient and is useful in identifying trends of under- or over-testing. A higher-than-expected ratio may indicate potential over-testing, while a lower ratio might suggest under-utilization of diagnostics.

Based on HMIS data, the national average value is approximately 2 tests per patient. This figure serves as an indicative norm for assessing Patient to test ratio across

$$\textbf{PATIENT TO TEST RATIO} = \frac{\text{Average number of lab tests undertaken (OPD +IPD) in a lab per month}}{\text{Average number of total footfall (OPD +IPD) in a month}}$$

(Source: HMIS portal)

Figure 6. Formula for calculating patient to tests ratio

different facility levels. However, the patient to test ratio depend on various factors like local disease prevalence, case load, disease outbreaks, community perception etc.

Chapter 04

IN-HOUSE VS OUTSOURCE LABORATORY TESTS

Free Diagnostics Services Initiative – 2019 has recommended minimum number of tests that should be available at various levels of healthcare facilities, including – Ayushman Aarogya Mandir – Sub Health Centres (AAM-SCs) & Primary Health Centres (AAM-PHCs), Community Health Centres (CHC), Subdistrict Hospital (SDH), and District Hospital (DH).

Facility Level	AAM-SC	AAM-PHC	CHC/ BPHL	SDH	DH/ IPHL
Recommended No. of Lab tests	14	63	97	111	134

Table 3. Recommended number of tests at each level of heath care facility

The service delivery recommended in FDSI guideline 2019 is through 'Hub & Spoke' model and States have adopted the service delivery either through in-house or PPP models. Few States have also adopted mixed models (Hybrid mode) wherein, the high volume - low-cost tests are undertaken through in-house mode and selective low volume- high-cost tests are outsourced to the PPP service provider.

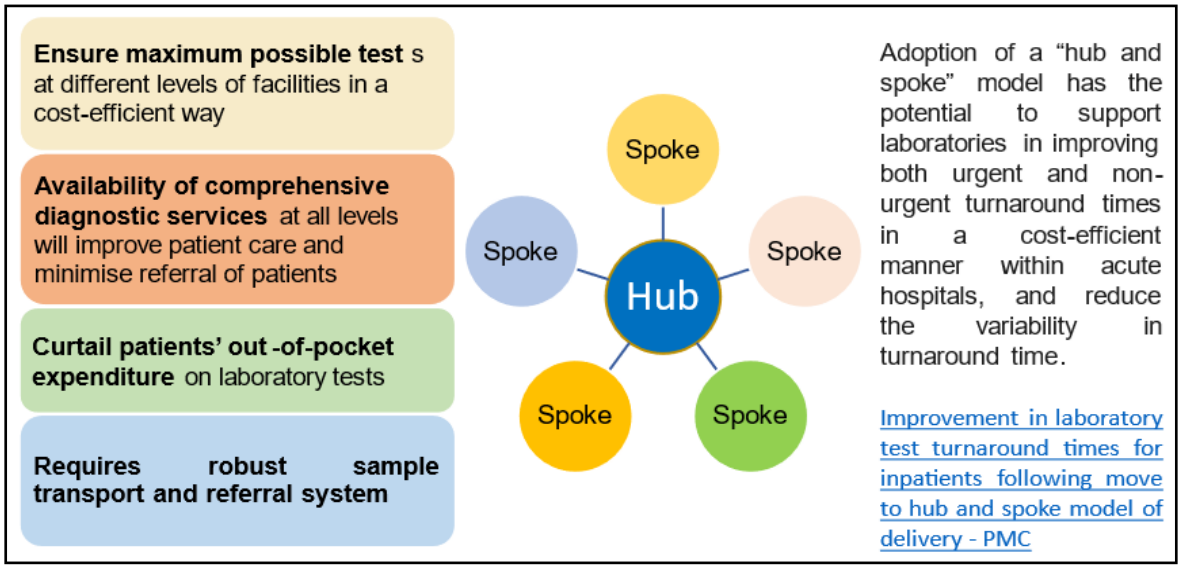


Figure 7. Hub and Spoke Model

The PPP model of service delivery is based on percentage discount over the CGHS rate list and service provider identified through a tender process, where the PPP service provider offers the maximum discount. Another model of service delivery being a negotiated amount for a package of tests, at each level of healthcare facility (Per sample model). This model is often found to promote over-testing and is not cost-effective as the tests included in the package may not be required by the patients every time.

Few States/UTs have successfully managed to get a bundled contract (Rental – reagent model) involving provision of high-end lab equipment, with reagents, controls & consumables along with preventive maintenance & calibration by the OEM. This model though costly but ensures uninterrupted supply of reagents/consumables for the equipment and its periodic maintenance & calibration.

Analysis of the available service delivery models, the in-house model with a curated package of tests (High Costs – low volume) is the most cost-effective model and is recommended for the states for adoption.

IN-HOUSE	
ADVANTAGES	**CHALLENGES**
Facility-based availability of in-house resources	Trained HR availability
Ownership & sustainable model	Absence/retention issues
Optimal utilization of HR	Periodic training & Skill building
Quality control	Equipment maintenance
Effective monitoring	Supply chain of reagents & consumables
Cost-effective savings	
Disaster preparedness	

OUTSOURCE (PPP) MODEL	
ADVANTAGES	**CHALLENGES**
Accessibility	Monitoring issues
Easy to scale	Non-adherence to SLA & MoU
Trained Manpower	Low quality of service delivery
Low absenteeism	Costly as compared to in-house model
Sample collection, transport & reporting	Denial of services in case of legal issues
Negotiable	On ground disparity

Table 4. In-house Vs Outsourcing Model of diagnostics

The low volume-high-cost tests recommended for outsourcing to PPP service provider for effective resource utilisation is as follows. The tests listed below is often not prescribed so frequently and is usually done in a higher tertiary care centre/DH. States can constitute an expert committee and have their own bouquet of tests specific to the local context.

'Hub & Spoke' model requires a well-established sample transport mechanism for transporting lab samples for the tests ordered by MOs from lower health facilities to higher level of health care facilities (CHC/SDH/DH) where the appropriate lab equipment is available. A list of appropriate technical specifications for the major diagnostic equipment is listed in Annexure III.

Few States have successfully established in-house sample transport mechanism,

wherein the already established mechanism for transport of TB samples is utilised by providing incentive to the TB Runner. Other States have engaged front line healthcare workers (STS, HA, and volunteers from Self Help Groups) for transporting lab samples with an incentive ranging from INR 5 - INR 10 per Km. A suggested list of essential tests at the facility and recommended test for sample transportation is listed in Annexure IV. The guideline for sample transportation as recommended in clinical establishment act should be followed while implementing sample transport system. https://clinicalestablishments.mohfw.gov.in/sites/default/files/2025-09/Draft%20Minimum%20standards%20sample%20collection%20and%20transport%20policy%2029-8-25.pdf

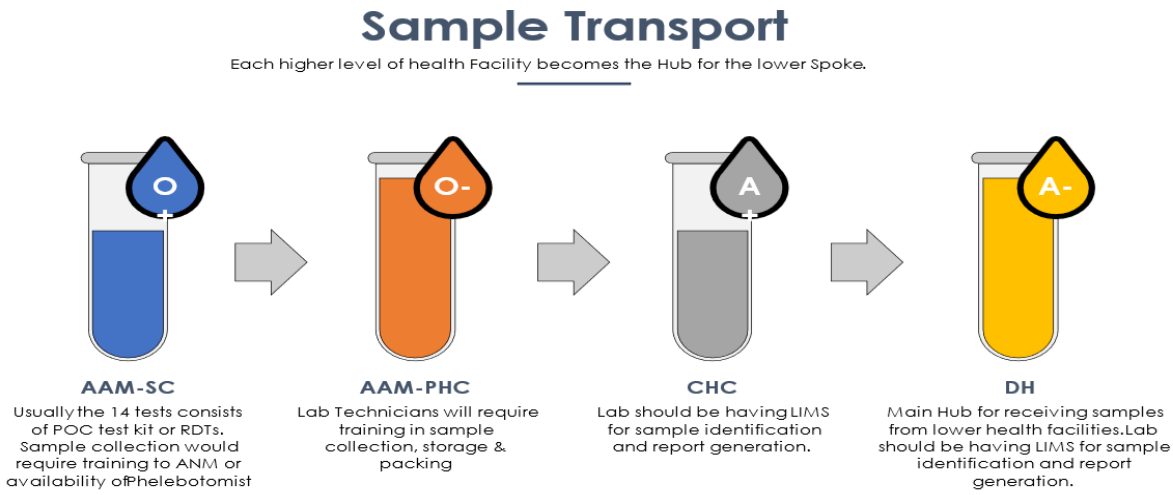


Figure 8. Requisite for Sample transport

Usually high cost & low volume tests may be outsourced as per the state specific expert committee suggestion for a hybrid model of service delivery. Tests for viral markers, serology, endocrinology (Hormones), histopathology, cancer markers, etc which are not done at the facility, can be outsourced to the PPP service provider on a discounted rate over the CGHS notified rate list.

HIGH VOLUME- LOW COST TESTS THROUGH IN-HOUSE MODE AND LOW VOLUME-HIGH COST TESTS THROUGH PPP MODE

Tests recommended through In-house capacity:

HIGH-VOLUME & LOW-COST TESTS – RECOMMENDED FOR IN-HOUSE TESTING (97 TEST)

Fully Automated Biochemistry Analyser
Blood sugar,
24-hours urinary protein,
Glucose Tolerance test (GTT),
S. Bilirubin (T),
S. Bilirubin direct and indirect,
Serum creatinine,
Blood Urea, SGPT, SGOT, S. Alkaline Phosphatase,
S. Total Protein,
S. Albumin & AG ratio,
S. Globulin,
S. Total Cholesterol,
S. Triglycerides,
S. VLDL, S. HDL,
S. LDL, S. GGT,
S. Uric acid, S. Amylase, S. Iron,
S. Total Iron binding capacity, S. LDH,
Glycosylated haemoglobin (HbA1C), S. Calcium,
Fluid analysis (Cell count, biochemistry including Glucose, Protein, LDH)

Blood gas analyser
Arterial Blood gas test

Electrolyte Analyser
S. Sodium
S. Potassium
S. Ionised Calcium
S. Chloride
S.Magnesium

Haematology analyser (5-part)
Haemoglobin,
Total leucocyte count,
Differential leucocyte count,
Platelet count,
Complete blood count,
CSF analysis (Glucose, CSF protein, ADA, cell count)

ESR Analsyer
Erythrocyte sedimentation rate

Automated Coagulation analyser
Prothrombin Time (PT) and INR,
Activated partial thromboplastin time,
Mixing stand and Factor VIII Assay for Hemophilia

HPLC
Glycosylated haemoglobin (HbA1C),
Haemoglobin electrophoresis

Microscopy
Peripheral blood film,
Malaria (MP Slide),
Urine Microscopy,
Stool for ova and cyst,
Semen analysis,
Sputum, pus etc. for AFB, Smear for Leprosy,
Gram staining for clinical specimen,
Throat swab for Diphtheria

Turbidometer
RA factor (Quantitative),
Urine for microalbumin,
CRP (including newborn) (Quantitative)

Elisa Machine
Test for Dengue,
JE IgM - Blood, CSF (confirmatory),
Scrub typhus Test*,
Test for Leptospirosis*,
Test for Chikungunya,
IgM for Measles,IgM for Hepatitis A,
IgM for Hepatitis E

NAAT Machine
NAAT Machine for TB
Early Infant Diagnostic test for HIV - Qualitative HIV-1 DNA PCR (ICTC),
Quantitative virological nucleic acid test for HIV

Sickle cell test rapid for screening of
Sickle cell anaemia*,HCG Kit test,
Urine Dipstick Test,
RPR/VDRL test for syphilis,
Hepatitis B surface antigen test,
HCV Antibody Test (Anti HCV),
Test for Dengue,
Typhoid test (IgM),
rK39 for Kala Azar*,
Test for drug overdose (Card Test),
Blood group and Rh typing,
Blood cross matching,
Reticulocyte count,
Absolute eosinophil count,
Bleeding time and clotting time,
Fibrinogen degradation products (FDP),
D-Dimer,
Coombs test direct with titre,
Coombs test indirect with titre
Sickling Test for screening of Sickle cell anaemia*,
NESTROFT Test for screening of Thalassemia*,
DCIP test for screening HbE hemoglobinopathy*,
Stool for Occult Blood
Visual Inspection Acetic Acid (VIA)
Stool for Hanging Drop (Vibrio Cholera)
Blood, Urine and Other Cultures
Mycobacterial Culture and DST.

Suggested List of test for Outsourcing :

LOW VOLUME - HIGH COST TESTS – RECOMMENDED FOR OUTSOURCING (37 Tests)

Chemiluminescence analyser
HIV test (Antibodies 1 and 2
Hepatitis B surface antigen test,
IgM antibody to hepatitis B core antigen,
HCV Antibody Test (Anti HCV)
S.TSH (including for new-born screening)
S. Free T3,
S. Free T4
S. Ferritin,
S. Beta HCG,
Prolactin,
S. Anti-Mullerian hormone (AMH)
S. Alfa Feto protein

S.CA-125, S. CEA
S. Procalcitonin
S. PSA
S. Vitamin B12, S. Vitamin D
TORCH IgM and IgG
S. Thyroid peroxidase antibody
Anti-cyclic citrullinated peptide (anti-CCP)

Flow Cytometer
CD4 count

PCR
Viral load count for HCV
Viral load count for HBV

Automated Organism Identification Bacterial identification and Antimicrobial sensitivity system
Mycobacterial culture and DST,
Organism identification and antimicrobial sensitivity for cultures

Flurometer
Quantitative test for G6PD enzyme deficiency

Electrophoresis machine
Haemoglobin electrophoresis,
Protein electrophoresis

Immunofluorescent microscopy
Anti-nuclear antibody (ANA)

Virology
Viral Load Count for HCV,
Viral Load Count for HBV,
HIV- Early Infant Diagnostic
Quantitative Virological Nucleic Acid Test for HIV

Cytology
Pap Smear
Histopathology
Immunohistochemistry
Bone Marrow Examination

Chapter 05

CLASSIFICATION OF LABORATORY COMMODITIES

To effectively design and manage laboratory logistics systems, it is essential to classify laboratory commodities in a systematic manner. Given the vast number of items involved, such classification helps streamline decision-making in supply chain management.

Reagents and controls

Laboratory commodities can be broadly grouped into three categories:

- **Reagents:** These are chemical or biological substances used in laboratory tests to detect or quantify an analyte (the substance being measured). Reagents differ significantly in terms of cost, shelf life, storage requirements (such as cold or cool chain), availability, and associated hazards.
- **Consumables:** These are single-use items required during testing and are discarded after use. They include both **test-specific consumables** (e.g., microscope slides and cover slips) and **general laboratory consumables** (e.g., bleach, alcohol, gloves) that are used across various tests.
- **Equipment specific Controls:** Laboratory controls are equipment specific and are measures that are put in place to eliminate the risk of non-conforming outcomes. It ensures the accuracy, reliability and timeliness of lab results by minimising the equipment measurement errors. Controls should be stored in cool place (Refrigerator) as per the manufacturer's recommendation.

IT platform like DVDMS has a diagnostic module where the stock state of the reagents and consumables can be maintained. Indenting of the reagents and consumables should be done on a monthly basis (Cyclical indents) rather than as and when the stocks are depleted. A reserve stock of minimum 2 months should be held at the health facility, to avoid stock outs and denial of services.

Storage

For laboratory commodities that require a cold chain, must be maintained like Syphilis RDT Kit, HIV tests kits, haematology controls, biochemistry controls, coagulation reagents, VDRL test kits etc, which should be stored in a refrigerator between prescribed temperature. Cold storage is critical for maintaining the shelf life of certain products, and if they are removed from cold storage and not used immediately, they can be irrevocably damaged. All cold storage units should have a continuous temperature

monitoring device and uninterrupted electricity.

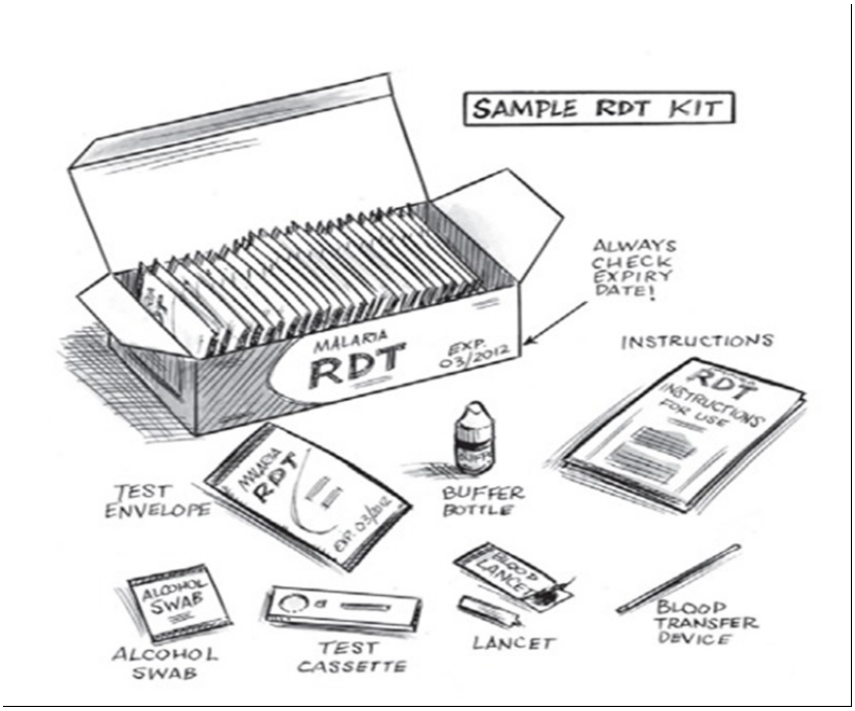


Figure 9. RDTs/ consumables for storage

Flammable substances such as gasoline, ethanol, acetone should be stored separately and in small quantities from other commodities and should be kept in in a well-ventilated area, away from open flames and electrical appliances, and marked with the hazard symbol.

The reagents and especially Rapid Diagnostic test Kits should be checked and stored in the order of first-to-expire, first-out (FEFO) system. All lab commodities should be labeled and stored in freezers as per manufacturer's storage instructions. In case of RDTs and commodities gets damaged, discrepancy report must be raised, and usage of damaged RDTs should be prohibited.

The length of the supply pipeline should accommodate the shelf life of products. A pipeline with fewer levels and shorter review periods is best for reagents and consumables with short shelf lives, as it allows for less stock to be held and more frequent turnover.

Shelf life

Laboratory commodities, particularly certain control agents, have very short shelf lives. The lab should ensure First-in, First-out (FIFO) system for the stock management to minimise the risk of items expiring before use. Storage conditions like temperature, humidity, and exposure to light can significantly impact the shelf life and quality of lab commodities.

Categorization of laboratory equipment

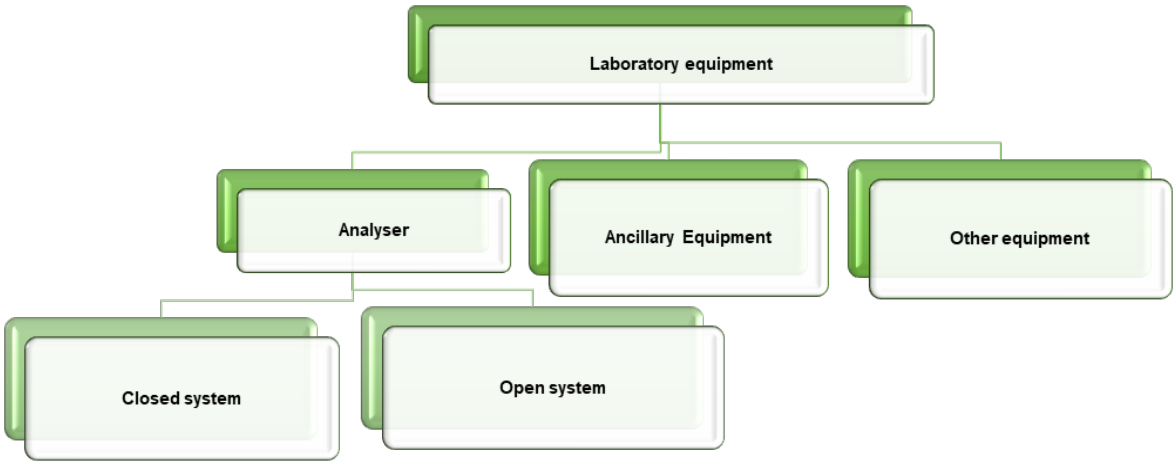


Figure 10. Category of laboratory equipment

Laboratory equipment can be classified into:

- **Analyzers:** These are core instruments that use consumables and reagents to perform specific diagnostic tests and analyses, often requiring service contracts for repairs and maintenance.
- **Ancillary Equipment:** These provides support and assistance to the analytical process. Includes freezers, washers, incubators, and readers, usually serviced by local biomedical engineers.
- **Other Equipment:** Includes biosafety cabinets, autoclaves, and water purification systems that may require infrastructure modifications, installation validation, and annual certifications.

Lab technicians should be adequately trained on conducting tests running controls, corrective and preventive actions required for managing out of range results by multi-skilling and on-job training for handling the analysers and its interpretation. State training programmes involving a Pathologist is recommended for capacity building and multi-skilling of the existing Lab technicians.

Open vs. Closed Systems

Product Selection is an important consideration for achieving cost-effective solution to support the goal of the program. While procuring lab commodities, particularly in the selection of diagnostic equipment it is important to know whether the instrument is a part of a closed or open system. Closed system are laboratory instruments that require specific brands of reagents, while open system do not. Closed system may create a dependence on a single source of supply, but they often ensure a higher level of reagent quality. Generally, in the Indian market, most of the high-end analysers are closed systems.

Open System allow reagents from different manufacturers but require validation by the end user before testing can commence. For e.g. Semi-automated biochemistry analyser, Optical emission spectrometers, spectrophotometers, chromatography machine (HPLC) etc. While choosing Open system, the key considerations are inter-operability, data storage and transfer, customisation option, vendor support and training.

Advantages/ disadvantages of open and closed systems:

	Open systems	Closed systems
Advantages	Increased competition for reagents;	Greater control over reagent quality
	Decreased difficulty in obtaining stock	Tighter inventory control may be required
	Reduced commodity diversity – ability to share products across multiple open platforms	
Disadvantages	Potential for lower quality	Reagents are single or sole-sourced
	Potential for greater variability in test results	Increased commodity diversity across the laboratory network
		Required use of vendor specific controls and service providers

Table 5. Advantages/ disadvantages of open and closed systems.

The choice of an open or closed system should be based on state-specific needs, with both systems enhancing efficiency and accuracy when implemented correctly. The high-end diagnostic equipment are generally closed systems and should be procured bundled with CAMC/AMC and supply of the reagents, consumables and controls.

Chapter 06

INVENTORY MANAGEMENT

Efficient inventory management is crucial for the uninterrupted functioning of diagnostic services in public health facilities. The Drug and Vaccine Distribution Management System (DVDMS) developed by the Ministry of Health and Family Welfare (MoHFW), Government of India, provides an integrated IT solution for managing drugs, vaccines, and diagnostic consumables across various levels of the healthcare system. The Diagnostic Module of DVDMS supports real-time tracking and management of diagnostic services, including test availability, equipment, reagents, and consumables.

To use the diagnostic module of the DVDMS platform, user has to map the number of tests undertaken in-house and the number of tests being outsourced. In the second step, the state has to map the reagents and consumables with the tests master and the equipment master.

All Purchase orders (PO) either centralised or decentralised procurement should be uploaded on the DVDMS portal for stock visibility at the facility.

Accessing the Diagnostic Module

To access the Diagnostic Module:

1. Visit the portal: https://dvdms.mohfw.gov.in/
2. Use credentials provided by the administrative authority.

Figure 11. DVDMS central dashboard main page

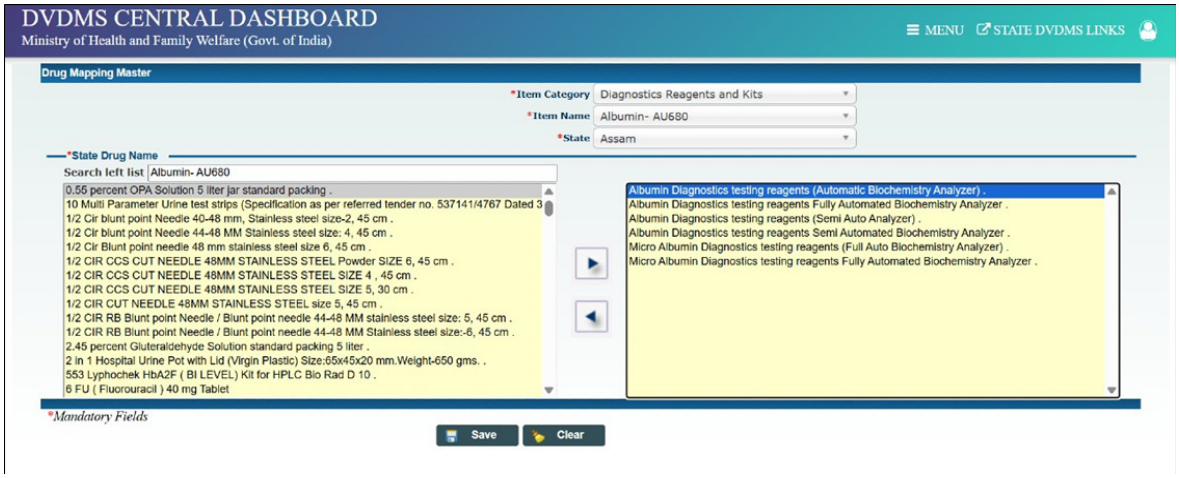


Figure 12. Reagent mapping with the tests master

Diagnostic Detail Dashboard

This dashboard offers a real-time overview of diagnostic service delivery and inventory. Key components include:

- Reagent category
- General category
- Total reagents
- General equipment
- Total equipment
- Total number of test

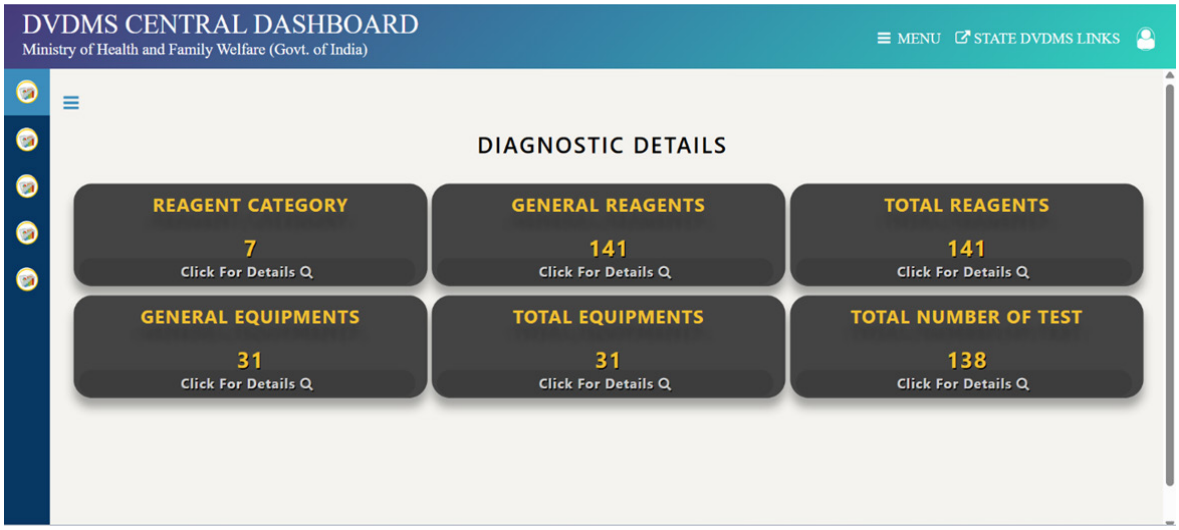


Figure 13. Diagnostic details page

Master Pages in DVDMS – Diagnostic Module

1. Equipment Master

The Equipment Master page is used to map and maintain an updated list of diagnostic equipment available at each facility. This includes:

- Serial number
- Equipment name
- Model and make name
- General equipment name

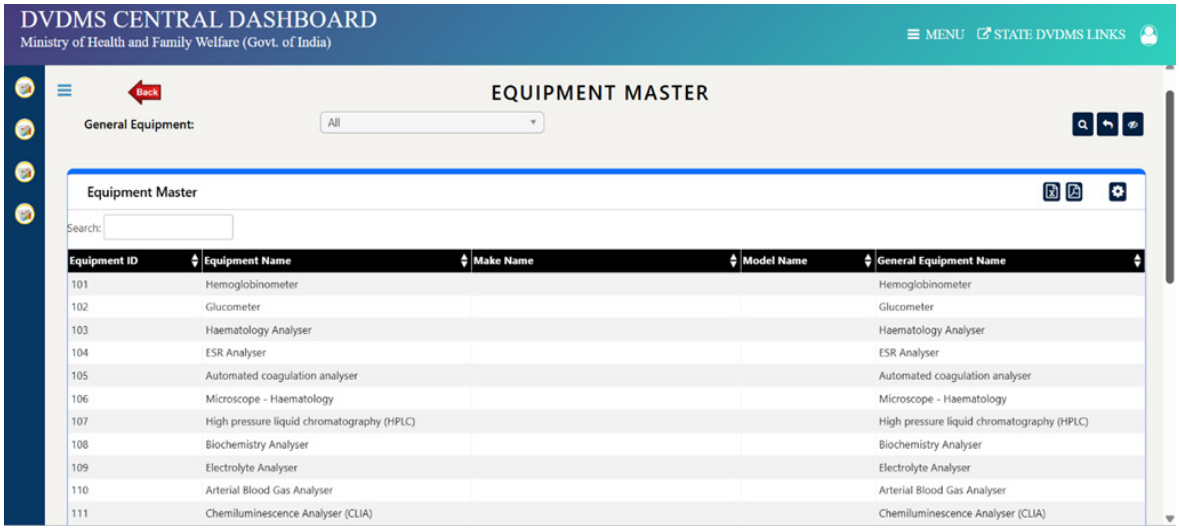


Figure 14. Equipment master page

2. Reagent Master

The Reagent Master manages the inventory of reagents linked with each test. Proper configuration here helps avoid stock-outs and ensures timely procurement.

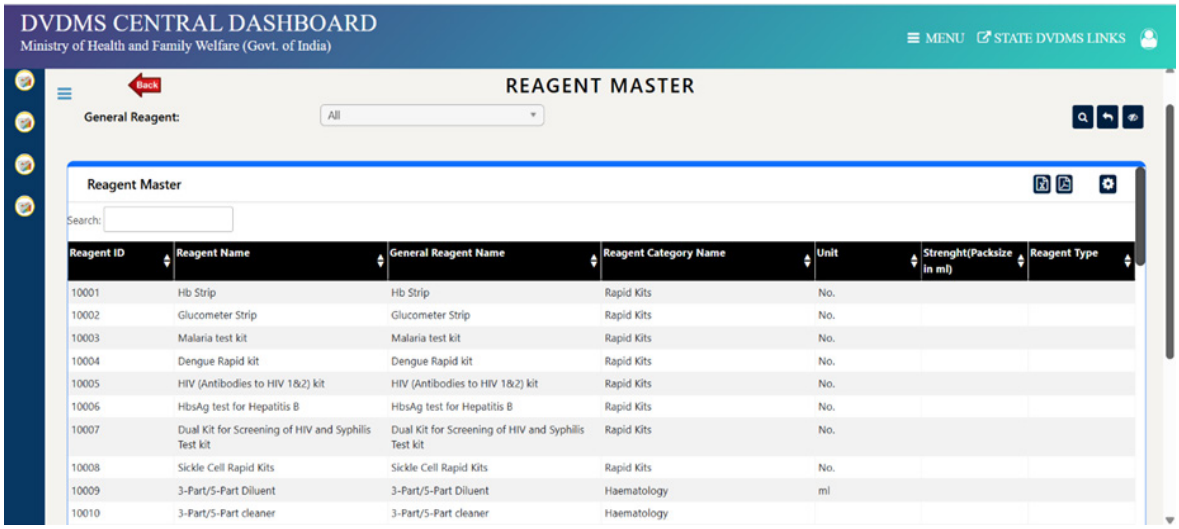


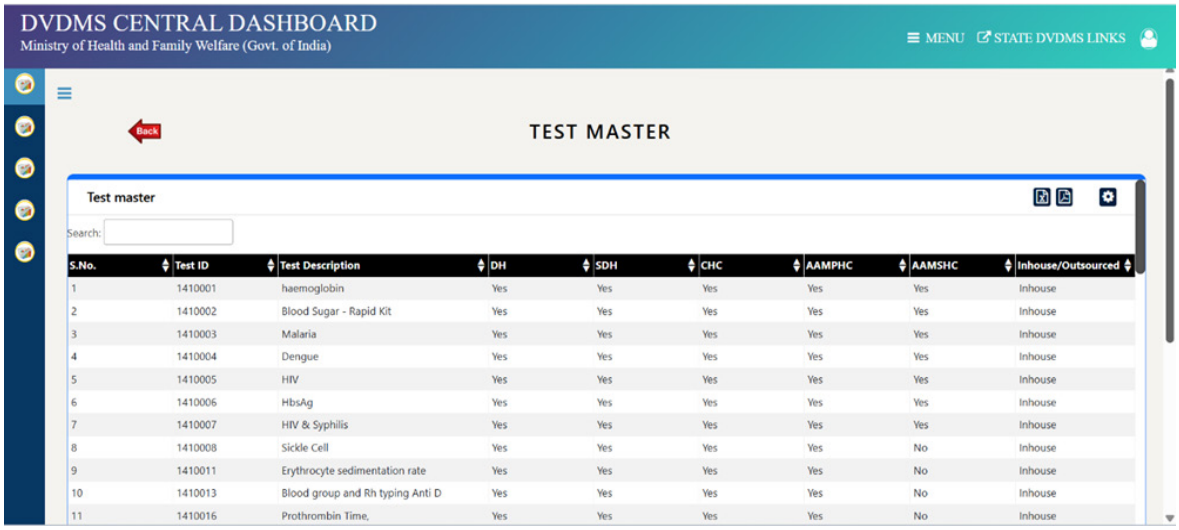
Figure 15. Reagent master page

3. Test Master

The Test Master defines all diagnostic tests offered at various levels of care. This module helps standardize and track:

- Test names and codes
- Applicable levels (PHC, CHC, DH, etc.)
- Test is available inhouse/outsourced

It ensures that every facility can update or modify test availability as per approved package of diagnostic services.



S.No.	Test ID	Test Description	DH	SDH	CHC	AAMPHC	AAMSHC	Inhouse/Outsourced
1	1410001	haemoglobin	Yes	Yes	Yes	Yes	Yes	Inhouse
2	1410002	Blood Sugar - Rapid Kit	Yes	Yes	Yes	Yes	Yes	Inhouse
3	1410003	Malaria	Yes	Yes	Yes	Yes	Yes	Inhouse
4	1410004	Dengue	Yes	Yes	Yes	Yes	Yes	Inhouse
5	1410005	HIV	Yes	Yes	Yes	Yes	Yes	Inhouse
6	1410006	HbsAg	Yes	Yes	Yes	Yes	Yes	Inhouse
7	1410007	HIV & Syphilis	Yes	Yes	Yes	Yes	Yes	Inhouse
8	1410008	Sickle Cell	Yes	Yes	Yes	Yes	No	Inhouse
9	1410011	Erythrocyte sedimentation rate	Yes	Yes	Yes	Yes	No	Inhouse
10	1410013	Blood group and Rh typing Anti D	Yes	Yes	Yes	Yes	No	Inhouse
11	1410016	Prothrombin Time,	Yes	Yes	Yes	Yes	No	Inhouse

Figure 16. Test master page

Test Availability 2.0

The Test Availability 2.0 module enhances visibility of state-wise test availability across public health facilities. Features include:

- Facility-wise test mapping
- Number of tests available in house
- Number of tests outsourced
- Number of tests available at facility

This tool is particularly useful for monitoring diagnostic service readiness under the Free Diagnostics Service Initiative (FDSI).

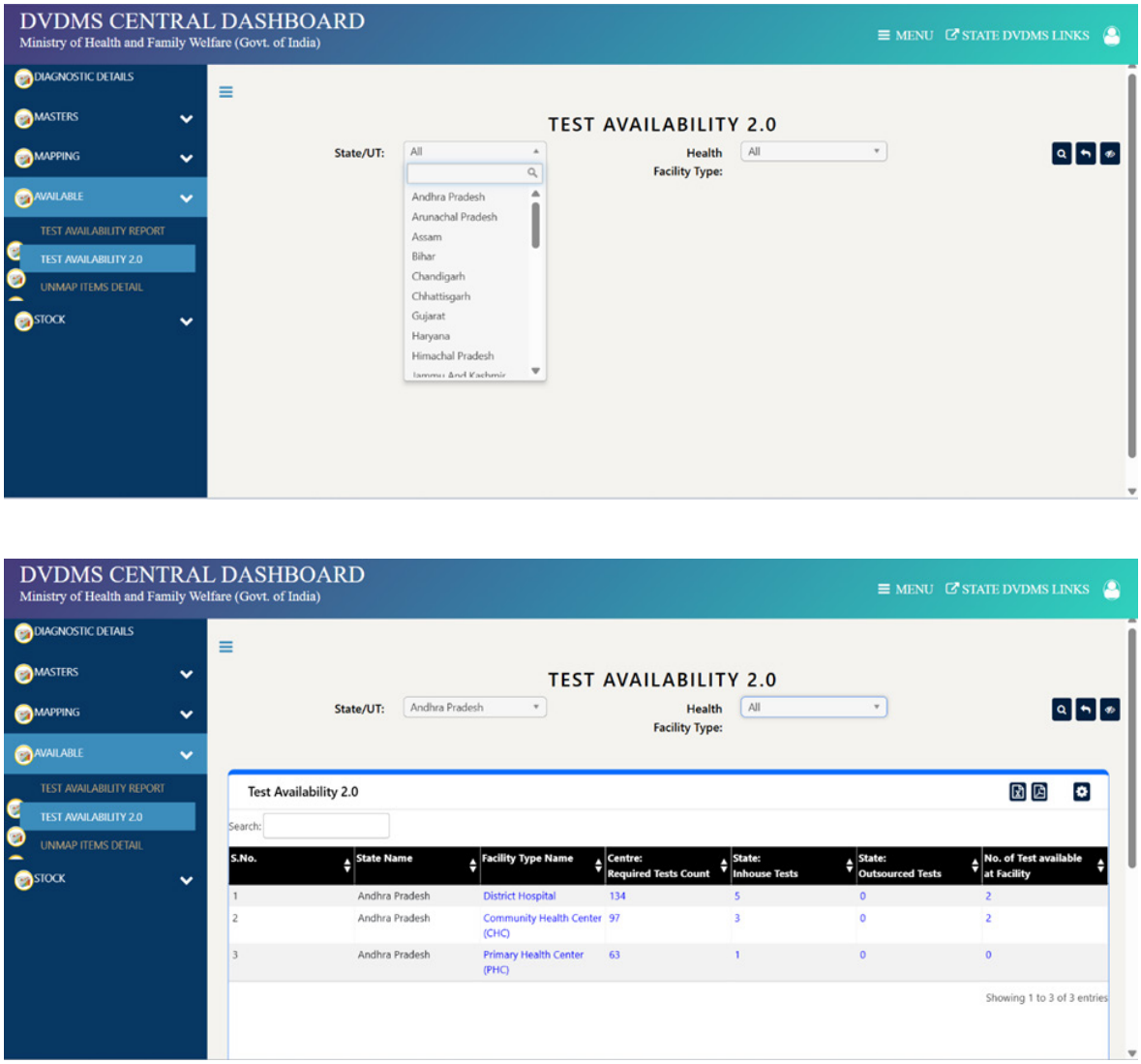


Figure 17. Test availability 2.0 page

The Diagnostic Module of DVDMS is a robust tool for managing laboratory inventories and diagnostic services in public health settings. By effectively utilizing the master pages and dashboards, facilities can ensure efficient test delivery, prevent stock-outs, monitor equipment performance, and improve the overall quality of diagnostics.

Regular training of staff and timely data entry are critical to the successful implementation of this module. With comprehensive usage, DVDMS can become a backbone for evidence-based diagnostics planning and service optimization across the country.

Mapping of laboratory equipment with available reagents and consumables for integration on DVDMS diagnostic module is placed as **Annexure V**

Chapter 07

LABORATORY PROCESSES

Laboratory testing is crucial for clinical decision-making and patient management. Its key functions include:

- Screening for disease (population-wide, targeted, individual, or opportunistic)
- Confirming or ruling out diagnoses
- Monitoring disease progression and treatment response
- Assessing disease severity

With growing reliance on lab services, it's essential to understand that test results can be influenced by preanalytical, analytical, and postanalytical factors. Notably, most errors occur in the preanalytical (62%) and postanalytical (23%) phases, and around 25% of these errors can impact patient care.

The testing process of a specimen comprises of three distinct phases. Every laboratory test undergoes these three phases.

- **Preanalytical phase:** All procedures or processes occurring before the actual testing of the specimen
- **Analytical phase:** All procedures or processes related to actual testing of the specimen.
- **Postanalytical phase:** All procedures or processes involved following test performance

A. Preanalytical Phase

Prior to the actual analysis of a specimen, various factors can influence the accuracy of test results. These errors, occurring before the sample is analyzed, fall within the preanalytical phase. This phase includes physiological or biological influences, as well as procedures related to specimen collection, handling, storage, and transportation. The key preanalytical variables are outlined in Table. The majority of problems associated with laboratory test results are due to errors in preanalytical phase.

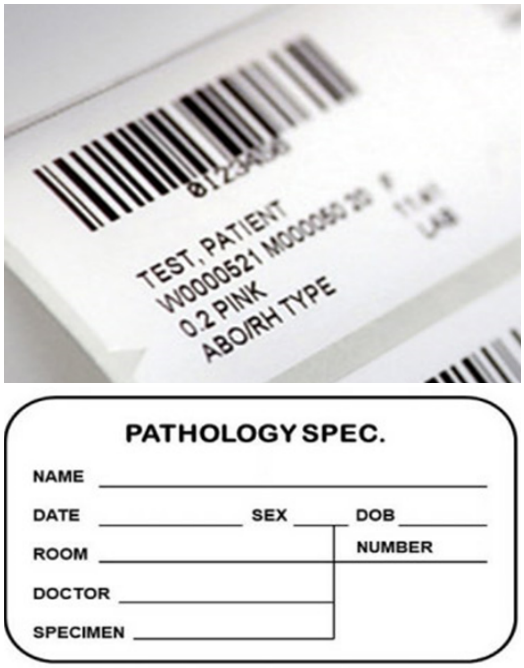
Preanalytical variables affecting laboratory test results	
• Patient identification • Patient preparation • Selection of specimen type • Specimen collection • Labelling of specimen	• Transport of specimen • Identification of specimen • Handling and processing of specimen at the testing site • Physiological variables

Table 6. Preanalytical variables

1. Patient Identification

Accurate patient identification is a critical step prior to specimen collection, as errors at this stage can lead to misdiagnosis and potentially life-threatening consequences due to inappropriate treatment based on incorrect laboratory results. Ideally, two identifiers should be used to confirm the patient's identity. Ayushman Bharat Health Account (ABHA) ID should be integrated in all IT software for sample identification and tracking. ABHA IDs helps in line-listing of the patients and their subsequent follow-up.

Figure 18. Patient ID Tag



2. Patient Preparation

The timing of sample collection is critical for certain tests, such as therapeutic drug monitoring and measurements of cortisol or glucose levels. For accurate results, blood glucose and lipid profile tests should be performed after an overnight fast. Factors like diurnal variation and body posture can also influence the levels of specific analytes and should be accounted for during sample collection. Smoking prior to specimen collection can affect test results by elevating white blood cell count, glucose, cortisol, growth hormone, cholesterol, and triglyceride levels.

3. Selection Of Appropriate Specimen

The correct type of specimen, appropriate specimen container, and suitable anticoagulant must be selected based on the specific test that has been ordered. The types of blood specimen collected includes serum, plasma and whole blood.

- **Serum:** The fluid portion of blood that remains after clotting has occurred,

typically 30 to 60 minutes after collection is serum. It is commonly used for most biochemistry, immunology, and serology tests. Serum should be separated by centrifugation only after complete clotting of the sample. The colour code of the vacutainer and the used for based on the additive is listed below:

Stopper Color	Additive/ Anticoagulant	Uses
Lavender or purple	K2EDTA spray-dried	Complete blood count
Pink	Spray-dried K2 EDTA	Blood bank pre-transfusion testing
Light blue	Sodium citrate	Coagulation tests
Gray	Sodium fluoride and potassium oxalate	Glucose, lactate, blood alcohol
Green	Sodium heparin, lithium heparin	Chemistry, osmotic fragility, blood gases, electrolytes, ionized calcium
Black	Buffered sodium citrate	ESR (Westergren)
Yellow	Sterile containing sodium polyanethol sulfonate	Serum for microbiology culture
Royal blue	None; free from trace elements and heavy metal	Trace metal analysis
Red	None (plain tube)	Chemistry, blood bank, serology or immunology
Gold or red-gray	Clot activator separation gel	Chemistry

Abbreviations: K2EDTA, ethylenediaminetetra-acetic acid dipotassium; ESR, erythrocyte sedimentation rate

Table 7. Commonly used specimen collection tubes, their contents, and uses

- **Plasma:** The liquid component of blood that remains when an anticoagulant is used to prevent clotting is plasma. The coagulation tests require plasma and also the preferred specimen for measuring potassium and ammonia levels.
- **Whole blood:** Most of the haematology tests are usually carried out using whole blood specimens, obtained from arterial, venous, or capillary sources.

4. **Sample Collection:** Sample collection should be done by laboratory technician (LT) at all levels of healthcare facilities. In case of absence of LTs, CHO (Nurse) and ANMs can be trained for conducting phlebotomy and Rapid Diagnostic Tests.

- Sample collection room should have a comfortable blood-letting chair, vacutainers and sterilised bottles/containers for collection of specimens, Bar code printer for sample identification.
- Sample collection timings should be well displayed outside the room and usually should be from 0800h to 1200h. Notified list of diagnostic tests undertaken by the health facility should also be displayed for patient information.
- Early morning (fasting) samples should be collected on appointment or by the duty LT in the CHC, First Referral Units (FRUs), 24 X 7 PHCs. LTs should be available on-call after working hours for emergency tests.

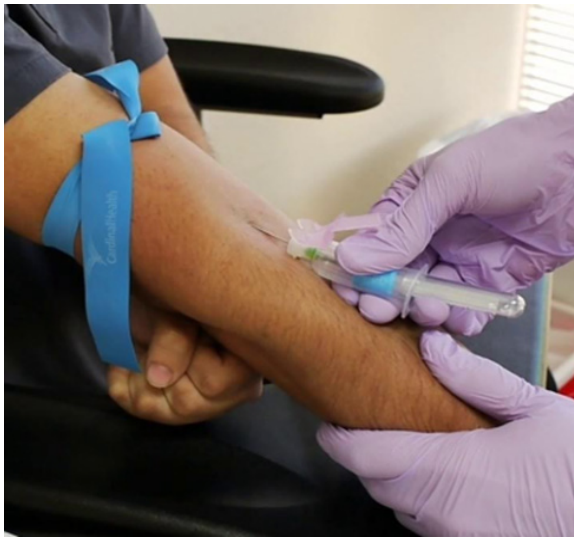


Figure 19: Sample collection

- Trained ANMs & CHOs can be utilised for phlebotomy at PHCs and CHCs to support the LTs on PMSMA days.

5. **Specimen Labelling**

Immediately after collection, the specimen tube must be labelled in the presence of the patient and accompanied by the appropriate request form when sent to the laboratory. The labels should be clear and ideally barcode generated. Manual label should consist of patient name and age as two identifiers. Precaution should be taken to ensure that the barcode is correctly pasted over the vacutainer and there is no cross-marking over the barcode, to avoid rejection. The sample and the accompanying requisition form must be verified for accurate and complete identification details, before accepting a specimen into the laboratory.

Sample Integrity is dependent on accurate pre-analytical processes. Sample integrity is affected by sample transport time, temperature and stability (Packaging

& preservation and maintaining cold chain). Improper storage, mishandling, human errors, degradation and contamination of samples are the common causes for sample rejection.

Reasons For Specimen Rejection

- Non-labelled sample/ Incorrectly labelled specimen
- Insufficient sample volume
- Haemolyzed sample
- Timing of sample collection – fasting/ post-prandial etc.
- Contaminated sample/ clotted sample

B. Analytical Phase

The Analytical phase is the core stage of the laboratory testing process, where the actual testing or analysis of the patient specimen takes place

The primary aim of this phase is to accurately and reliably measure or detect the analytes/substances being tested within the patient sample. Few steps of analytical phase includes:

- Aliquoting (transferring a portion of sample into smaller tubes, well and assemble in respective instrument.
- Dilution and mixing of analyte concentration if too high as per equipment requirement to ensure its homogeneity.
- Equipment Calibration: Before patient samples are run, analytical instruments must be calibrated which involves running known standards to establish a standard curve or calibration curve.
- Quality control materials (QCs) are run frequently to monitor the performance of the analytical system
- Result generation and verification: Once the analysis is complete, the equipment generates raw data, which is then converted into quantitative results (for e.g., mg/dL, units/L, cell count) or qualitative results (e.g., positive/negative, present/absent).

The analytical phase is critical because it directly generates the data that healthcare providers use to make diagnostic and treatment decisions.

Laboratory information management system

Laboratory Information Management System (LIMS) is a crucial software solution in modern healthcare, particularly for optimizing diagnostic patient workflows in hospitals. It manages the complete lifecycle of laboratory specimens, from the

moment of sample collection through final diagnostic reporting.

A LIMS is typically specimen-based, focusing on the sample's journey, from sample registration, processing, tracking, test management till execution of report. LIMS interfaces seamlessly with various high-end laboratory equipment (e.g., Analyzers, PCR machines etc), automating data collection directly from these devices, thus eliminating manual data entry, improving accuracy and efficiency.

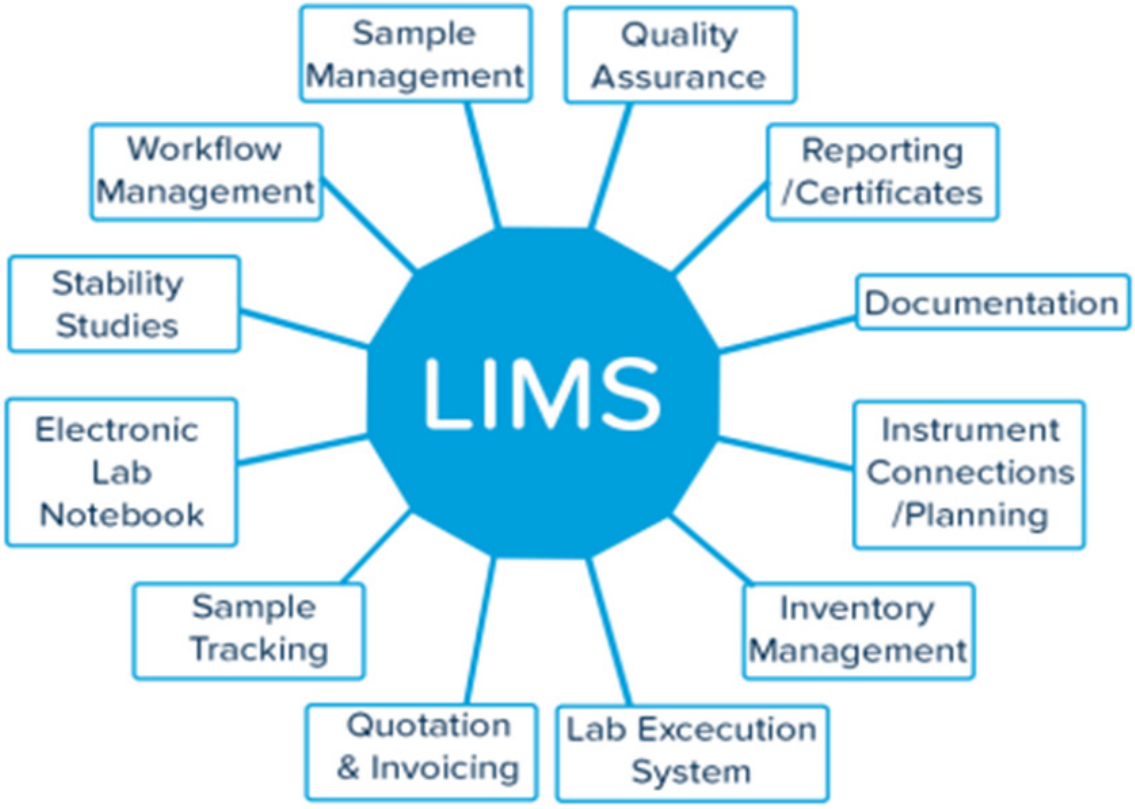


Figure 21. Laboratory Information Management System

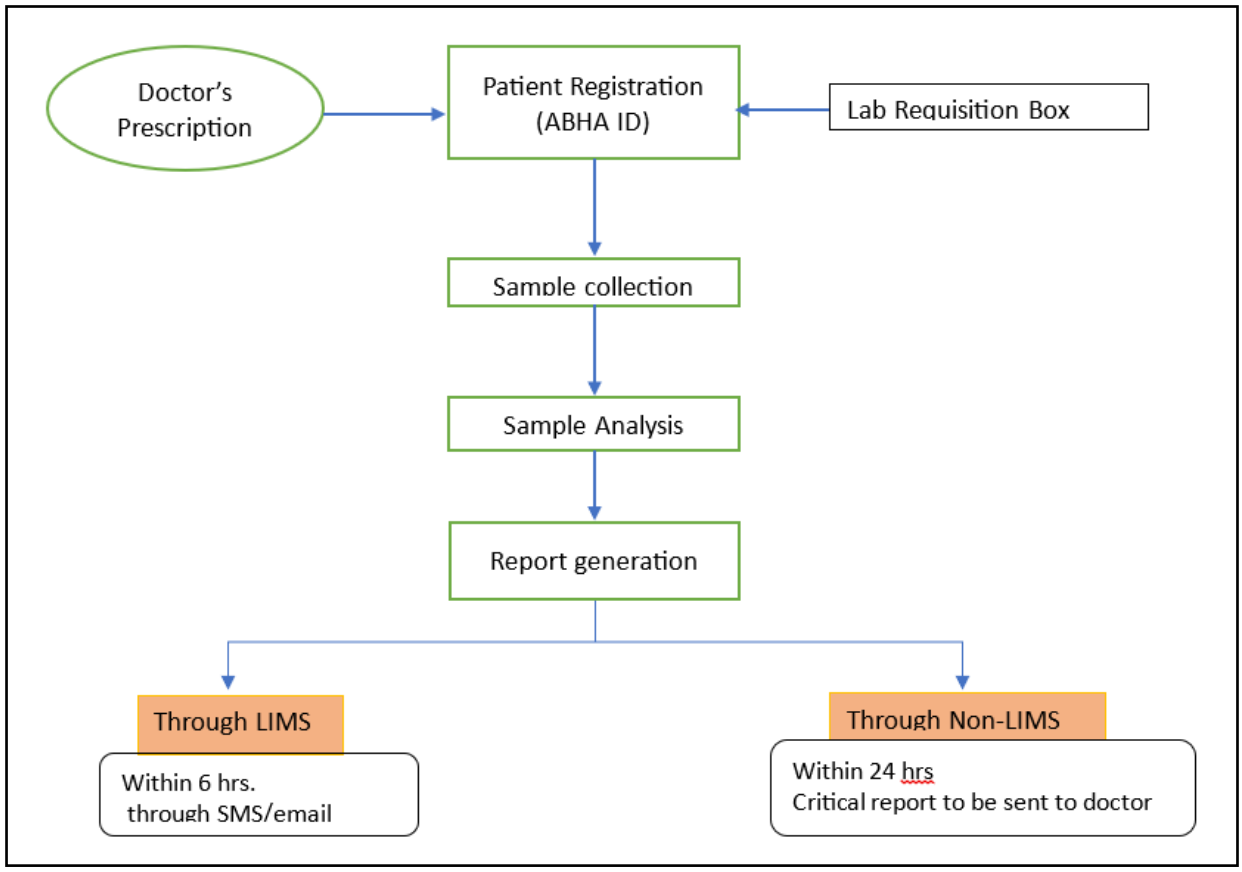
It automates result validation based on predefined rules, flagging abnormal or critical values for immediate review and action. It acts in biphasic by digital reports delivery to clinicians and even directly to patients (via patient portals or automated SMS/email notifications), significantly reducing turnaround times.

LIMS plays a key role in laboratories meeting Quality standards, decreasing transcription errors, reducing turnaround time from specimen receipt to reporting of results, and improving patient outcomes.

There are two common types of LIMS:

- • **Module within a hospital information system (HIS)-** A LIMS within HIS serves mostly as a means to capture results and a few key elements of data.
- • **Stand-alone LIMS-** A dedicated LIMS shares most of the components listed above and can support all the laboratory functions.

As a backup, laboratories may choose to keep paper-based records (in case computerized information system not available) to manage workflow, quality and audit trail for the samples processed in the laboratory.



1. Turn Around time from sample collection to report generation should not exceed more than 24 hours except for tests like Culture, and others which requires analytical time more than 24hrs.
2. Patient without prescription should not be entertained.

Figure 22. Work Process Flow

Chapter 08

LABORATORY SAMPLE TRANSPORTATION

Key Principles of Sample Transport

Sample transportation relies on three core principles:

a) **Time -** Certain specimens, such as arterial blood gases or samples for serum/ plasma chemistry tests, require urgent processing. For instance, serum/plasma samples should be centrifuged and separated within 2 hours of collection to maintain integrity.

b) **Temperature –** Some samples are sensitive to temperature fluctuations and require special handling. Cold chain protocols must be followed, using ice packs within insulated containers to maintain appropriate temperatures. This is especially important for analytes such as ACTH, PTH, ammonia, acetone, and fatty acids.

c) **Stability –** Photolabile samples, like bilirubin, degrade upon light exposure and may yield erroneous results. Loss of sample stability due to improper transport conditions can lead to breakdown of components, resulting in analytical errors and jeopardizing patient safety.

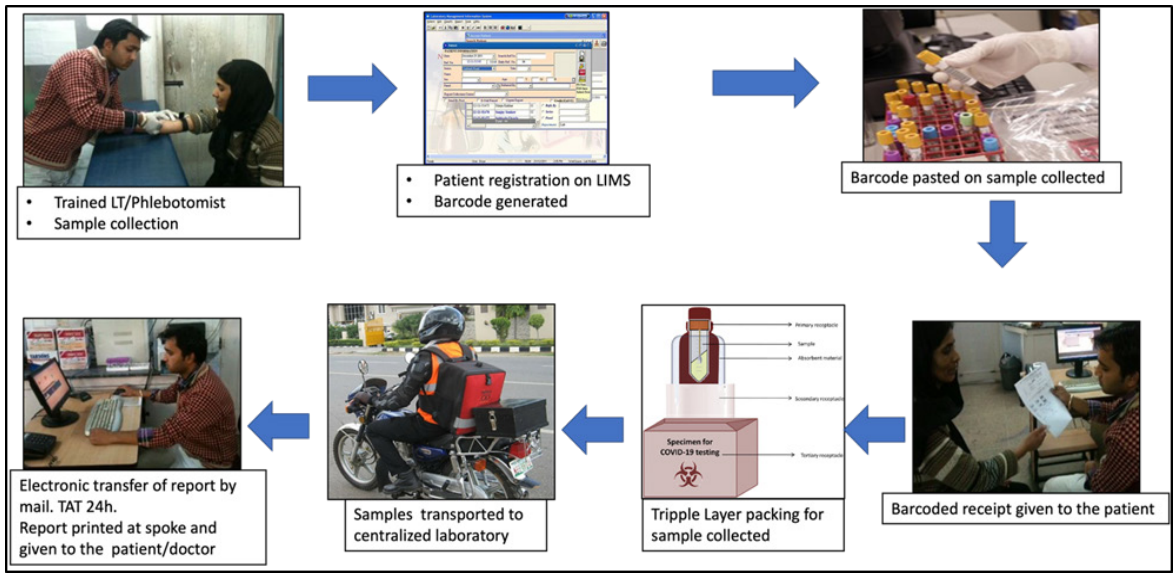


Figure 23. Sample Delivery Workflow

Pre-requisite for Sample transportation:

The following are the pre-requisite for sample transportation:

a) **Sample Collection and Storage:** Ensuring the right sample is collected at the right time, using proper techniques for collection, storage, and transport, is fundamental to good laboratory practices. Samples must be picked up from health facilities on the same day they are collected and promptly transported to the designated hub or mother laboratory for testing. Timeliness in sample handling is critical, and selecting the appropriate mode of transportation poses a significant challenge. Additionally, accurate sample identification—such as through barcoding or QR coding—prior to transport remains a key hurdle in many public health facilities. Recommended sample type for test, its correct collection method, volume, storage and transport requisite is listed in **Annexure VI.**

b) **Packaging of Specimen:** WHO recommends basic triple packaging system for safe transportation of infectious substances and diagnostic specimen.

   i) Primary receptacle – A well labelled primary water-tight, leak-proof receptacle containing the specimen and wrapped with adequate absorbent material to absorb all fluid in case of breakages.

   ii) Secondary receptacle – A second durable, water-tight, leak-proof receptacle with enough absorbent material to enclose and protect the primary receptacle.

   iii) Outer shipping package – The secondary receptacle is placed in an outer shipping package which protects it and its content from outside such as physical damages and water while transit.

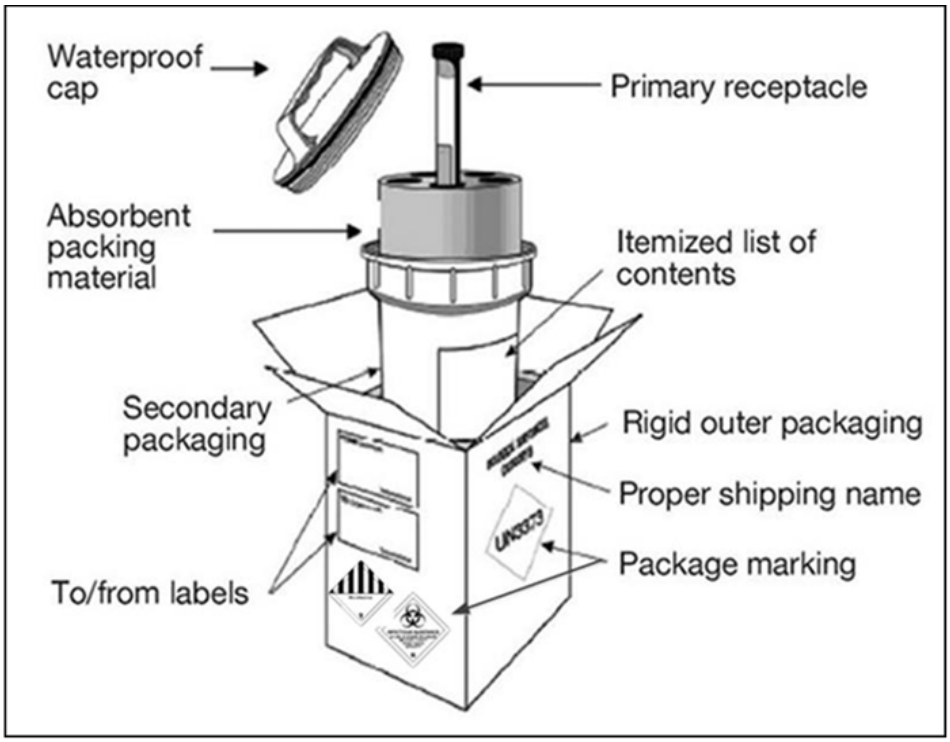


Figure 24. A diagrammatic representation of the Standard Triple Packaging

(Source: ICMR guidelines)

c) Precautions to be taken:

- **Timeliness:** Ideally, samples should be transported within 30 minutes of collection and preferably not later than 2 hours.
- **Temperature Maintenance:** In general, samples must be stored and transported at 2–8°C, unless specified otherwise. Cerebrospinal fluid (CSF) and other internal body fluids can be maintained at room temperature.
- Specimen for bacterial culture should not be stored for more than 24hrs before processing.
- Urine, stool, viral specimen, sputum, swabs, etc need to be stored at 4°C
- CSF and other body fluids for culture have to be kept at 37°C
- Blood for culture should be kept at room temperature and processed within 4 hours. Do not refrigerate blood culture samples.
- Stool swab, rectal swab, liquid stool must be transported within 4hours. Fresh stool should be delivered in 8hours.
- Serum sample can be stored up to 1 week in refrigerator 2-8 degree centigrade and when transported should be placed in ice pack boxes/cold chain boxes.

States/UTs should procure sufficient universal shipping boxes complying with triple-layer protection standards. The specimen data forms, letters, and other types of information that identify or describe the specimen and identify the shipper and the receiver should be taped to the outside of the secondary receptacle.

Turn Around Time: Timely result of diagnostic test is the key in timely and comprehensive management of patients. The turnaround time of a diagnostic sample starts with the sample collection at the health facility where the tests are prescribed, and the end point is printing/ e-receipt of the tests result at the health facility.

Components of turnaround time

For assessing efficiency of processes at different stages of sample cycle in terms of turn round time, States/UTs should monitor pre- analytical, analytical and post-analytical time separately.

Prescribed turn-around time

Recommended turn-around time	Recommended time	Maximum permissible time for report generation and delivery to patient
Routine tests	Within 24 hours	Within 48 hours
Advanced tests	24 hours	Within 2- 3 days
Emergency tests	Immediately	Within 2 hours

Table 8. Recommended turnaround time for samples

General Operational Principles

- **Same-day Pickup:** Samples must be picked up from all government health facilities on the same day of collection and transported to the designated hub or mother laboratories.
- **Time Recording:** The exact dispatch time of samples should be recorded electronically at the health facility by designated staff (lab technician/ANM/service provider's phlebotomist).
- **Emergency Pick-up:** At District Hospitals (DHs) and Sub-District Hospitals (SDHs), emergency samples must be picked up within 15 minutes to ensure timely testing and intervention. For Community Health Centres (CHCs), the emergency pick-up should occur within one hour. In such cases, documentation should clearly justify the urgency of the request to facilitate prioritization and appropriate handling.
- **Cumulative Transport Time:** Transportation from multiple health facilities (spokes) to the primary receiving laboratory (hub) should not exceed 2 hours from the starting point of the pick-up route.

Sample Pick-up Frequency

Facility Type	Frequency	Time
PHCs	Once daily	Around 12 Noon
CHCs/FRUs/24x7 PHCs	Twice daily	11 AM and 4 PM
Emergency sample (on call)	As applicable	Any time

Table 9. Sample pick-up frequency in health care facilities

Sample Segregation

Upon arrival at hub laboratories, samples must be systematically categorized based on the type of tests required. Samples intended for routine tests are processed directly at the hub laboratory itself. However, those requiring advanced or specialized testing should be appropriately packaged and forwarded to the designated mother laboratory, typically at the L1 or District Hospital (DH) level, for further analysis. This segregation ensures efficient workflow and optimal use of laboratory resources.

Sample Transport – Service Delivery

- **In-House Model:** Lab sample transportation from AAM-SC level to higher health facilities (PHC/CHC) with focus on delivering to a hub (BPHL/IPHL) for the tests not undertaken at the health facility is of prime importance as it directly contributes to reduction in OOPE for the patients as sample transport ensures that samples only move and not patients. Similarly samples from BPHL should be linked with

IPHL. Field experiences have shown that the expenditure incurred on sample transportation (INR 5 to INR 6 per Km) is a cost-effective option for implementation in the states. Samples can be transported by the TB runners, STS, Health Assts, volunteers from SHGs. Appropriate colour codes can be given for each level of healthcare facility where the sample is to be carried/ dropped using colour-coded sample packaging boxes for delivery at the right place.

- **PPP Model:** States can also engage courier services, have MoU with the State transport department, Indian Postal services, other public/private transport system for safe delivery of samples to the hub labs from the periphery. The cost for the services offered in the PPP mode will be on the tendered rate, within the benchmark cost of INR 5 to INR 6 per Km.

Cold Chain Management

To preserve sample integrity and prevent degradation the following are mandatory:

- Refrigerators with power back-up at all health facilities for storing samples and reagents.
- Cool boxes with temperature monitoring devices during transportation.
- The temperature should be monitored from sample pickup to receipt at the laboratory.
- Data from temperature devices should be downloaded at the hub/mother/testing laboratory.

Documentation and Monitoring

It is essential to maintain thorough documentation regarding the dispatch of samples. Facilities must record the dispatch time and clearly note any deviations, including the reasons for early or delayed pickups. These details should be logged systematically to ensure transparency, accountability, and ease of review during audits or evaluations. Transport data should be analysed on a daily basis by the state nodal officials and the facility in-charge to identify any operational issues or irregularities.

Chapter 09

SAFETY IN LABORATORIES

Laboratory personnel are often exposed to a range of hazards, including chemicals, infectious agents, fire, electrical shocks, and gas leaks. Additionally, the environment may be at risk of contamination from hazardous substances and waste generated during laboratory activities.

Each laboratory should develop its own safety manual that identifies potential hazards and outlines appropriate mitigation strategies. Staff should be adequately trained on these safety measures. The safety policies must include clear guidelines on the use and disposal of sharps, bio-waste, reagents, and other laboratory waste, in compliance with local and national regulations.

Training all laboratory personnel in standard precautions is crucial. A code of practice should detail the essential laboratory procedures and best practices fundamental to sound microbiological techniques. Overall, laboratory safety aims to safeguard both personnel and the environment from potential risks associated with hazardous materials.

General Safety Measures

- All laboratory personnel must be familiar with and consistently adhere to established safety policies and procedures.
- A detailed inventory of hazardous materials used in the laboratory should be maintained and regularly updated.
- An eye wash station should be available, either as a stand-alone unit or attached to a sink.
- Containers and equipment holding biohazardous materials must be clearly labeled with the biohazard symbol (Figure 13).
- Staff should be well-trained in responding to both fire-related and non-fire emergencies, including major spills and gas leaks.
- Laboratories should be equipped with an adequate number of fire extinguishers, which must be easily accessible.
- All accidents, incidents, and injuries involving lab personnel should be documented and reported to the appropriate authority. Each report should detail the event, contributing factors, and any medical attention or first aid provided. These records should be reviewed periodically, even if there are no new entries, to identify patterns

and implement preventive measures.

- Eating, drinking, smoking, or chewing gum is strictly prohibited while working in the laboratory.
- Laboratory glassware must not be used for storing or consuming food or beverages.
- Appropriate clothing should be worn at all times, including chemically resistant lab coats or aprons.
- Needles, syringes, and other sharps must be handled with care. Use safety-engineered devices like self-sheathing needles whenever possible and dispose of all sharps in designated sharps containers.
- Chemicals should never be poured down the drain. Most must be treated as hazardous waste and disposed of accordingly.
- Compressed gas cylinders must be properly secured to prevent tipping. They should be capped when not in use or when the regulator is removed.
- In case of chemical exposure to the eyes or skin, immediately flush the affected area with running water for at least 20 minutes using the eye wash facility.

Figure 25 Biohazard symbol

Laboratory Safety Chemical Hygiene Plan (CHP)

The Chemical Hygiene Plan (CHP) is a written document designed to safeguard laboratory personnel from health risks associated with hazardous chemicals. It outlines the policies, procedures, and responsibilities necessary to ensure a safe working environment and compliance with laboratory safety standards.

The CHP is developed in accordance with regulatory laboratory requirements and includes the following key components:

- Standard Operating Procedures (SOPs) that address health and safety aspects of handling hazardous chemicals in the lab.
- Identification of chemical hazards and strategies to minimize their associated risks.
- Implementation of control measures aimed at reducing individual exposure to hazardous substances.
- Guidelines for arranging medical consultations and examinations when needed.
- Procedures for handling accidents or emergencies, which must receive prior approval before being put into practice.
- Additional protective measures for personnel working with particularly hazardous substances, such as carcinogens, reproductive toxins, and highly toxic chemicals.
- While handling bacterial cultures, the work area should be restricted from general use. And live culture sample should always be handled in laminar air flow chamber.
- Requirements to ensure that fume hoods and other protective equipment are functioning effectively.

Equipment Safety and Training

- The equipment should be used as per the manufacturere's instruction and designated purpose.
- The equipment should always be inspected for damage before use, and in case of non-performing or breakdown, the concerned biomedical engineer should be informed for corrective actions.
- Proper training on laboratory safety procedures and protocols should be ensured.
- The laboratory staff should be well-aware of the first aid kit, fire extinguisher handling and other emergency equipment.
- The way to emergency exit should be known to all the staff and protocol for emergency exit should be followed in such cases.

Laboratory Hygiene and Sanitation

Maintaining hygiene and sanitation in the laboratory is essential for ensuring a clean, safe, and contamination-free environment.

- Access to the laboratory should be restricted. Visitors and children must not be allowed into the testing areas.
- Laboratory staff must adhere to proper hygiene practices, including regular handwashing and the use of personal protective equipment such as lab coats, gloves, and eye protection.

- Workbenches should be thoroughly cleaned with sodium hypochlorite or a suitable disinfectant before and after each workday.
- All laboratory equipment must be cleaned both prior to and after use.
- Housekeeping staff should receive basic training in biomedical safety to ensure they understand laboratory waste handling and exposure risks. They should also be vaccinated against tetanus.
- A robust pest control system should be in place to maintain a hygienic workspace.
- All laboratory personnel involved in sample handling should be vaccinated against Hepatitis B, and antibody titres should be checked to confirm adequate protection.

Personal Hygiene

- Never smell, inhale or taste laboratory chemicals.
- Always wash hands with soap and water after removing gloves and before leaving the work area.
- Never eat, drink, chew gum or tobacco, smoke or apply cosmetics in the laboratory.
- Remove Personal Protective Equipment (PPE) such as gloves and lab coats before leaving the lab.
- Remove gloves before handling common items like phones, instruments, doorknobs, etc.
- Do not block emergency showers, eye washes, exits or hallways.

Electrical safety

Electrical safety measures help prevent the misuse of electronic instruments, electric shocks and other injuries, and ensure that any damaged devices, cords, or plugs are promptly reported for repair or replacement.

- Conduct annual checks to ensure proper earthing.
- Keep all electrical panels clear of obstructions and easily accessible at all times.
- Minimize the use of extension cords whenever possible.
- Use of UPS (Uninterrupted Power Supply) for high-end Analysers.

Chapter 10

SUGGESTED DIAGNOSTIC FOR NCD SCREENING AND DIAGNOSIS

The National Programme for Prevention and Control of Non-Communicable Diseases (NP-NCD), implemented under the National Health Mission, aims to address the rising burden of NCDs in the country. MoHFW has approved the "Operational Guidelines for NP-NCD (2023-2030)" focussing on strengthening infrastructure, human resources, health promotion, early diagnosis, management and referral continuum.

Under this initiative, population more than 30 years of age are targeted for screening for common NCDs, making it an integral part of the service delivery mechanism, through Ayushman Aarogya Mandirs, by promotion of wellness activities and targeted communication at the community level.

Figure 26. NP-NCD Diseases

Under the NP-NCD programme, 753 NCD clinics at the district level, 356 Day Care Centres (DCC) at the district level and 6238 NCD clinics at the Community health Centre (CHC) level have been established. Awareness for prevention and early detection of NCDs is carried out at all the levels through the NCD clinics at District & CHC level.

The following diagnostics are suggested at public healthcare facilities for screening and early diagnosis.

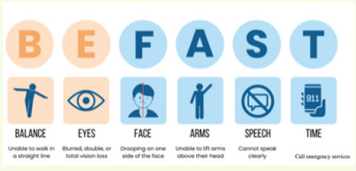
S. No.	NCD		Diagnostics for Screening at AAM SC/ PHC	Diagnostics for Confirmatory Diagnosis at DH
1.	**Hypertension**		Blood pressure measurement on 2 different occasions (SBP>= 140 mmHg and DBP >= 90 mmHg)	Physician consultation Targeted organ damage assessment
2.	**Diabetes**		Blood Sugar (Glucometer)	Oral GTT HbA1C
3.	**Chronic Kidney Disease**		Urine for albumin/ protein (Urine Dipstick) Serum Creatinine	eGFR Renal Function Test
4.	**Chronic Obstructive Pulmonary Diseases and Asthma**		Pulse oximetry Peak Expiratory Flow Rate	Spirometry Chest Xray
5.	**Non- Alcoholic Fatty Liver Disease**		Weight, BMI, Waist circumference, Waist-to-hip ratio (Central obesity)	Ultrasonography Liver Function Tests
6.	**Cancer**	**Oral Cancer**	Visual inspection	Biopsy
		Breast Cancer	Clinical Breast examination	Ultrasonography Mammography (DBT) Fine-Needle Aspiration Biopsy
		Cervical Cancer	VIA Screening	Biopsy
7.	**ST-Elevation Myocardial Infarction (STEMI)**		ECG (12 channel)	Coronary angiography
8.	**Stroke**		Based on clinical signs, BP 	CT MRI

Table 10. Suggested diagnostic for NCD screening and diagnosis

Chapter 11

QUALITY ASSURANCE AND QUALITY CONTROL

Maintaining quality in laboratory services is essential, as test results play a critical role in patient diagnosis and treatment. A well-functioning laboratory must implement and adhere to a robust quality system to ensure the accuracy and reliability of its test results. This quality is maintained through two key mechanisms: Quality Assurance (QA) and Quality Control (QC).

Quality Assurance (QA) involves managing the overall quality of every stage in the testing process. This includes the pre-analytical, analytical, and post-analytical phases—covering activities like staff training, inter-laboratory comparisons, equipment maintenance, and result reporting. QA ensures that:

- The right test is being carried out on the right specimen from the right patient.
- The right result and the right interpretation are obtained.
- The right result is given to the right person at the right time.

Quality Control (QC) refers to the statistical monitoring of a test's accuracy and precision. It serves as a daily checkpoint to assess the reliability of the testing process. If QC measures fall outside acceptable limits, test results should not be released. QC helps ensure that:

- The test is working properly.
- Technical aspects of the test—temperature, checks, controls—are valid.
- Results are correct, acceptable, and valid.

Given the critical importance of quality in laboratory services, a laboratory Quality Assurance (QA) program is typically developed and implemented to systematically monitor and evaluate laboratory operations and services. To ensure accountability and clarity, there should be documented procedures for each component of the QA process. Generally, the national reference laboratory oversees the QA program, which applies across all levels of the laboratory system. Key components of a QA program include:

- **Quality Control (QC)**: This involves measures to assess the accuracy and reliability of testing procedures. For instance, samples with known results can be retested to confirm that both the test and the procedure are functioning correctly. Quality control activities are often carried out in collaboration with internationally accredited laboratories.
- **External Quality Assurance (EQA):** EQA is used to identify laboratories, testing sites, or technicians that are not meeting performance standards. It typically

involves three evaluation methods: on-site assessments, proficiency testing, and blinded rechecking of test results.

- **Safety Measures:** These ensure the application of universal precautions to prevent the transmission of HIV and other blood-borne pathogens in laboratories and testing sites. Adhering to these safety practices helps protect patients, laboratory staff, and other healthcare workers.
- **Supervision:** Regular supervisory visits enhance the quality of testing and staff performance. These visits may include checking inventory levels, updating stock records, discarding expired supplies, observing work practices, troubleshooting performance issues, and offering on-the-job training.

Challenges In Quality Assurance and Quality Control

- Lack of standardized laboratory tests, techniques, and procedures.
- Lack of internal quality control (QC) materials.
- Lack of procedures and knowledge for visual inspection of laboratory commodities and for disposal of expired or damaged commodities

Recommendations for Quality Assurance (QA) and Quality Control (QC) of Laboratory Commodities

- **Integrate Commodity Management into the QA Program:** Commodity management should be a core component of the laboratory's quality assurance system. Logistics procedures—including inventory control, proper recording and reporting, and appropriate storage—must be followed diligently. Adhering to these processes ensures that essential commodities are consistently available and maintained in good condition, thereby supporting the reliability of laboratory services.
- **Implement and Enforce Internal and External QC Retesting Protocols:** Since visual checks alone cannot always confirm the quality of reagents and other test materials, both internal and external retesting should be incorporated into QC practices. These procedures help detect issues that may compromise test accuracy. While various factors contribute to test outcomes, the quality of the commodities used plays a crucial role, and QA protocols can help identify deficiencies early.
- **Conduct Routine Visual Inspections of Commodities:** Laboratory commodities should undergo regular visual inspection to help identify any damage or deterioration. These inspections should be performed at multiple stages: upon receipt, before use, when nearing expiration, and whenever a quality concern arises. Inspections should focus on detecting:
    - Mechanical damage, such as:
    - Torn or water-damaged packaging

- Missing or unreadable labels, including expiry dates
- Missing components (e.g., absence of chase buffer in a test kit)
- Chemical damage, indicated by:
- Discoloration of reagents or chemicals
- Unusual odors for reagents or chemicals
- Caking or clumping of powdered substances

- **Establish Procedures for Handling Damaged, Expired, or Suspect Commodities:** Commodities that are damaged, expired, or suspected to be compromised should be removed from inventory without delay. Retaining such items can waste storage space, lead to accidental use, and negatively impact test results. Laboratories should implement clear protocols for identifying, segregating, and safely disposing of unusable commodities, ensuring they are also removed from inventory records to prevent misuse.

Internal quality control

The foundation of implementing Internal Quality Control (IQC) in a laboratory begins with selecting the appropriate IQC strategy. This involves choosing suitable statistical criteria or control rules, and determining the number of control measurements based on the desired quality standards for the test and the actual performance of the method used.

Key aspects of IQC practice include:

- Identifying and addressing errors that may occur during the testing (examination) phase within the laboratory.
- Taking corrective measures to reduce these errors.
- Ensuring regular equipment calibration and conducting method verification or validation.
- Performing quality control checks for both quantitative and qualitative test procedures.

IQC for Quantitative Tests

IQC plays a crucial role in ensuring the accuracy and consistency of quantitative laboratory test results by enabling early detection of errors. The Levy-Jennings chart is the most widely used graphical tool to monitor daily quality control values. Most modern analyzers come equipped with built-in software to generate these charts. In the absence of such features, laboratories can create LJ charts manually using Excel. Alternatively, labs can utilize commercially available IQC software tools, LIS (Laboratory Information System) modules, or middleware solutions. LJ charts help identify trends (gradual changes) and shifts (sudden changes) in the quality control of tests.

Reagent Lot Verification

Maintaining consistency of test results is critical. Changes in reagent lots can impact the accuracy and reliability of patient results. Ensuring lot-to-lot consistency is especially important for analytes that are monitored over time, such as CBC, HbA1c, TSH, tumor markers, and liver enzymes.

Before using a new lot of reagents, its performance should be evaluated against the current lot while the existing lot is still available. When comparing reagent lots, alternatives to patient samples may include:

- Reference materials or QC products from the manufacturer that come with method-specific and reagent-lot-specific target values.
- Proficiency testing samples that have peer-group determined average values.
- This process ensures uniformity and reliability in testing, particularly in longitudinal patient monitoring.

External Quality Assessment

EQA involves assessing a laboratory's performance by comparing its results with those from other laboratories using predefined criteria. It is one of the most effective tools to evaluate the accuracy of clinical test results. Therefore, laboratories are encouraged to participate in EQA programs for all applicable tests, wherever feasible.

EQAS programme are presently being run by the CMC, Vellore for biochemistry and AIIMS, New Delhi for haematology tests. States can nominate their Apex referral institutes/INIs for having the state specific EQAS programme.

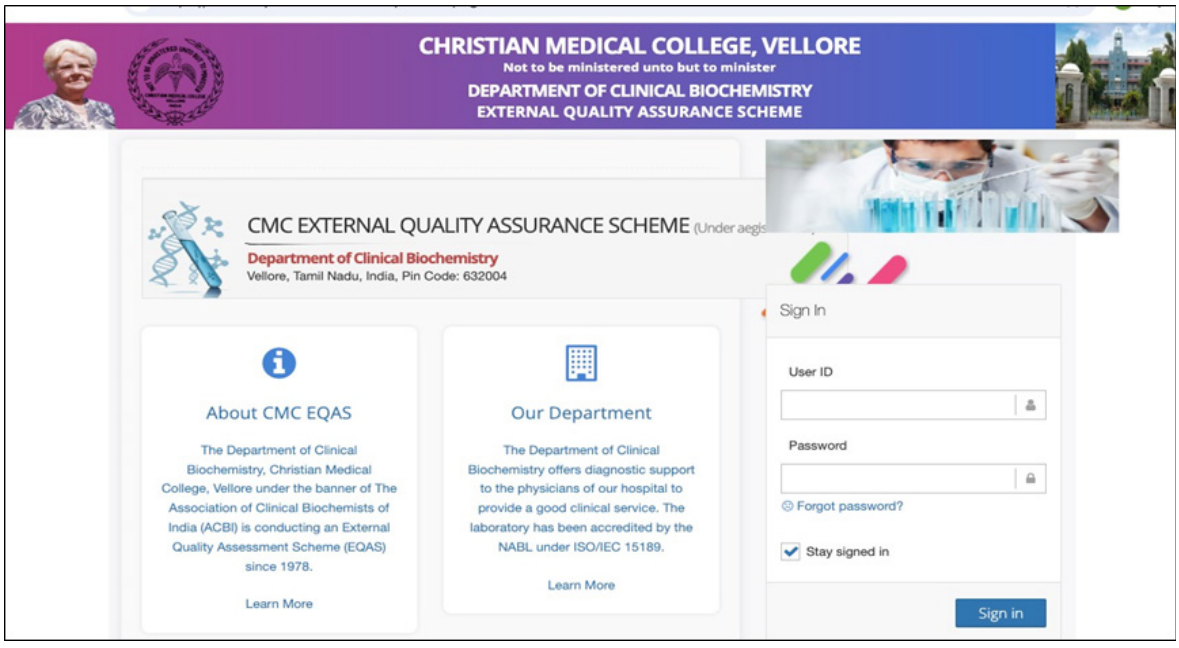


Figure 27. CMC Vellore EQAS Registration Portal

Benefits of EQA participation:

- Evaluates overall laboratory performance for individual tests
- Acts as an early warning system for identifying issues
- Helps detect systematic errors
- Provides objective evidence of testing quality
- Highlights areas where additional training may be needed

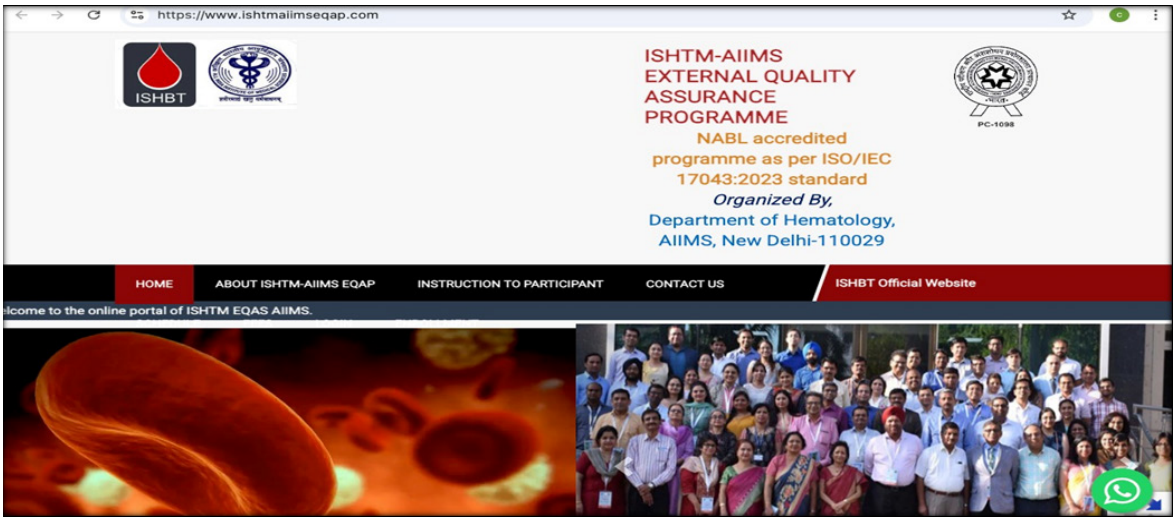


Figure 28. AIIMS- New Delhi EQAS Registration Portal

Key steps in a EQA process:

1. The laboratory registers for one or more EQA programs.
2. The EQA provider dispatches test materials at scheduled intervals.
3. The laboratory analyzes the samples and submits the results to the EQA provider within the specified timeframe, often through an online portal.
4. The provider evaluates the results and shares performance metrics such as z-scores or Standard Deviation Index (SDI). Labs can assess their own performance and benchmark against peer laboratories.
5. If performance scores fall outside acceptable limits, the lab must implement corrective and preventive actions.
6. Laboratories should use performance feedback to improve operational procedures and ensure ongoing quality enhancement.

When properly implemented, EQA fosters technical competence and continuous quality improvement in laboratories. EQA providers are accredited under ISO/IEC 17043:2010, and laboratories should preferably enrol in such accredited programs to ensure credibility and standardization.

Chapter 12

CHECKLIST FOR CLINICAL LABORATORIES & SPILL MANAGEMENT

A checklist for clinical lab services should cover safety, quality control, equipment maintenance and staffing. Key areas include PPE, emergency probes, chemical handling, waste disposal, instrument calibration, and staff training. The checklist should also address pre-analytical, analytical and post-analytical phases of testing as well as quality assurance measures.

NQAS has developed detailed checklist for lab services approved by MoHFW which can be accessed from the following link: https://qps.nhsrcindia.org/national-quality-assurance-standards/nqas-Guidelines

Few areas of concern for monitoring in clinical laboratories:

Check point	Area of concern	Activity
Safety	PPEs	• Availability of PPEs (gloves, face masks, googles, gowns etc.) • Training on donning and doffing
	Chemical Safety	• Proper storage and labelling of chemicals • Spill management protocol and availability of spill kits • Availability of material safety datasheet (manufacturer's instructions)
	Fire Safety	• Availability of fire extinguishers, emergency exit fire exit roofs
	Bio-hazard safety	• Proper handling and disposal of bio-hazard waste • Availability of sharp containers, puncture-proof bio hazard needle destroyer/ syringe cutter • Biomedical waste disposal and training of safe handling and segregation of infectious material
	Electrical Safety	• Regular maintenance and inspection of electrical equipment • Proper earthing and insulation of electrical outlets/ Power point sockets and equipment

Check point	Area of concern	Activity
Quality Control	Pre-analytical Phase	• Proper patient identification and specimen collection procedures • Appropriate specimen containers and storage conditions • Timely transport of specimens to the laboratory
	Analytical Phase	• Regular calibration and maintenance of laboratory equipment • Use of quality control materials and participation in external quality assurance programs • Documentation of all quality control activities.

Table 11. Comprehensive checklist for laboratory

Spill Management

A SoP for spill management is a lab setting prioritises safety by outlining steps to contain, clean-up, and prevent further hazards from chemical or biological spills. Key elements include assessing the spill, containing the spill, neutralising the spill (if applicable), cleaning the area, and properly disposing of contaminated materials. All labs should have universal spill kit "Spill Kit" for any handling any contingency.

General Spill management

1. Assess and alerts: Assess the spill size, type of material and potential risk. Alerts other in the immediate area and evacuate if necessary.
2. Personal protective Equipment (PPEs): Don appropriate PPE, gloves, safety goggles, N95 Face masks, etc. while handling and disposing the spill.
3. Containment: Use Universal Spill Kit (absorbent pads, spill towel/ paper) to soak up the spill. This is important to absorb and confine the spill and prevent further spread.
4. Neutralisation (If applicable): If dealing with acids, base, carefully neutralise the spill using appropriate reagents following specific instructions and safety. Specific neutraliser for:
    - Acids: Use sodium bicarbonate (baking soda), sodium carbonate or calcium carbonate.
    - Hydrofluoric acid (HF): Use calcium carbonate or a specialised HF acid neutraliser
    - Bases: Use citric acid, sodium bisulphate or a base neutraliser from a spill kit
    - Bromine: Use a 5% solution of sodium thiosulfate and an inert absorbent

5. Use appropriate cleaning agent and method, working from the outer edge of the spill towards the centre. Ensure proper contact time from the disinfectant used.
6. Disposal: Dispose off all contaminated material (absorbent, PPs etc) in designated containers for chemical or biohazardous waste, following stablished protocols.
7. Documentation and reporting: Record the spill incident, including the materials involved, action taken, any injury or exposures.
8. Restock supplies: Replenish any spill kit material used during the clean-up process with fresh stock.

ANNEXURES

ANNEXURE I

LIST OF EQUIPMENT AT IPHL AND BPHL

A. Integrated Public Health Laboratory

Sl. No.	Equipment name
1	High pressure liquid chromatography (HPLC)
2	Chemiluminescence analyser
3	Nucleic Acid Amplification Machine
4	Automated antimicrobial susceptibility system (AST)
5	Automated Coagulation analyser
6	RT PCR machine
7	Automated Blood culture Machine
8	Flow Cytometer
9	ELISA Reader and Washer
10	Urine analyser
11	5-part Haematology analyser
12	Fully Automated Biochemistry Analyser
13	Automated ESR analyser
14	Electrolyte Analyser
15	Electrophoresis machine
16	Blood gas analyser
17	Immunofluorescent microscopy
18	Turbidometer
19	Binocular Microscope with LED illumination
20	Fluorometer
21	Digital Hemoglobinometer
22	Vortex mixer
23	VDRL rotator/shaker
24	Deep freezer
25	Hot air oven
26	Incubator

Sl. No.	Equipment name
27	Vertical Autoclave
28	Micropipettes
29	Histopathology equipment
30	Centrifuge
31	Microcentrifuge machine
Additionally, 13 type of Rapid Diagnostic Tests (RDTs) and other supporting equipment like pH meter, Needle destroyer etc.	

B. Block Public Health Laboratory

Sl. No	Equipment
1	Nucleic Acid Amplification Machine
2	Coagulation Analyzer
3	q-PCR System
4	ELISA Reader and Washer
5	3-part haematology Analyzer
6	Fully Automated Biochemistry Analyzer
7	ESR Analyzer
8	Electrolyte Analyser
9	Blood Gas analyser
10	Urine Analyzer (Semi-automated)
11	Turbidometer
12	Bio safety Cabinet (Class II)
13	Binocular Microscope with LED illumination
14	Digital Haemoglobinometer
15	Glucometer
16	HbA1C Analyser
17	Micropipettes
18	Incubator
19	Hot Air oven
20	Autoclave
Additionally, 11 type of Rapid Diagnostic Tests (RDTs) and other supporting equipment like pH meter, Needle destroyer etc.	

ANNEXURE II

D.O. LETTER FROM JS(POLICY) REGARDING ESSENTIAL EQUIPMENT/ DIAGNOSTICS AT AYUSHMAN AROGYA MANDIRS (AAM)

SAURABH JAIN, IAS
JOINT SECRETARY
Tele : 23062870
E-mail : js.policy-mohfw@gov.in

सत्यमेव जयते

आज़ादी का अमृत महोत्सव

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

D.O. No. Z.15015/17/2024-NHM-I
Dated 3rd October 2024

Dear Sir / Madam

The availability of essential medicines, diagnostics and medical equipment at Ayushman Arogya Mandir are vital to the delivery of comprehensive primary health care services. Although, most of the equipment and consumables are listed in IPHS 2022 and are components of various programmes/kits under NHM, it has been observed during the field visits that unavailability or improper mapping of essential equipment creates bottlenecks for the delivery of 12 packages.

2. In view of the above, a standard kit with a bag has been developed by MoHFW consisting of common medical equipment required for clinical examination tailored to the 12 packages. The list of equipment and indicative cost of standard kit for Medical Officers, Community Health Officers (CHOs), Auxiliary Nurse Midwives (ANMs) and Accredited Social Health Activists (ASHAs) is placed as Annexure.

3. As majority of the equipment are already available at AAM, only gap filling will be required along with Rs. 1500 per unit as cost of bag to house the equipment. I request the States/UTs to ensure the availability of all the diagnostics/equipment at all Ashman Aragua Mandir and any additional budget, if required, may be proposed under the FMRs pertaining to free diagnostics scheme.

With Regards,

Yours sincerely,

3/10/24

(Saurabh Jain)

Encls.: As above

To
Additional Chief Secretary/Principal Secretary/ Secretary (H&FW) - All States/UTs

Copy to:
1. Mission Director, National Health Mission -All States/UTs
2. PSO to Secretary (HFW), MoHFW
3. Sr PPS to AS MD
4. ED NHSRC

Room No. 246, A-Wing, Nirman Bhawan, New Delhi-110 011

DETAILS OF STANDARD EQUIPMENT KIT

A. MEDICAL OFFICER (MO) KIT AT AAM-PHC

A	Content Details
1	BP Apparatus (Digital)
2	Glucometer
3	Patient Health Questionnaire (PHQ-9)
4	Tongue depressor
5	Measuring Tape
6	Near Vision Chart
7	Thermometer (Digital)
8	LED Torch
9	Percussion Hammer
10	Angled Mouth Mirror
11	Tuning Fork (512 Hz)
12	Stethoscope
13	Pulse Oximeter (Fingertip)
14	Otoscope
15	Bag
16	Ophthalmoscope

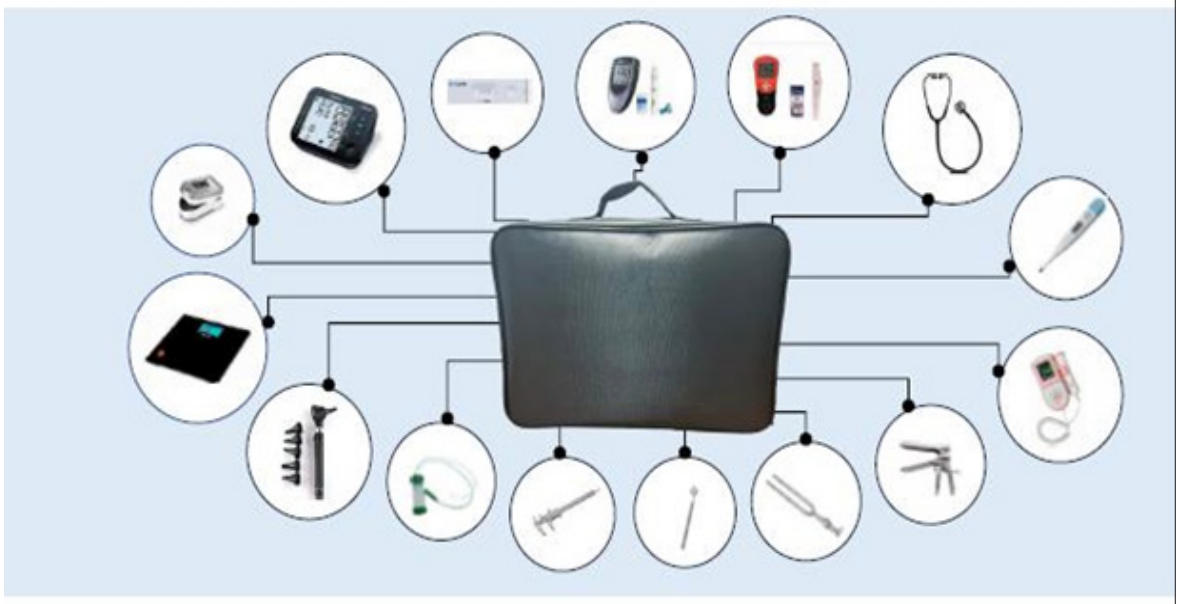
B	FOR COMMON CANCER SCREENING
1	Gloves
2	Cotton roll
3	Gauze
4	Distilled water (400 ml)
5	Bowl
6	Acetic Acid
7	Job Aids for Common Cancer Screening
8	Swab Sticks
9	Vernier Calipar
10	Cusco's Speculum

A. Community Health Officer (CHO)/ Medical Officer (MO) Kit Bag

Keep everything in one place: This bag helps store all the kit components in an organised way.

- Double padded
- Water-proof
- 2 Layered bag

Material used: The fabric used is Tetron 1680, a nylon-based fabric. Fiber inserts are used for rigidity and rubber sheets for a finished look. The bag is made of double-padded, waterproof material.



Pockets to hold multiple items so that even small items can have a dedicated storage pocket.

Padded dividers: Adjustable dividers help in creating the perfect space according to the requirement.

Sturdy handle to carry it easily. Also comes with an attachable sling.

COMMUNITY HEALTH OFFICER (CHO) KIT AT AAM-SHC

A	Content Details
1	BP Apparatus (Digital)
2	Glucometer
3	Hemoglobinometer
4	Patient Health Questionnaire (PHQ-9)
5	Tongue depressor
6	Measuring Tape
7	Mucus Extractor
8	Cord cutting Scissors
9	Near Vision Chart
10	Thermometer (Digital)
11	LED Torch
12	Angled Mouth Mirror
13	Fetoscope
14	Tuning Fork (512 Hz)
15	RDTs (Malaria, Dengue, Syphilis, HBsAg, Pregnancy, HIV, HCV)
16	Urine test kits (Dipstick)
17	Stethoscope
18	Pulse Oximeter (Fingertip)
19	Otoscope
20	Bag

B	FOR COMMON CANCER SCREENING
1	Gloves
2	Cotton roll
3	Gauze
4	Distilled water (400 ml)
5	Bowl
6	Acetic Acid
7	Job Aids for Common Cancer Screening
8	Swab Sticks
9	Vernier Calipar
10	Cusco’s Speculum

B. ANM Kit Bag

Keep everything in one place: This bag helps in storing all the components of the kit in an organised way.

- Double padded
- Water-proof
- 2 Layered bag

Material used: The fabric used is Tetron 1680, a nylon-based fabric. Fiber inserts are used for rigidity and rubber sheets for a finished look. The bag is made of double-padded, waterproof material.

- Bands to hold items in place and Mesh pockets to keep items visible and handy.
- Storage for PoC devices and larger equipment. Side straps to hold the items in place.
- Sturdy handle to carry it easily. Also comes with an attachable sling to carry it easily on the field.
- Side pockets for more storage.

B. ANM KIT AT AAM-SHC

A	Content Details
1	Digital BP Machine
2	Digital Glucometer
3	Digital HB meter
4	Digital Weighing Machine- Adult
5	Fetoscope
6	Urine Multi reagent Dipsticks

A	Content Details
7	Consumables for HB meter (HB strips)
8	Consumables for Glucometer (Glucometer strips)
9	Gel bottle for Fetal Doppler (200-250 ml)
10	HIV Syphilis dual kit + buffer bottle (30ml)
11	Digital Thermometer
12	Small ice pack place compartment (17.30x10.30x4.50 cms)
13	BMW section as one compartment 3 Polythene bag (Red, Yellow & Blue)
14	BMW section as one compartment (Hub Cutter- 10x6x6 cm)
15	3 pair of Gloves
16	Cotton roll
17	Sanitizer bottle (small) (100 ml)
18	Spirit bottle (60 ml)
19	MUAC Measurement Tape
20	Urine Pregnancy Test
21	Urine collection bottles (Min 5)
22	Measuring Tape (for abdominal exam)
23	EDD Wheel
24	ANMOL FAQ booklet
25	Register (ANC)
26	Pen, Pencil
27	MCP Cards
28	Bag

D. ACCREDITED SOCIAL HEALTH ACTIVIST (ASHA) KIT AT VILLAGE

SN	Content Details
1	Baby Feeding Spoon
2	Mucous Extractor
3	Thermometer
4	LED Torch
5	Baby Blanket
6	Digital Wrist Watch
7	Communication Kit (ASHA KUNJI)
8	Bag
9	Weighing scale for newborn (Salter Scale)

ANNEXURE III

MINIMUM TECHNICAL SPECIFICATIONS FOR MAJOR MEDICAL EQUIPMENT

LIST OF EQUIPMENT AT DH/IPHL LEVEL

S No	EQUIPMENT	REC TECH SPECS
1	MRI	1.5 Tesla
2	CT Scan	64 Slice
3	Digital X-ray Machine	500 mA
4	USG Machine	2D/ 3D
5	ECG Machine	12 Channel
6	High Pressure Liquid Chromatography (HPLC)	5 Parameters (HbA, HbA2, HbS, HbF, HbA1C)
7	Chemiluminescence Analyzer	Fully automated
8	Biochemistry analyzer	Fully automated
9	Hematology Analyzer	5 Part differential analyzer
10	Coagulation analyzer	Fully Automated (4-channel)
11	Electrolyte Analyzer	Ion-Selective Electrode Analyzer
12	Electrophoresis machine	Hb + Protein
13	Blood Gas Analyzer	Wet Blood Gas Analyzer
14	Blood culture system	Automated System depending on work load
15	Urine Analyzer	Automated
16	PCR machine	Quantitative PCR (qPCR)

LIST OF EQUIPMENT AT CHC/ BPHL LEVEL

S No	EQUIPMENT	REC TECH SPECS
1	Digital X-ray Machine	300 mA
2	USG Machine	2D-USG machine
3	ECG Machine	12 Channel
4	Biochemistry analyzer	Fully Automated
5	Hematology Analyzer	5 Part/ Fully automated
6	Coagulation analyzer	Semi-automated
7.	Urine Analyzer	Automated

S No	EQUIPMENT	REC TECH SPECS
8.	ESR analyser	Test: Manual with reading using ESR analyzer
9.	ELISA Reader & Washer	96-well
10.	Electrolyte analyser	Automated
11.	Microscope	Binocular Eye Piece LED
12.	Turbidometer	
13.	Multipara Monitor	5-parameter
14.	NAAT machine	TrueNat Duo/Quarto

LIST OF EQUIPMENT AT AAM-PHC LEVEL

S No	EQUIPMENT	REC TECH SPECS
1	Biochemistry Analyser	Semi-automated
2	Haematology Analyser	3-Part
3	Binocular Microscope	Binocular Microscope
4	NAAT Machine	TrueNat Duo

ANNEXURE IV

FACILITY-WISE RECOMMENDED ESSENTIAL IN-HOUSE LAB TESTS AND TESTS FOR OUTSOURCING

Facility Level	Equipment	Essential Tests at Health Facility	Sample Transport to Nearest Hub (PHC/CHC/DH)
AAM-SHC	Hb meter Glucometer RDTs Urine Dipstick	Haemoglobin Pregnancy Test Kit Urine dipstick test (10 parameter) Blood sugar (RBS) Malaria RDT HIV (Antibodies to HIV 1&2) Dengue test Kit (NS1) VIA Test HbsAg test for Hepatitis B Syphilis RDT Sickle Cell RDT Water testing for faecal contamination (H2S test) & chlorination (Paper Strip test)	Sputum for AFB DBS or whole blood with HPLC for screening positive Sickle cell disease Whole blood sample for haematology (CBC) & biochemistry tests as prescribed by MO/Specialist & for follow-up.

Facility Level	Equipment	Essential Tests at Health Facility	Sample Transport to Nearest Hub (CHC/DH)
AAM-PHC	• Hb meter • Glucometer • Haematology analyser (3-part) • Semi-biochemistry Analyser • Manual/ microscopy tests • Urine test • Microscope • RDTs	• Haemoglobin • CBC, Total leucocyte count, Differential leucocyte count, Platelet count • Blood group and Rh typing, BT and CT • Blood sugar, Glucose Tolerance Test (GTT) • S. Bilirubin (T), S. Bilirubin direct and indirect • Serum creatinine, Blood Urea, Uric acid, SGPT, SGOT, S. Alkaline Phosphatase • S. Total Protein, S. Albumin & AG ratio, S. Total Cholesterol, S. Triglycerides, S. VLDL, S.HDL, S. LDL	• Peripheral blood film, Reticulocyte count, Absolute eosinophil count, Erythrocyte sedimentation rate • Sickling Test for Sickle cell Anaemia, • Quantitative test for G6PD enzyme deficiency • Stool for Occult Blood, • Serum Calcium, Serum Sodium, S. Potassium • Prothrombin Time (PT), Activated partial thromboplastin time (APTT) • Urine for micro albumin, Urine Culture and antimicrobial sensitivity,

Facility Level	Equipment	Essential Tests at Health Facility	Sample Transport to Nearest Hub (CHC/DH)
		• Visual Inspection by Acetic Acid (VIA) • rK39 for Kala Azar, • TB – Mantoux, Sputum for AFB • MP slide method and Malaria rapid test • Human chorionic gonadotropin (HCG) • Urine test for pH, specific gravity, leucocyte esterase, glucose, bilirubin, urobilinogen, ketone, protein, nitrite; • Urine Microscopy, Urine for creatinine and Albumin to creatinine ratio (ACR), 24-hours urinary protein, • Stool for ova and cyst; • Test for Dengue, • RPR/VDRL test for syphilis, • HIV test (Antibodies 1/2 and HIV 1/2), Hepatitis B surface antigen test, HCV Antibody Test (Anti HCV) • Typhoid test (IgM)	• Smear for Filaria*, Smear for RTI/STD, Gram staining for clinical specimen, Throat swab for Diphtheria • RA factor (Quantitative), CRP (including new born) (Quantitative) • TSH (including for new-born screening), • Pap smear

Facility Level	Equipment	Essential Tests at Health Facility	Sample Transport to Nearest Hub (SDH/ DH)
CHC	• Hb meter • Haematology analyser (5 Part) • Glucometer • Biochemistry Analyser • Electrolyte Analyser (Indirect ion selective electrode) • Automated coagulation analyser	• Haemoglobin, Total leucocyte count, Differential leucocyte count, Platelet count, Complete blood count, Erythrocyte sedimentation Rate • Blood sugar, Glucose Tolerance test (GTT), 24-hours urinary protein, Urine for creatinine and Albumin to creatinine ratio (ACR), S. Bilirubin (T), S. Bilirubin direct and indirect, Serum creatinine, Blood Urea, SGPT, SGOT, S. Alkaline Phosphatase, S. Total Protein, S. Albumin & AG ratio, S. Globulin, S. Total Cholesterol, S. Triglycerides, S. VLDL S.HDL, S. LDL, S. GGT, S. Uric acid, S. Amylase, S. Iron, Total Iron binding capacity, Glycosylated	• Throat swab for Diphtheria, • Stool for hanging drop for Vibrio Cholera • Cytology, • Pap smear, • Histopathology, • Haemoglobin electrophoresis, • Blood culture, • Urine Culture, • Other cultures (pus, throat swab etc.) • Organism identification and antimicrobial sensitivity for cultures

Facility Level	Equipment	Essential Tests at Health Facility	Sample Transport to Nearest Hub (SDH/ DH)
	• Nucleic Acid Amplification Machine • RDTs • Microscope • Urine Analyzer • ESR analyser • ELISA Reader & Washer • Turbidometer	haemoglobin (HbA1C), Serum Calcium, RA factor (Quantitative), CRP (including new-born) • S. Sodium, S. Potassium, S. Magnesium; Prothrombin Time (PT) and INR, Activated partial thromboplastin time; • Nucleic Acid Amplification Test (NAAT) for TB, Early Infant Diagnostic test for HIV - Qualitative HIV-1 DNA PCR (ICTC) • Blood group and Rh typing, Human chorionic gonadotropin (HCG), Urine for micro albumin, Urine test for pH, specific gravity, leucocyte esterase, glucose, bilirubin, urobilinogen, ketone, protein, nitrite; Urine Microscopy, Stool for Occult Blood, Typhoid test (IgM), rK39 for Kala Azar • Blood cross matching, Reticulocyte count, Absolute eosinophil count, Bleeding time and clotting time, Stool for ova and cyst, Semen analysis, RPR/VDRL test for syphilis, Sputum, pus etc. for AFB, Smear for Filaria, TB – Mantoux, Troponin - I/ Troponin – T, Fibrinogen degradation products (FDP), D-Dimer, Coombs test direct with titre Coombs test indirect with titre • Sickling Test for screening of Sickle cell anaemia, Sickle cell RDT • NESTROFT Test for screening of Thalassemia • DCIP test for screening HbE • Quantitative test for G6PD enzyme deficiency, • Malaria (MP Slide),	• S.TSH (including for new-born screening), • S. Free T3, S. Free T4, • S. Ferritin, S. Beta HCG, Prolactin, S. Anti-Mullerian Hormone (AMH), Rubella IgG, Anti-cyclic citrullinated peptide (anti-CCP), • HIV test (Antibodies 1 and 2), Hepatitis B surface antigen test, HCV Antibody Test (Anti HCV), • Test for Dengue

Facility Level	Equipment	Essential Tests at Health Facility	Sample Transport to Nearest Hub (SDH/ DH)
		• Smear for RTI/STD, Gram staining for clinical specimen, Visual Inspection Acetic Acid (VIA)	

Facility Level	Equipment	Essential Tests at Health Facility	Sample Transport to Nearest Hub (SDH/ DH)
DH	• Hb meter • Haematology analyser (5 Part) • Glucometer • Biochemistry Analyser • Electrolyte Analyser (Indirect ion selective electrode) • Automated coagulation analyser • Nucleic Acid Amplification Machine • RDTs • Microscope • Cation Exchange High Pressure Liquid Chromatography (HPLC) • Chemiluminescence Analyzer • Blood Gas Analyzer • Blood culture system • Urine Analyzer • PCR machine	• Haemoglobin, Total leucocyte count, Differential leucocyte count, Platelet count, Complete blood count, CSF analysis (Glucose, CSF protein, ADA, cell count), Fluid analysis (Cell count, biochemistry including Glucose, Protein, LDH and cytology) • Blood sugar, Glucose Tolerance test (GTT), 24-hours urinary protein, Urine for creatinine and Albumin to creatinine ratio (ACR), S. Bilirubin (T), S. Bilirubin direct and indirect, Serum creatinine, Blood Urea, SGPT, SGOT, S. Alkaline Phosphatase, S. Total Protein, S. Albumin & AG ratio, S. Globulin, S. Total Cholesterol, S. Triglycerides, S. VLDL S.HDL, S. LDL, S. GGT, S. Uric acid, S. Amylase, S. Iron, Total Iron binding capacity, S. LDH, Glycosylated haemoglobin (HbA1C), Serum Calcium, RA factor (Quantitative), CRP (including new-born); • S. Sodium, S. Potassium, S. Ionised Calcium, S. Chloride, S. Magnesium; Prothrombin Time (PT) and INR, activated partial thromboplastin time, Mixing study and Factor VIII Assay for Hemophilia, Arterial blood gas test, • Nucleic Acid Amplification Test (NAAT) for TB, Early Infant Diagnostic test for HIV - Qualitative HIV-1 DNA PCR (ICTC) • Blood group and Rh typing, Human chorionic gonadotropin (HCG), Urine for micro albumin, Urine test for pH, specific gravity, leucocyte esterase, glucose, bilirubin, urobilinogen, ketone, protein, nitrite; Urine Microscopy, Stool for Occult Blood, Typhoid test (IgM), rK39 for Kala Azar	

Facility Level	Equipment	Essential Tests at Health Facility	Sample Transport to Nearest Hub (SDH/ DH)
		• HIV test (Antibodies 1 and 2), Hepatitis B surface antigen test, HCV Antibody Test (Anti HCV), IgM antibody to hepatitis B core antigen (IgM anti-HBc), Rapid antigen detection test for Bacterial meningitis, S. Procalcitonin, S. PSA, S. Vitamin B12, S. Vitamin D, TORCH IgM and IgG, S. Thyroid peroxidase antibody, ANA, CD4 count, Viral load count for HCV, Viral load count for HBV, Quantitative virological nucleic acid test for HIV, Test for drug overdose	

ANNEXURE V

MAPPING OF LABORATORY EQUIPMENT AND THEIR REAGENTS

REAGENT CATEGORY	EQUIPMENT	REAGENTS & CONSUMABLES	AU	TESTS
Rapid Kits	Hemoglobinometer	Hb Strip	Number	haemoglobin
	Glucometer	Glucometer Strip	Number	Blood Sugar
	Nil	Malaria test kit	Number	Malaria
	Nil	Dengue Rapid kit	Number	Dengue
	Nil	HIV (Antibodies to HIV 1&2) kit	Number	HIV
	Nil	HbsAg test for Hepatitis B	Number	HbsAg
	Nil	Dual Kit for Screening of HIV and Syphilis Test kit	Number	HIV & Syphilis
	Nil	Sickle Cell Rapid Kits	Number	Sickle Cell
Haematology	Haematology Analyser	BC-3000 Agappe Diluent	ml	Common reagents and consumables for performing the tests listed as- CBC with 24 parameters (BASO, WBC, LYM, MON, NEU, EOS, BAS, LYM%, MON%, NEU%, EOS%, BAS%, RBC, HCT,MCV, RDW-SD, RDW-CV, HGB, MCH, MCHC, PLT, PCT, MPV, PDW-SD, PDW-CV.)
		BC-3000 Agappe E2 cleaner		
		BC-3000 Agappe Lyse		
		BC-3000 Agappe probe cleaner		
		BC-3000 Agappe Rinse		
		Haematology External QC Haematology Internal QC	-	
	ESR Analyser	Sodium Citrate (3.8% or 4%)	ml	Erythrocyte sedimentation rate
	Manual	Blood grouping sera Anti D	ml	**Common reagents for performing the test:** Blood group and Rh typing
		Blood grouping sera Anti B		
		Blood grouping sera Anti A		
	Automated coagulation analyser	Neoplastine (PTINR)	ml	Prothrombin Time,
	Microscope	Giemsa stain	ml	Activated Partial Thromboplastin Time,
		Leishman stain	ml	Thrombin Time
		Coombs Reagent	ml	Peripheral Blood Film
		D-10 haemoglobin A1c Program	ml	Coombs Test (Direct and Indirect with Titre)

	High pressure liquid chromatography (HPLC)	HbA1C direct 20	ml	Haemoglobin Electrophoresis
			ml	HbA1C test
Biochemistry	Biochemistry Analyser	Glucose -AU 680	ml	Blood Sugar
		Total Bilirubin- AU680	ml	S. Bilirubin (Total)
		Direct Bilirubin- AU680	ml	S. Bilirubin (Direct, and Indirect)
		Creatinine- AU680	ml	Serum Creatinine
		Urea- AU680	ml	Blood Urea
		SGPT(XL)	ml	SGPT
		SGOT(XL)	ml	SGOT
		Alkaline phosphatase - AU680	ml	S. Alkaline Phosphatase
		Total protein- AU680	ml	S. Total Protein
		Albumin- AU680	ml	S. Albumin
		Test kit Albumin	ml	AG Ratio
		Erba Biochemistry kit	ml	S. Globulin
		Cholesterol- AU680	ml	S. Total Cholesterol
		Triglyceride- AU680	ml	S. Triglycerides
		LDL (XL)	ml	S. VLDL
		HDL Cholesterol- AU680	ml	S. HDL
		Liquid Reagent LDL Cholesterol Kit (DIRECT)	ml	S. LDL
		Coral Gamma Glutamyl Transferase (GGT) Biochemistry Reagent	ml	S. GGT
		Uric acid- AU680		S. Uric Acid
		Erba Biochemistry kit	ml	S. Amylase
			ml	S. Iron
			ml	S. Total Iron Binding Capacity
			ml	24-Hours Urinary Protein
			ml	Fluid analysis (Cell count, biochemistry including Glucose, Protein, LDH and cytology)
		Test kit for LDH	ml	S. LDH
	Electrolyte Analyser	Reagent Pack (Cal A, Cal B)	ml	**Single reagents pack for performing the tests:** S. Calcium
				S. Sodium
				S. Potassium

				S. Ionised Calcium
				S. Chloride
				S. Magnesium
		Washing Solution (Activation) Washing Solution (Cleaning) Washing Solution (Deproteinizer) Linearity Control Materia	-	-
	Arterial Blood Gas Analyser	Blood Gas Reagent Pack	ml	**Multiple reagents pack for performing the test:** Arterial Blood Gas Test
		Electrodes conditioner	ml	
		Refill solution for ISE electrodes (K/Na/Cl/Ca/pH),	ml	
	Chemiluminescence Analyser (CLIA)	Ferritin-Roche assay	ml	S. Ferritin
		Beta HCG assay	ml	S. Beta HCG
		Prolactin-Beckman assay	ml	Prolactin
		AMH Roche assay	ml	S. Anti-Mullerian Hormone (AMH)
		AFP-Calset-Roche	ml	S. Alfa Feto Protein
		CA-125 assay-Roche	ml	S. CA-125
		CA-125-Roche-Calset		
		CEA-Roche	ml	S. CEA
		CEA-Roche-calset		
		PSA-Beckman assay	ml	S. PSA
		Vitamin B12-Roche assay	ml	S. Vitamin B12
		Vitamin-B12-Roche-calset		
		Vitamin D-Beckman	ml	S. Vitamin D
		Anti TPO-Beckman	ml	S. Thyroid Peroxidase Antibody
		Anti-CCP	ml	Anti-Cyclic Citrullinated Peptide (Anti-CCP)
		TSH-Beckman	ml	S. TSH (Including for New-Born Screening)
		Free T3- Beckman	ml	S. Free T3
		Free T4- Beckman	ml	S. Free T4
		Torch reagent	ml	TORCH IgM and IgG
Microbiology	Binocular Microscope LED	Culture Media	mg	Urine Culture
		Culture Media	ml	Fungal Culture

		KOH solution (for preparing direct mounts)	ml	
		Culture Media	mg	Other Cultures (Pus, Throat Swab, etc.)
		Culture Media	mg	Culture for Diphtheria
		Culture Media	mg	Fungal Culture
	Automatic Blood Culture Machine	Blood culture bottle Adult/Paediatric	ml	Blood Culture
Serology	Flow Cytometer	BD FACSCount™ CD4 Reagents	Number	CD4 Count
	PCR	HCV PCR	ml	Viral Load Count for HCV
		HBV PCR	ml	Viral Load Count for HBV
	NAAT (Truant/CBNAAT)	Card Based	Number	Nucleic Acid Amplification Test (NAAT) for TB
		Card based	Number	Early Infant Diagnostic Test for HIV - Qualitative HIV-1 DNA PCR (ICTC)
		Card based	Number	Quantitative Virological Nucleic Acid Test for HIV
Cytology & Histopathology	Microscope	Pap Stain	ml	Cytology
				Pap Smear
	Microtome	Slide filing cabinet	Number	**Multiple reagents are required for performing the test:** Histopathology
		Isopropyl alcohol	ml	
		Xyline	ml	
		Formalin	ml	Immunohistochemistry
				Bone Marrow Examination
		Paraffin wax	kg	
		Embedding O ring	Number	
		Tissue capsule - Plastic	Number	
		Tissue capsule - Steel	Number	
		Microtome blade	Number	

ANNEXURE VI

RECOMMENDED SAMPLE STORAGE AND TRANPSORTATION

S No	Test	Sample Type	Vacationer Color	Fasting Required	Collection Method & Volume	Storage	Transport	Indications	Special Precautions	Storage Duration
1	CBC	Venous Blood	Lavender (EDTA)	No	Venipuncture, 2-5 mL	Room Temp (if processed with in few hours) 2-8°C if delayed	Immediate; 2-8°C if delayed	Fatigue, weakness, Fever, Inflammation, Bruising, or bleeding and treatments, such as chemotherapy or radiation therapy	Mix with anticoagulant, avoid haemolysis	Process within 6 hours, 24 hours if refrigerated
2	Blood Sugar	Venous Blood	Gray (Sodium Fluoride, Potassium Oxalate)	Yes (for fasting test)	Venipuncture, 2-3 mL	Room Temp (if there processed within an hour) 2-8°C if delayed	Immediate; 2-8°C if delayed	Screening/monitoring diabetes, pre-diabetes symptoms of hyper/hypoglycemia	Confirm fasting for fasting test, avoid haemolysis	Process within 1 hour, 72 hours if refrigerated
3	RFT	Venous Blood	Red/Yellow (Serum Separator)	No	Venipuncture, 3-5 mL	2-8°C if not processed immediately	Immediate; 2-8°C if delayed	Assess kidney function, monitor kidney diseases, Hypertension, diabetes	Avoid haemolysis, process promptly	Process within 1-2 hours; 48 hours if refrigerated
4	LFT	Venous Blood	Red/Yellow (Serum Separator)	Preferred (optional)	Venipuncture, 5 mL	2-8°C if not processed immediately	Immediate; 2-8°C if delayed	Assess liver function, diagnose liver diseases, monitor treatment, evaluating effect of medication	Avoid haemolysis, process promptly	Process within 4-6 hours; 48 hours if refrigerated
5	HbA1c	Venous Blood	Lavender (EDTA)	No	Venipuncture, 2-5 mL	Room Temp (if processed within few days) 2-8°C if delayed	Prompt; refrigerate if delayed	Monitor long-term glucose control, diagnose diabetes , pre- diabetes assessing risk diabetes complication	Mix with anticoagulant, avoid haemolysis	Process within 7 days; 2 weeks if refrigerated
6	Sputum Test	Sputum	Sterile Container	No	Collect 5-10 mL in sterile ontainer	Room Temp (if processed within 1-2 hours) 2-8°C if delayed	Immediate; 2-8°C if delayed	Diagnose respiratory infections	Ensure sputum, not saliva; collect under supervision	Process within 2 hours; 24 hours if refrigerated
7	Semen Analysis	Semen	Sterile Container	No	Collect 1.5-5 mL by masturbation	Room Temp and processed within 1 hour	Within 1 hour, keep at body temp	Evaluate male fertility, assess vasectomy results Investigating suspected cases of azoospermia or oligospermia	Keep at body temp, avoid contamination	Process within 1 hour, affects motility if delayed
8	Pap Test	Cervical Cells	No Vacutainer	No	Collect with brush/spatula, N/A	Sample usually fixed on a slide immediately and does not require cold storage. Liquid- based cytology samples should be stored at room temp.	Room Temp in slide container or preservative medium	Screen for cervical cancer, detect precancerous conditions	Avoid contamination, process promptly	Fixed slides can bestored indefinitely if properly fixed and Protected. Liquid- based samples should be processed within 2-4 weeks

S No	Test	Sample Type	Vacationer Color	Fasting Required	Collection Method & Volume	Storage	Transport	Indications	Special Precautions	Storage Duration
9	Urine Tests	Urine	Sterile Container	No (varies)	Midstream clean-catch, 10-20 mL	Room Temp (if processed within 2 hours) 2-8°C if delayed	Immediate; 2-8°C if delayed	Screen metabolic/ kidney disorders, diagnose UTIs, Detecting substances or drugs	Ensure clean-catch sample, proper labelling	Process within 2 hours; 24 hours if refrigerated
10	Lipid Profile	Venous Blood	Red/Yellow (Serum Separator)	Yes (9-12 hours)	Venipuncture, 5 mL	2-8°C if not processed immediately	Immediate; 2-8°C if delayed	Assess cardiovascular risk, monitor lipid therapy diagnose lipid metabolism disorders	Confirm fasting, avoid haemolysis	Process within 2 hours; 48 hours if refrigerated
11	Electrolytes	Venous Blood	Red/Green (Lithium Heparin)	No	Venipuncture, 3-5 mL	Room Temp (immediate); 2-8°C if delayed	Immediate; 2-8°C if delayed	Diagnose electrolyte imbalances, monitor fluid balance/kidney	Avoid haemolysis, process promptly	Process within 1 hour; 24 hours if refrigerated
12	Thyroid Assay	Venous Blood	Red/Yellow (Serum Separator)	No	Venipuncture, 3-5 mL	2-8°C if not processed immediately	Immediate; 2-8°C if delayed	Evaluate thyroid function, diagnose thyroid disorders, monitor thyroid treatment, assess fertility, investigate pregnancy-related issues.	Avoid thyroid medications before test	Stable for 7 days at 4°C
13	D-Dimer	Venous Blood	Light Blue (Sodium Citrate)	No	Venipuncture, 2-3 mL	Room Temp (if immediate); 2-8°C if delayed	Immediate; 2-8°C if delayed	Assess clotting disorders, detect DVT, PE, or DIC	Mix with anticoagulant, avoid haemolysis	Process within 4 hours; 24 hours if refrigerated
14	CRP (C-Reactive Protein)	Venous Blood	Red/Yellow (Serum Separator)	No	Venipuncture, 3-5 mL	2-8°C if not processed immediately	Immediate; 2-8°C if delayed	Diagnose inflammation, monitor infection or autoimmune disorders	Avoid haemolysis, process promptly	Process within 1-2 hours; 48 hours if refrigerated
15	Prothrombin Time (PT)	Venous Blood	Light Blue (Sodium Citrate)	No	Venipuncture, 2-3 mL	Room Temp (if processed within a few hours); 2-8°C if delayed	Immediate; 2-8°C if delayed	Evaluate clotting function, monitor anticoagulant therapy	Mix with anticoagulant, avoid haemolysis	Process within 4 hours; 24 hours if refrigerated
16	ESR (Erythrocyte Sedimentation Rate)	Venous Blood	Lavender (EDTA)	No	Venipuncture, 2-3 mL	Room Temp (if immediate); 2-8°C if delayed	Immediate; 2-8°C if delayed	Diagnose inflammation, monitor autoimmune diseases or infections	Mix with anticoagulant, avoid haemolysis	Process within 6 hours; 24 hours if refrigerated
17	Vitamin D	Venous Blood	Red/Yellow (Serum Separator)	No	Venipuncture, 3-5 mL	Room Temp (if processed within hours); 2-8°C if delayed	Immediate; 2-8°C if delayed	Assess Vitamin D deficiency, monitor bone health, and calcium metabolism	Avoid haemolysis, process promptly	Process within 1 hour; 48 hours if refrigerated
18	Ferritin	Venous Blood	Red/Yellow (Serum Separator)	No	Venipuncture, 3-5 mL	Room Temp (if immediate); 2-8°C if delayed	Immediate; 2-8°C if delayed	Evaluate iron storage, diagnose anemia, assess iron deficiency or overload	Avoid haemolysis, process promptly	Process within 1-2 hours; 48 hours if refrigerated
19	Iron Studies	Venous Blood	Red/Yellow (Serum Separator)	No	Venipuncture, 3-5 mL	Room Temp (if immediate); 2-8°C if delayed	Immediate; 2-8°C if delayed	Assess iron deficiency, monitor iron overload conditions (e.g., hemochromatosis)	Avoid haemolysis, process promptly	Process within 1-2 hours; 48 hours if refrigerated

S No	Test	Sample Type	Vacationer Color	Fasting Required	Collection Method & Volume	Storage	Transport	Indications	Special Precautions	Storage Duration
21	PSA (Prostate-Specific Antigen)	Venous Blood	Red/Yellow (Serum Separator)	No	Venipuncture, 3-5 mL	Room Temp (if processed within hours); 2-8°C if delayed	Immediate; 2-8°C if delayed	Screen for prostate cancer, monitor treatment or recurrence	Avoid haemolysis, process promptly	Process within 1-2 hours; 48 hours if refrigerated
22	Troponin	Venous Blood	Red/Yellow (Serum Separator)	No	Venipuncture, 3-5 mL	2-8°C if not processed immediately	Immediate; 2-8°C if delayed	Diagnose heart attack (myocardial infarction), monitor heart muscle damage	Avoid haemolysis, process promptly	Process within 4-6 hours; 48 hours if refrigerated
23	Amylase	Venous Blood	Red/Yellow (Serum Separator)	No	Venipuncture, 3-5 mL	2-8°C if not processed immediately	Immediate; 2-8°C if delayed	Diagnose pancreatitis, assess pancreatic function	Avoid haemolysis, process promptly	Process within 1-2 hours; 48 hours if refrigerated
24	Lipase	Venous Blood	Red/Yellow (Serum Separator)	No	Venipuncture, 3-5 mL	2-8°C if not processed immediately	Immediate; 2-8°C if delayed	Diagnose pancreatitis, assess digestive enzyme activity	Avoid haemolysis, process promptly	Process within 1-2 hours; 48 hours if refrigerated
25	Blood Culture	Venous Blood	Sterile Container	No	Venipuncture, 10 mL per bottle (2 sets)	Room Temp (do not refrigerate)	Transport to lab immediately	Detect bacterial or fungal infection in the bloodstream	Ensure sterile collection	Incubated immediately; culture results in 24-72 hours
26	Malaria Parasite Test	Venous Blood	Lavender (EDTA)	No	Venipuncture, 2-5 mL	Room Temp (if processed within a few hours); 2-8°C if delayed	Immediate; 2-8°C if delayed	Detect malaria parasites in the blood	Avoid hemolysis, prepare thick/thin smear	Process immediately or within 6 hours
27	Dengue NS1 Antigen	Venous Blood	Red/Yellow (Serum Separator)	No	Venipuncture, 3-5 mL	2-8°C if not processed immediately	Immediate; 2-8°C if delayed	Early detection of dengue virus during the acute phase	Avoid hemolysis, process promptly	Process within 1-2 hours; 48 hours if refrigerated
28	Dengue IgM/IgG	Venous Blood	Red/Yellow (Serum Separator)	No	Venipuncture, 3-5 mL	2-8°C if not processed immediately	Immediate; 2-8°C if delayed	Diagnose recent or past dengue infection	Avoid hemolysis, process promptly	Process within 1-2 hours; 48 hours if refrigerated
29	Typhoid (Widal Test or TyphiDot)	Venous Blood	Red/Yellow (Serum Separator)	No	Venipuncture, 3-5 mL	2-8°C if not processed immediately	Immediate; 2-8°C if delayed	Diagnose typhoid fever caused by Salmonella typhi	Avoid hemolysis, process promptly	Process within 1-2 hours; 48 hours if refrigerated
30	Leptospira IgM Antibody	Venous Blood	Red/Yellow (Serum Separator)	No	Venipuncture, 3-5 mL	2-8°C if not processed immediately	Immediate; 2-8°C if delayed	Diagnose leptospirosis, especially in cases of fever with a history of exposure to contaminated water	Avoid hemolysis, process promptly	Process within 1-2 hours; 48 hours if refrigerated
31	PCR for Viral Infections	Nasal/Throat Swab or Blood	Sterile Container	No	Swab or Venipuncture, 2-5 mL	Room Temp (if processed immediately); 2-8°C if delayed	Immediate; 2-8°C if delayed	Detect viral infections like influenza, COVID-19, or others via molecular testing (PCR)	Use viral transport media for swabs	Process within 24-48 hours

S No	Test	Sample Type	Vacationer Color	Fasting Required	Collection Method & Volume	Storage	Transport	Indications	Special Precautions	Storage Duration
33	CSF Analysis (Culture, Cell Count, Protein, Glucose)	CSF	Sterile Container	No	Lumbar puncture, 1-5 mL	Room Temp (if processed immediately); 2-8°C if delayed	Immediate; 2-8°C if delayed	Diagnose meningitis, encephalitis, or other central nervous system infections	Ensure sterile collection, process promptly	Process within 1-2 hours; culture results within 24-72 hours
34	Peripheral Blood Smear	Venous Blood	Lavender (EDTA)	No	Venipuncture, 2-5 mL	Room Temp (if processed within a few hours); 2-8°C if delayed	Immediate; 2-8°C if delayed	Diagnose malaria, dengue, or other blood-borne infections through microscopic examination	Avoid hemolysis, prepare smear immediately	Process immediately or within 6 hours
35	HIV (Rapid/ELISA)	Venous Blood	Red/Yellow (Serum Separator)	No	Venipuncture, 3-5 mL	Room Temp (if processed immediately); 2-8°C if delayed	Immediate; 2-8°C if delayed	Screen for HIV infection, especially in cases of fever with risk factors or unexplained weight loss	Avoid hemolysis, process promptly	Process within 1-2 hours; 48 hours if refrigerated
36	Tuberculosis (TB) Test (Mantoux or IGRA)	Blood/ Sputum /CSF	Sterile Container	No	Venipuncture for IGRA; Sputum or CSF for culture	Room Temp (for IGRA), Sputum at 2-8°C	Immediate, 2-8°C if delayed	Diagnose TB in patients with chronic fever, cough, or weight loss	Avoid contamination, proper storage	IGRA: Process within 8 hours; Sputum within 24 hours
37	Leishmaniasis (rK39 Antigen)	Venous Blood	Red/Yellow (Serum Separator)	No	Venipuncture, 3-5 mL	Room Temp (if processed immediately); 2-8°C if delayed	Immediate; 2-8°C if delayed	Diagnose visceral leishmaniasis in patients with prolonged fever and weight loss	Avoid hemolysis, process promptly	Process within 1-2 hours; 48 hours if refrigerated
38	Scrub Typhus IgM	Venous Blood	Red/Yellow (Serum Separator)	No	Venipuncture, 3-5 mL	2-8°C if not processed immediately	Immediate; 2-8°C if delayed	Diagnose scrub typhus in patients with fever and rash, especially after exposure to forested areas	Avoid hemolysis, process promptly	Process within 1-2 hours; 48 hours if refrigerated
39	Rheumatoid Factor (RF)	Venous Blood	Red/Yellow (Serum Separator)	No	Venipuncture, 3-5 mL	2-8°C if not processed immediately	Immediate; 2-8°C if delayed	Diagnose rheumatoid arthritis, particularly in patients with joint pain and fever	Avoid hemolysis, process promptly	Process within 1-2 hours; 48 hours if refrigerated
40	Hepatitis Panel (A, B, C)	Venous Blood	Red/Yellow (Serum Separator)	No	Venipuncture, 3-5 mL	2-8°C if not processed immediately	Immediate; 2-8°C if delayed	Diagnose viral hepatitis in patients with fever, jaundice, and liver dysfunction	Avoid hemolysis, process promptly	Process within 1-2 hours; 48 hours if refrigerated

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