ETHIOPIAN ESSENTIAL HEALTH LABORATORY DIAGNOSTICS LIST

Ethiopian Public Health Institute

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National Essential Health Laboratory Diagnostics List

First Edition

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Foreword

The National Essential Laboratory Diagnostics List (NELDL) for Ethiopia is a comprehensive and essential resource that stands as a testament to the Ethiopian Public Health Institute's commitment to advance the availability and accessibility of essential laboratory diagnostics in the country. This document is the result of dedicated efforts from all stakeholders and partners, and its creation marks a significant milestone in our journey towards improving the provision of quality healthcare services.

The primary aim of this document is to streamline and optimize diagnostic practices across the healthcare tier system and landscape of Ethiopia. By identifying a carefully curated list of essential laboratory diagnostics (ELDL), the institute aspires to standardize laboratory testing services that need to be offered at the different tiers of the healthcare delivery system, along with strengthening supporting systems such as specimen referral linkages and transportation systems to ensure equitable access for all communities to essential diagnostic services. The preparation of this NELDL underscores the unwavering dedication of the institute to advance the provision of quality laboratory services in the country, and its successful implementation is believed to promote the quality of healthcare services and improve patient outcomes.

The development of this document involved a rigorous and collaborative process, with experts from various professional disciplines and stakeholders contributing their invaluable insights. Through extensive public health facility assessments, document reviews, thoughtful deliberations, and evidence-based decision-making, it was possible to develop comprehensive lists of essential laboratory tests that are relevant to the needs of clinical care and treatment services provided at the different tiers of the country's health system.

Implementation of the NELDL will mark a significant turning point in improving the quality of healthcare services provided across all tiers of the health system. By incorporating and prioritizing these essential diagnostics into routine practice, we envision quicker and more accurate diagnoses, leading to improved treatment decisions and monitoring of effectiveness, and ultimately, better patient outcomes. Additionally, this document has the potential to guide resource allocation, ensuring that our healthcare infrastructure is optimized to deliver these vital services effectively and efficiently.

As we embrace the opportunities presented by the NELDL, we recognize its potential to revolutionize the scope of laboratory service delivery and contribute to the overall well-being of our citizens. This document goes beyond a mere list of essential laboratory diagnostics; it embodies and symbolizes our shared commitment to build healthier Ethiopians. We understand that the NELDL is a living document requiring regular reviews and updates to remain relevant in with rapidly changing world of laboratory medicine. As innovations and advancements of invitro diagnostic technologies continue, the list of essential laboratory diagnostics will also evolve, adapting to new challenges and emerging needs.

We extend our gratitude to all those who have contributed to the development of this crucial document and look forward to witnessing its positive impact on the health and well-being of our people.

Mesay Hailu (Ph.D.)
Director General,
Ethiopian Public Health Institute.

Message from the Deputy Director General for Health Laboratory Services

It's with great pleasure that I emphasize the importance of implementing NELDL to promote the availability and accessibility of quality diagnostic testing services in Ethiopia. The NELDL for Ethiopia is a strategic tool designed to prioritize the introduction and implementation of essential laboratory diagnostic tests at the different tiers of the healthcare service delivery system while ensuring equitable access for all in need. The compilation and publication of this comprehensive NELDL marks a significant milestone in the country's efforts towards the development of a resilient, sustainable and responsive national health laboratory system. Informed by rigorous consultations and expert insights, this document is carefully designed to align with the national strategy for improving the accessibility and quality of laboratory diagnostic services through enhancing health facility infrastructure, including equipping with appropriate diagnostic technologies and analytical system, improving supply chain management system, strengthening specimen referral system and building the capacity of human resource at all levels of the country's healthcare service delivery system.

Along with the recently published Strategic Plan for Health Laboratory System (2023-2027), this document is believed to promote our collective commitments to fostering collaborations and partnerships across governmental, non-governmental, and partner institutions towards achieving the anticipated milestones and ultimate goals well within the plan's implementation period. The NELDL helps to ensure that limited resources are directed towards high-impact testing services for clinical and public health interventions like disease prevention, diagnosis, care and treatment, and monitoring of health outcomes. At the implementation level, systematic alignment and integration of strategies and activities is crucial for optimized use of resources and harmonized advancement of the national laboratory system and is recognized as the best approach to harnessing the full potential of all our health laboratory programs towards ensuring equitable access to quality diagnostics for all Ethiopians. The successful implementation of the NELDL does not only significantly contribute to the improvement of equitable access to quality healthcare services but also allows for evidence-based decision-making for the informed formulation of healthcare policies and strategies that would guide the development and strengthening of responsive systems to address current and emerging health challenges.

I extend my heartfelt gratitude to the tireless efforts of individual experts and organizations who have contributed to the realization of this essential document. A special commendation is

due to the National Laboratory Capacity Building Directorate for their leadership and dedication in spearheading the development of the NELDL document. I would also like to use this opportunity to express the unwavering commitment of my office to do whatever is in its power to lead and coordinate all efforts for the seamless implementation of this very important initiative towards improving the availability and accessibility of quality laboratory diagnostic services to all Ethiopian citizens at all times.

Saro Abdella (Ph.D.)

Deputy Director General for Health Laboratory Services,

Ethiopian Public Health Institute.

Acknowledgements

The Ethiopian Public Health Institute would like to express its acknowledgements to all individuals and organizations that have made immense professional contributions to the successful development of this National Essential Health Laboratory Diagnostics List.

The institute would also like to express its sincere appreciation and thanks to regional health bureaus and all stakeholders involved for their generous provision of technical support. Lastly, special thanks goes to FIND for their technical and financial support at every stage of the document's preparation.

Executive Summary

The NELDL for Ethiopia is a document, which outlines the key essential laboratory tests that should be available at different tiers of public healthcare facilities and easily accessible to all healthcare service providers for informed clinical decisions and patient management. The development of the NELDL is also aimed at facilitating the introduction and implementation of essential tests to support public health related survey and surveillance activities for early detection of disease outbreaks and aversion of potential public health emergencies. Prioritizing essential laboratory diagnostics helps optimize resource allocation, ensuring that limited resources are directed towards high-impact testing services for clinical and public health interventions. Furthermore, it facilitates a standardized approach to quality healthcare service delivery, enhancing consistency and equity in service provision.

The NELDL document also guides policy development, enabling evidence-based decision-making and fostering alignment with international laboratory quality standards and best practices. Thus, the document is designed to serve as a roadmap for improving the availability and accessibility of quality laboratory testing services to all in need through effective planning and implementation at all levels of the healthcare service delivery system in the country. This executive summary provides an overview of the NELDL document of its aim, component, structure, the strategies of its implementation and the expected outcomes.

The aim: The NELDL document aims to prioritize essential laboratory diagnostic tests that need to be available and routinely performed at different levels of public healthcare facilities for accurate patient diagnosis, monitoring the effectiveness of care and treatment services and prognosis of health outcomes. The National List is also aimed at guiding the development of strategies and operational plans for the promotion of quality diagnostic services through enhancing health facility infrastructure including, equipping with appropriate diagnostic technologies, improving supply chain management system, strengthening specimen referral and transportation system and building the capacity of human resource, among other key laboratory programs. The NELDL is believed to serve as an invaluable tool for resource mobilization and evidence-based allocation for the advancement of laboratory diagnostic services across the nation's public healthcare facilities.

Key components and structure: The NELDL covers a comprehensive list of essential diagnostics, encompassing the areas of disease prevention, diagnosis, and curative care and treatment. It incorporates findings from public health facility assessments, desk reviews on testing needs of programs and inputs from various stakeholders, including healthcare professionals, and experts from relevant fields. The document is structured in a user-friendly manner; categorizing diagnostics based on laboratory disciplines, healthcare levels, and targeted populations. Additionally, it provides guidance and recommendations for the development of implementation strategies, a quality assurance system, and monitoring and evaluation mechanisms.

The NELDL implementation strategy: The implementation strategies described in this document were developed based on the findings obtained from public healthcare facility assessments. Key steps followed in the development of the NELDL implementation strategies included aligning objectives with desired outcomes, identifying inputs, developing activity and process work plans, defining outputs, determining expected outcomes and impacts, and setting measurable indicators. Key elements for implementation, among others, include procuring the necessary equipment, training laboratory professionals, enhancing the supply chain management system for reagents and consumable supplies, implementing robust quality assurance programs, and strengthening specimen referral and transportation system. Regional health bureaus will support the implementation of the strategies by mobilizing resources and aligning with regional health priorities. The smooth and effective implementation of the strategies is believed to help achieve the desired outcomes and impacts.

Expected outcomes: The proper implementation of the NELDL at all levels of the healthcare service delivery system offers several benefits and potential positive impacts. Some of these include:

- Improved Disease Detection and Management: The availability of essential laboratory tests will enable the timely and accurate diagnosis of a wide spectrum of diseases, including infectious diseases like malaria, tuberculosis, and HIV/AIDS. Early detection allows for prompt initiation of treatment, reducing morbidity and mortality rates.
- Enhanced Treatment Decisions: Accurate and reliable results from essential diagnostic tests guide healthcare providers in making informed care and treatment decisions.

Tailoring treatment to individual patient profiles results in better health outcomes and reduces the likelihood of inappropriate or ineffective treatments.

- Enhanced Quality of Care: Access to essential laboratory diagnostics enhances the quality of patient care by providing clinicians with reliable information to guide their medical decisions and patient management. This ultimately leads to better patient outcomes and improved patient satisfaction.
- Reduced Disease Burden: By facilitating early detection and timely initiation of appropriate treatment, essential diagnostic tests can contribute to lowering the overall disease burden in Ethiopia. This reduction has a cascading effect on public health, lessening the strain on healthcare facilities and resources.
- Focused Public Health Interventions: Accurate diagnostic data generated from essential diagnostic tests provides insights into the epidemiology of diseases such as incidence, prevalence, distribution, and trends. This information supports targeted public health interventions, such as vaccination campaigns and disease control programs.
- Strengthened Healthcare System: The implementation of ELDL fosters the development of a resilient and sustainable health system that features a well-structured laboratory diagnostic network spanning different levels of the healthcare system, a functional system for specimen referral linkage and testing services, improved overall healthcare infrastructure including, standardized instrumentation and technology management practices, streamlined procurement and supply chain management of laboratory commodities, and others, all working in synergy to ensure the provision of quality testing services in support of healthcare, public health research and effective responses to health emergencies.
- Optimized Resource Allocation: The ELDL implementation strategy considers the country's resource constraints. By focusing on essential and cost-effective tests, resources can be allocated more efficiently, maximizing the impact of available funding.
- Capacity Building and Skill Enhancement: Training laboratory personnel at all levels does not only improve the accuracy of test results but also enhances the knowledge and skills of the laboratory workforce. This strengthened expertise contributes to the overall growth and capacity of the health sector.

- Data-Driven Decision-Making: Real-time data generated by health laboratories compressively implementing the ELDL allows for evidence-based decision-making. Health policymakers can use these data to adjust strategies, allocate resources, and plan for future healthcare, public health emergency management and health research needs.
- International Collaborations and Recognition: Successful implementation of the ELDL can promote the healthcare innovations and modern laboratory diagnostics to improve the health and well-being of its citizens, as well as contribute its share to global health security. Collaborations and partnerships with global health organizations and partners can enhance the country's visibility and access to modern laboratory sciences and technologies.

Abbreviations and Acronyms

AFB	Acid-Fast Bacilli
ALT	Alanine Amino-Transferase
APTT	Activated Partial Thromboplastin Time
AHP	Analytical Hierarchy Process
BF	Blood Film
CBC	Complete Blood Cell Count
CK-MB	Creatine Kinase Muscle-Brain subunits
CSH	Comprehensive Specialized Hospital
ELDL	Essential Diagnostic List
EFDA	Ethiopian Food and Drug Authority
EHSP	Ethiopian Health Service Package
EID	Early Infant Diagnosis
EPHI	Ethiopian Public Health Institute
ESR	Erythrocyte Sedimentation Rate
FBS	Fasting Blood Sugar
Hgb	Hemoglobin
HbA1C	Hemoglobin A1C
Hct	Hematocrit
HBsAg	Hepatitis B Surface Antigen
HCV	Hepatitis C Virus
HIV	Human Immunodeficiency Virus
INR	International Normalized Ratio
IVD	In Vitro Diagnostic
LFT	Liver Function Tests
MCH	Mother and Child Health
MoH	Ministry of Health
NELDL	National Essential Diagnostic List
NTWG	National Technical Working Group
PCV	Packed Cell Volume;
PT	Prothrombin Time
PTT	Partial Thromboplastin Time

RBS	Random Blood Sugar
RFT	Renal Function Tests
RPR	Rapid Plasma Reagin
SIDM	Society to Improve Diagnosis in Medicine
TB	Tuberculosis
TSH	Thyroid-Stimulating Hormone
UHC	Universal Health Coverage
VL	Viral Load
WHO	World Health Organization

1. Introduction

1.1 Background

Laboratory service is an essential component of the Ethiopian health care system that supports the diagnosis and clinical management of patients, the detection and prevention of epidemic or pandemic prone diseases and health researches. A capable and responsive health laboratory system is key for the accurate diagnosis of diseases for treatment planning, monitoring the effectiveness and prognosis of treatment outcomes, and detection of drug resistance. The availability and accessibility of quality-assured diagnostics would assist in the optimal use of the Essential Medicine List (EML). Although Ethiopia has had EML for many years and the vital role of diagnostics for its effective use was long recognized, a document that provides details on the list of essential diagnostics for was not developed.

One of the key targets of the Sustainable Development Goal 3 (Good Health and Well-Being) is achieving Universal Health Coverage (UHC) by 2030 as stated under section 3.8. This specific target, aims to ensure that all people have access to healthcare services when and where needed without incurring financial hardship. Thus, to achieve the stated UHC target, it is critical that everyone is able to access quality and affordable diagnostic laboratory services. Against this background, the World Health Organization (WHO) initiated the development of Essential Laboratory Diagnostic List (ELDL) in 2014 to address the critical need for standardized, prioritized, and cost-effective diagnostic tests. The ELDL was first published in 2018, comprising a curated list of key medical tests required to diagnose and manage common health conditions at various levels of healthcare settings. It was to serve as guidelines and recommendations to aid countries in strengthening their diagnostic capacities towards ensuring universal access to essential diagnostics. Following WHO recommendations, India and Nigeria were the first countries to develop their National Diagnostics Lists.

Publication of a National Essential Laboratory Diagnostics List (NELDL) is vital for the promotion and effective use of invitro diagnostics (IVD) for improved quality of healthcare, advanced health researches and evidence-based management of public health emergences. It facilitates and catalyzes strategic collaborations and partnerships among stakeholders and partners working for the advancement of health laboratory capacity and services for the accurate diagnosis of disease conditions and timely detection of harmful pathogens of public

health concern. A full-fledged implementation of a NELDL at all levels of the healthcare system presents immense opportunities to address the multitude of problems impeding equitable access of citizens to high-quality diagnostic testing services. Knowledge translation based on data generated by a laboratory system implementing, a NELDL is one of the crucial inputs to crafting sound policies, strategies, programs, initiatives and implementation guidelines that aim to improve the health and well-being of populations, provide more effective health services and quality products, and build a resilient and sustainable health system.

Recently, the African Society for Laboratory Medicine (ASLM) has released a guide intended to provide countries in Africa with guidance around developing a NELDL or revising their existing documents to accelerate the implementation and effective use of IVDs. Appreciating the urgent need to improve the availability of accessible, quality diagnostics in public health facilities, the Ethiopian Public Health Institute (EPHI) established a Task Force for the development of a NELDL as an opportunity to improve diagnostic services across the country's health system. The initiative was also anticipated to complement the essential list of medicines for Ethiopia and the interconnected implementation of which is believed to elevate the quality of healthcare at reasonable and affordable out-of-pocket expenses thus propelling the country's efforts towards achieving the Universal Health Coverage of the SDG by 2030.

1.2 Development and Organization of Health Laboratory Services in Ethiopia

In Ethiopia, the early days of formal public health laboratory diagnostic services date back to the introduction of modern healthcare to the country around the end of the 19th century and the beginning of the 20th century. As such, it is safe to assume that modest laboratory diagnostic services were associated with the establishments of the Russian, Harar Ras Mekonen and Minilik II Hospitals in 1897, 1903 and 1906, respectively. Some evidences also indicate that personal physicians of Emperor Minilik and the palace's pharmacists were also using microscopes for the investigations of certain ailments, but that also happened during the last ten years of the 19th century. Although the scope of modern clinical laboratory diagnostic services has continued to grow along with the establishment of more public hospitals prior to, during and after the Italian fascist occupation, its development took a remarkable turn with the establishment of the Imperial Medical Research Institute in 1940 which later evolved into Institute Pasteur d'Ethiopie following the contractual agreement made between the Imperial Ethiopian Government and the Government of France in 1952. The French team of the Institute

Pasteur of Paris developed the first well-organized laboratory departments, which included bacteriology, parasitology, serology/immunology, hematology, clinical and analytical chemistry. The institute, which was later renamed as Imperial Central Laboratory and Research Institute at the termination of the contract agreement with the Government of France in 1964, has played a crucial role in the development of medical laboratory sciences and diagnostics in the country. It was home to the first school of medical laboratory sciences and technology and has continued supplying a large number of qualified laboratory professionals to the healthcare system until the middle of 1990. Starting from its time as Imperial Central Laboratory and Research Institute, the institute has been spearheading the establishment of Regional Reference Laboratories, building and strengthening their capacities for the provision of advanced clinical diagnostic and public health testing services. The institute's reference laboratories have not only been serving as the referral and reference testing centers of the nation but also as the backbone of the national health laboratory system by contributing to the development of national strategies, programs, initiatives and implementation approaches for building the capacities of diagnostic laboratories at different tiers of the healthcare system. Throughout their existence, the EPHI's National Reference Laboratories have been responsible for the evaluation and validation of new methods and technologies, the definition of testing algorithms for effective results for patient management, standardization and the harmonization of diagnostic services offered at different levels of the laboratory system. In this regard, the publication of this NELDL is just one piece of EPHI's multi-faceted undertaking to ensure the availability and accessibility of quality laboratory diagnostic services to all Ethiopians.

The Ethiopian health laboratory system closely follows the country's healthcare delivery system, including hospitals, health centers, and health posts. The standalone Regional Reference Laboratories provide advanced referral diagnostic testing services to all public and private healthcare facilities, starting from the lowest to the highest based on their geographic proximities and pre-defined referral networks. The Ethiopian Laboratory System is comprised of four-tiered decentralized networks of laboratories arranged in a triangular manner with the National Reference Laboratories at EPHI being the top position (Level IV) and those associated with health centers occupying the broader base (Level I). Regional Reference Laboratories and laboratories associated with Specialized University Hospitals including, those of referral hospitals of the Uniformed Forces (Federal Army, Federal Police and Federal Prison Administration) and the National Blood Bank Laboratory Center are categorized under Level

III. All other hospital laboratories are grouped into Level II. As expected and in line with the needs of clinical care services provided at the healthcare facilities with which the laboratories are associated, the scope of the test menu and complexity of testing increase from the lowest level at health centers to the highest level at the National Reference Laboratories. As a mechanism to widen access, an integrated specimen referral linkage and transportation system has been designed and implemented to facilitate specimen referral from any lower tier to the next and beyond for advanced testing services. This organizational arrangement of the national health laboratory system and functional supporting systems have been instrumental for implementation and management of diverse laboratory programs including, the expansion of access to available diagnostic services. Although commendable progress could be made over the past years in building the capacity of the national health laboratory system to effectively support healthcare service delivery and public health emergency management systems including basic and operational health researches. There are still many outstanding challenges that need to be addressed for the system to become more responsive to the needs of its users. Inadequate infrastructure including instrumentations across all tiers, an inconsistent and unreliable supply chain of laboratory commodities, an inefficient system for the provision of equipment maintenance services and lack of clear standards on the scope of tests that are expected to be performed at each level of the laboratory and healthcare systems are among the key challenges currently confronting the laboratory system. It is believed that this NELDL document will serve as an invaluable tool in guiding the development of appropriate strategies and operational action plans to address most of the aforementioned challenges in a standardized, integrated and harmonized manner.

1.3 Background Factors Considered

Inconsistent availability and accessibility, or a total lack of essential health laboratory tests, especially in public health facilities in Ethiopia challenges the health system and remains one of the prominent bottlenecks for achieving the strategic goal of the UHC. To bridge this problem, the WHO, starting from 2018 is recommending and encouraging member countries to establish and implement a National Essential Diagnostic List. The EPHI, as the technical arm of the Ministry of Health (MoH) and the national responsible authority for building the capacity of the health laboratory system, has therefore taken the lead to develop the NELDL. To this end, the institute has established a National Technical Working Group (NTWG) comprising of laboratory experts from key stakeholders and partners. To design the NELDL,

the NTWG has led and coordinated the collection and analysis of data on the following relevant elements: health tier system, health policy, funding (availability and affordability of laboratory tests), epidemiological data (communicable & non communicable diseases), different guidelines, availability of the required infrastructure and human resources (Figure 1).

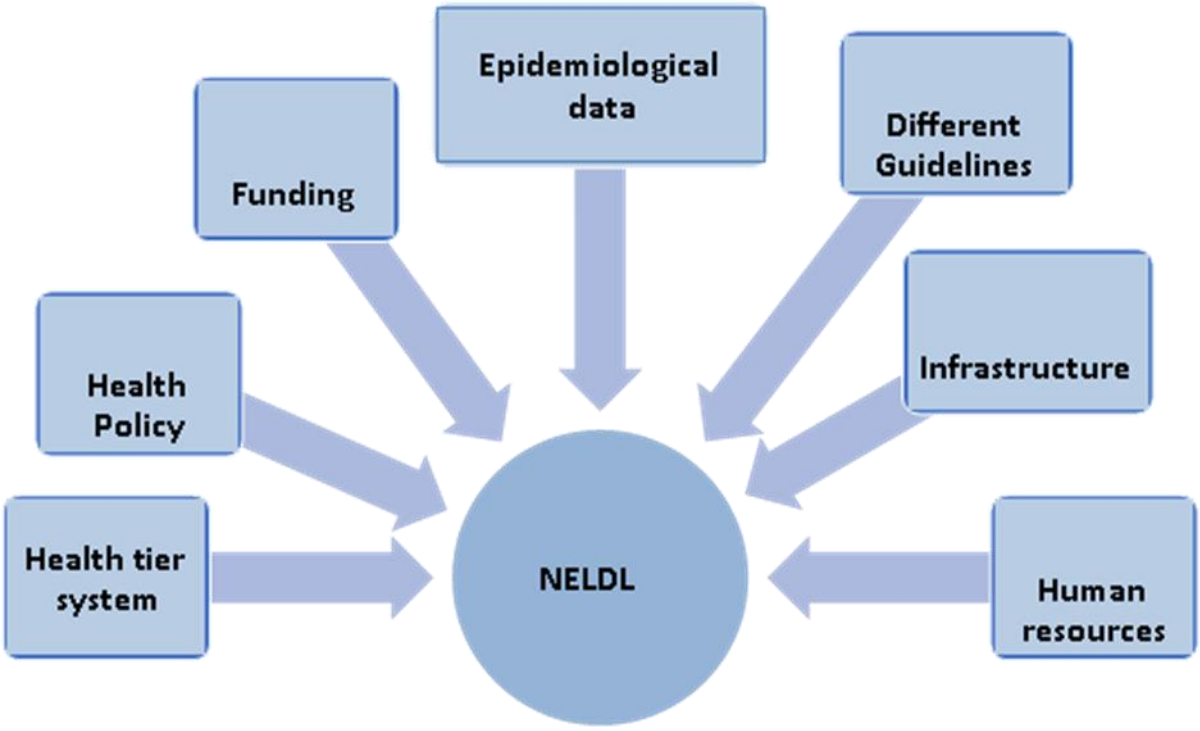

Figure 1: Important Elements Considered for the Development of the NELDL

The collaborative efforts extended to international guidelines, with inputs from the WHO generic EDL, the recently published ASLMs' EDL guidelines, and benchmarks from other countries, such as India's EDL. These collective documents facilitated and helped the systematic identification of laboratory tests associated with national vertical programs and those pertinent to epidemic or pandemic prone diseases. Throughout the process, critical factors like the disease burden, spanning diseases under vertical disease programs, and the necessary tests for effective management of public health emergencies were thoughtfully considered.

A comprehensive assessment of public health facilities was also conducted to ascertain current trends in laboratory service delivery. This assessment involved 203 healthcare facilities belonging to different tiers and utilized a structured questionnaire, which had been adapted and modified from WHO documents. The questionnaire assesses the most significant test types and their availability within the healthcare facility tier system. Challenges in providing laboratory

services within public health facilities were identified, including issues related to poor laboratory quality management system, supply shortages, and limited test accessibility. Notably, disparities in test types and pricing among different healthcare facilities were also observed.

The findings of this assessment informed the inclusion of specific criteria for prioritization, such as the top ten diseases, clinicians' test requirements, the test availability index, cost-effectiveness analysis, and the profile of laboratory personnel. These considerations were crucial for the development of the NELDL, aimed at enhancing the accessibility and quality of essential diagnostic tests within the healthcare system.

2. Rationale, Objectives and Scope

2.1 Rationale

The rationale behind the preparation of NELDL is to develop an essential IVDs list for Ethiopia. The list will guide the standardization of diagnostic services at different levels of the healthcare service delivery system. It also aims at ensuring equitable access to crucial laboratory diagnostics services, enhancing the quality of healthcare services, and guiding the effective utilization and integration of the essential IVDs within the national healthcare system to foster better diagnostic practices across the entire levels.

The list also helps to reduce over diagnosis and over treatment, by identifying unnecessary or redundant diagnostic tests and excluding them from the ELDL. It saves resources and prevents potential harm to patients. It can guide the development of laboratory infrastructure, workforce training, and procurement strategies. Furthermore, it supports the provision of efficient, patient-centered care and treatment services allowing timely diagnosis, fast clinical decisions and prompt interventions.

2.2 Objective

The objective of developing NELDL is to establish a prioritized essential IVDs across different levels of the healthcare service delivery system. It will provide baseline information for agencies and nongovernmental organizations that support the selection, procurement, supply, donation, or provision of IVDs in Ethiopia. Furthermore, it will inform in vitro diagnostics producing manufacturers about the diagnostic priorities of the country and the IVDs promoted as part of the comprehensive implementation of the NELDL at scale. The overarching objective is to contribute to Ethiopia's multi-faceted efforts to attain the UHC thorough guaranteeing its citizens full access to all essential health services at an affordable overall cost.

2.3 Scope of the Document

The scope of the NELDL is to provide a list of essential IVDs required for the diagnosis and monitoring of various diseases in Ethiopia. This list includes IVDs for communicable and non-communicable diseases that should be available at different levels of the country's health system. It also provides comprehensive information on requirements that need to be met to ensure the availability and accessibility of quality diagnostic services, such as infrastructure

including, equipment, a reliable system for supply chain management of other laboratory commodities, a quality assurance system, human and financial resources, and regulatory and licensing aspects of diagnostics. The list can be used by the MoH and its public health agencies and stakeholders for planning purposes and resource mobilization. Ultimately, it improves the capacity of the health system to achieve accurate diagnosis, save health resources, and improve patient outcomes.

Besides, the document defines several features of IVDs, including the purpose of the test, assay formats and specimen types per current international standards and practices, and relevant health care settings appropriate for the investigations of non-communicable and communicable endemic and epidemic-prone diseases.

This document on IVDs focuses on the diagnosis of a wide array of disease conditions in clinical chemistry, hematology, immunology, microbiology and other medical laboratory disciplines, and also discusses specialized testing services such as blood transfusions and targeted tests for surveillance activities. The NELDL enlists 14 diagnostic test categories; 7 differential IVDs to aid the diagnosis of a range of disease conditions, and 7 disease-specific IVDs in clinical settings of the health system, including national and regional reference laboratories, hospitals, health centers and health posts.

3. Principles and Processes for the Development of the NELDL

3.1 Principles

The values that governed the development of the NELDL were an unwavering commitment to ensuring universal and equitable access for all in need to quality and affordable diagnostic services, meeting diagnostic service needs anywhere at all times, and promoting diagnostic capacity at all levels of the healthcare tier system.

This NELDL document was developed by reviewing and utilizing a variety of references, including the Ethiopian Standard Agency IVDs requirements for all levels of healthcare facilities, the WHO guidelines, national health policy and strategy documents, the status and practices of diagnostic laboratory service provision at selected public health facilities, relevant national guidelines, and comments from various stakeholders and partners. Moreover, additional inputs have been obtained from the clinicians, nurses, Health Management Information System experts, laboratory professionals, pharmacy professionals, medical directors, and CEOs of the health facilities.

3.2 Processes

This NELDL was developed with the intention of ensuring the availability and accessibility of laboratory diagnostics for the provision of quality laboratory testing services and contributing to Ethiopia's efforts towards achieving the UHC by guaranteeing its citizens full access to all essential health services at an affordable overall cost. A NTWG comprising experts representing key stakeholders, partner organizations, academic institutions and professional associations was formed with clear terms of reference to develop this document.

The whole process in developing NELDL was based on a review of relevant national guiding documents, analysis of the available epidemiological data and findings from the current laboratory service delivery assessment. In-depth analysis of data and generation of evidences was conducted to define prioritization criteria, then ranking tests based on the criteria and finally establishing the NELDL. The step-by-step preparation phase is detailed in the below figure (Figure 2).

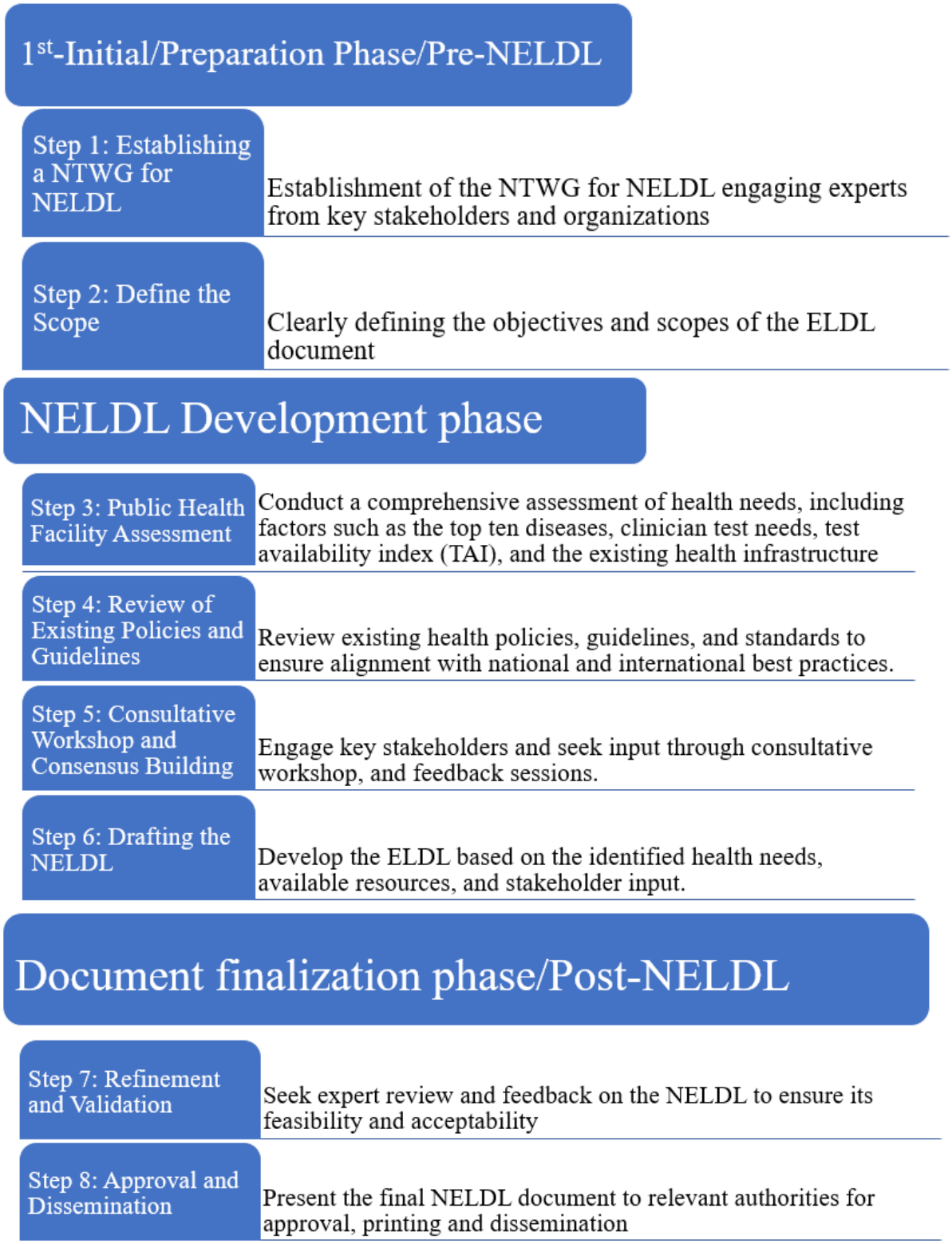

Figure 2: Key Phases and Steps Involved in the Development of the NELDL

Prioritization Exercise

3.3 Prioritization Criteria

An in-depth review of national health policy, strategic plans, essential health services package, pertinent guidelines and other vital documents related to the healthcare system and services in the country was conducted. And also an assessment was made across selected healthcare facilities in order to establish an evidence-based and logically prioritized list of necessary diagnostic tests. The goal was to rank the tests according to how important they are to patient care. The results of the review process and assessment findings showed a significant difference in the scope of laboratory services provided by the selected public healthcare facilities. This and other findings were crucial inputs in defining the prioritization criteria. The NELDL has been established using several criteria, including disease burden, test availability, leading causes of morbidity, reagents and supplies' availability, urgency of tests, cost-effectiveness, tests related to vertical disease prevention and control programs, clinician test preferences, infrastructure capacity, and personnel educational profile/qualification.

The NELDL document was developed for all levels of healthcare facilities, encompassing primary, secondary and tertiary healthcare levels, and standalone national and regional reference laboratories to standardize and prioritize essential diagnostic tests across the healthcare system. The test disciplines incorporated in the NELDL for primary and secondary level health facilities include general testing areas such as clinical chemistry, hematology, serology/immunology, bacteriology, mycology, urinalysis, and parasitology, alongside disease-specific tests for conditions like tuberculosis, *Human immunodeficiency virus (HIV)*, and COVID-19. Tertiary healthcare, National and Regional Reference Laboratories incorporate additional test disciplines such as molecular and other advanced laboratory testing, building upon the disciplines listed for primary and secondary level facilities.

3.4 Description of Prioritization Criteria

Disease Burden: It is the overall effect of a particular disease on a population, taking into account both mortality and morbidity rates that includes factors like prevalence, incidence, disability-adjusted life years (DALYs), and years of potential life lost (YPLL). Prioritizing an essential diagnostic list based on the disease burden of the country ensures that the most significant health problems and sufferings of the population are addressed.

Test Availability Index (AI): the AI refers to the laboratory test availability and accessibility to the target population in the given catchment through the public health facility.

Urgency of the test: Health facilities that provide health care services that necessitate the availability of urgently needed tests in the event of emergency case management.

Top Ten Diseases: Health facilities regularly identify the top ten diseases based on their contribution to mortality and morbidity. Prioritizing testing for these priority diseases helps direct resources to areas of greatest need, enabling interventions that can significantly improve health outcomes.

Clinicians' Test Needs: It is the demand and necessity of the test as perceived by the clinicians. Addressing the demand and necessity of the clinicians is crucial for effective and improved quality of health care service, which in turn improves patient outcomes.

Tests for Vertical Disease Programs: The prevention, diagnosis, and treatment of particular diseases established to be of high burden and public health relevance are the focus of vertical disease programs. Diseases with existing national programs include HIV, Tuberculosis, Malaria, neglected tropical diseases, cervical cancer, etc. The laboratory tests for maternal and child healthcare services (MCH) was also considered. Prioritizing laboratory tests for the diagnosis and treatment monitoring of vertical disease programs allows for a focused approach to combat specific diseases effectively and tackle complex health challenges systematically.

Cost Effectiveness: Cost effectiveness is selected as a prioritization criterion in order to maximize the health benefit from the available resources. It entails assessing the tests that offer significant health gains at a reasonable cost, enabling effective resource allocation.

Availability of the required infrastructure: Refers to the availability and readiness of the needed infrastructure and facilities to safely, efficiently and successfully perform a given laboratory test.

Reagents and supplies' availability status: Supply chain management aims to ensure the efficient movement of supplies and reagents throughout the chain from the manufacturer to the end user level, which impacts the feasibility of test availability and accessibility.

Laboratory personnel level of education: The level of education is the knowledge, skills and competencies needed to impart the quality of work the intended test requires.

3.5 Prioritization Analysis and Ranking

Prioritization of the available, ambitious list of laboratory tests, which is categorized in each tier system, is a complex process that involves considering multiple criteria for decision making. All the selected and established criteria have substantial values for test prioritization and finally contribute to having a short list of essential laboratory diagnostic tests. A careful prioritization of tests for public health facilities categorized by each tier system, can ensure that laboratory testing services are primarily targeted towards areas with high disease burden, most significant and realistic health problems of the population (Table 1).

Taking the objectives of the document and the nature of the established criteria into consideration, the tests are prioritized based on the Analytical Hierarchy Process (AHP) method. The AHP is a decision-making method that uses pairwise comparisons to assess the comparative importance of a criterion and assign a specific weight through the judgment of experts to derive priority scales. It is commonly used to make decisions systematically and in a structured way by assigning appropriate weights to all established criteria based on their relative importance to the scope of the document.

Table 1: Weights in percent assigned to the selected prioritization criteria

SN	Established Prioritization Criteria	Weight by expert decision
1	Disease burden	15%
2	Test availability index (TAI)	12%
3	Urgency of the test	12%
4	Top ten diseases	12%
5	Clinicians' test need	10%
6	Tests for vertical disease programs	10%
7	Cost-effectiveness/price of the test/budget impact	8%
8	Availability of the Required Infrastructure	8%
9	Personnel educational profile/qualification	7%
10	Reagents and supplies' availability status	6%

Prioritization criteria of the test presented in number or count or percentage was scored from 1 to 5. The range is decided and divided into five intervals of equal width based on the highest

number or count or percentage ‘n’ of each specific criterion and the lowest number or count or percentage is 1.

For those criteria, which either have no data in numerical forms or are not feasible to quantify like tests for vertical disease programs, urgency of the test, reagents and supplies’ availability status, and personnel educational profile/qualification are evaluated on the bases of ‘YES’ or ‘NO’ options. The laboratory tests available or required for the listed criteria are labeled ‘YES’ and then provided a score of 5 whereas a test that does not meet the requirement is labeled ‘NO’ and assign a score 1.

Essential Laboratory Diagnostic List

3.6 Primary Level of Healthcare

Ethiopia has implemented a three-tier healthcare service delivery system. One of the levels is the primary level of healthcare, which comprises a primary hospital, health center, and its satellite health posts. The arrangement of essential diagnostic tests for these health facilities differ as there are differences in the scope of clinical care services provided at each of the facilities, availability of budgetary resources and, existing infrastructure, among others.

3.6.1 List of Laboratory Tests at Health Posts

SN	Test category/Disease	IV Diagnostic test	Test purpose	Specimen type	Assay format	Equipment used
1	Clinical Chemistry	Glucose	To diagnose and screen for diabetes	Capillary Whole Blood	RDT /Glucometer	Glucometer
2	Hematology	Hemoglobin	To diagnose and monitor anemia	Capillary Whole Blood	Haemoglobinometer	Haemoglobinometer (POC)
3	Parasitology	Malaria	To identify malaria parasites	Capillary Whole Blood	RDT /Cassette	NA
4	Serology/Immunology	Qualitative HIV Antibody Test	To detect HIV antibodies	Capillary Whole Blood, plasma, oral fluid	Cassette/Device	NA
5	Serology/Immunology	Syphilis (TPHA/RPR/VDRL)	For the diagnosis or as an aid in the diagnosis of T. pallidum	Capillary Whole Blood	RDT /Cassette/Device	NA
6	Serology/Immunology	Pregnancy Test	To assess the status of pregnancy	Urine	RDT/ Cassette/Device	NA
7	Urinalysis	Urinalysis/dipstick	To detect urinary tract infections, glucose, blood, etc.	Urine	Multi-parameter strips /Dipstick	Strip based

3.6.2 List of Laboratory Tests at Health Centers

SN	Test Category /Disease	IV Diagnostic test	Test purpose	Specimen type	Assay format	Equipment used
1	Bacteriology & Mycology	Gram staining	As a critical test for rapid and presumptive diagnosis of infectious agents directly from specimens	All (pus, discharge sputum) except urine, stool and blood	Microscopic examination of slides as wet preparations or treated with organism-specific chemical stains (e.g. Gram stain)	Microscope
2	Bacteriology & Mycology	Molecular WRD test	Diagnosis of TB and Rif resistance	Sputum/Body fluid	Nucleic Acid Amplification Test (	Authomated/ semi-automated
3	Bacteriology & Mycology	LF-LAM	For the diagnosis of active TB in people living with HIV/AIDS	Urine	RDT for the detection of lipoarabinomannan (LAM) levels in the urine for PLWHIV	Point of Care Test (RDT)
4	Bacteriology & Mycology	*Cryptococcal* antigen	For screening and diagnosis of cryptococcal meningitis at ART sites	Capillary whole blood Venous whole blood,	*Cryptococcal* antibody-coated latex particles agglutinate with specimens containing *cryptococcal* antigen (CrAg)	N/A
5	Bacteriology & Mycology	Indian ink	As a critical test for rapid and presumptive diagnosis of infective agents directly from specimens	CSF, sputum and bronchoalveolar lavage fluid	Cryptococcus yeast cell surrounded by a characteristic polysaccharide capsule – Visualized microscopically, India Ink stains the background, revealing the extra cellular capsule	Microscope
6	Bacteriology & Mycology	KOH	For presumptive diagnostic of infective agents directly from specimen	Skin, scalp, nail scrap	KOH	Microscope
7	Bacteriology & Mycology	ZN/FM	Diagnosis/Treatment monitoring TB	Sputum/Body fluids	Microscope	Microscope

SN	Test Category /Disease	IV Diagnostic test	Test purpose	Specimen type	Assay format	Equipment used
8	Clinical Chemistry	Glucose	To screen and monitor for diabetes and intermediate hyperglycemia, to diagnose hypoglycemia	Serum/Plasma	Photometer	Semi-automated
9	Clinical Chemistry	Urea	To assess kidney function	Serum/Plasma	Photometer	Semi-automated
10	Clinical Chemistry	Creatinine	To monitor kidney function for management of severe infections	Serum/Plasma	Photometer	Semi-automated
11	Clinical Chemistry	GOT/AST	To assess liver function	Serum/Plasma	Photometer	Semi-automated
12	Clinical Chemistry	GPT/ALT	To assess liver function	Serum/Plasma	Photometer	Semi-automated
13	Clinical Chemistry	ALP	To aid in the diagnosis of hepatobiliary diseases and bone disorders	Serum	Photometer	Semi-automated
14	Clinical Chemistry	Uric Acid	To diagnose and monitor gout	Serum/Plasma	Photometer	Semi-automated
15	HIV	Qualitative HIV virological nucleic acid test (Early Infant Diagnosis for HIV (EID))	For the diagnosis of HIV infection in infants < 18 months of age	Capillary whole blood/Venous whole blood/Dried blood spots	Nucleic Acid Amplification Test (HIV/EID)	mWRD
16	Immuno-Hematology	COMPLETE BLOOD COUNT (CBC)	To evaluate overall health and to detect a wide range of disorders, including anemia, infections, leukemias, red blood cell, white blood cell and platelet abnormalities and primary immune disorders	Capillary blood EDTA venous blood	Automated hematology analyzer	CBC analyzer

SN	Test Category /Disease	IV Diagnostic test	Test purpose	Specimen type	Assay format	Equipment used
17	Immuno-Hematology	CD4 and CD8%	For staging advanced HIV disease and monitoring response to antiretroviral therapy. (In settings where viral load is not available)	Capillary whole blood Venous whole blood	Point-of care	Point of care
18	Immuno-Hematology	Blood Group and Rh	To determine A, B and O groups and Rh type	Capillary or EDTA venous blood	Slide agglutination test	NA
19	Immuno-Hematology	Erythrocyte sedimentation rate	It is used as indication of presence of disease	Capillary or EDTA venous blood	Sedimentation of red blood cells	Plastic Citrated ESR Graduated Pipette Tube
20	Parasitology	Direct microscopy for ova or parasite	Microscopy of fresh faeces for detection of trophozoites, ova, cysts & larvae of the parasite	Stool/faeces	Wet smear	Microscope
21	Parasitology	Peripheral smear for malaria and other parasite detection	For the diagnosis of one or more human malaria species (*P. falciparum, P. vivax, P. malariae, P. ovale*) and *Borrela spps*	Capillary/Venus blood	Blood Staining	Microscope
22	Parasitology	Skin snip	For the detection of *microfilariae* of *O. volvulus*	Skin snip	Wet smear	Microscope
23	Parasitology	Wet mount	For the detection of *T. vaginalis*	Urine Vaginal discharges	Wet smear	Microscope
24	Serology/Immunology	Pregnancy test	To aid in the early detection of pregnancy	Urine (early morning)/Serum/Plasma	Rapid diagnostic test (RDT)	NA
25	Serology/Immunology	Pallidum-Haem-Agglutination (TPHA) Rapid Test Cassette	For the diagnosis or as an aid in the diagnosis of *T. pallidum*	Capillary or Venous whole blood	Agglutination/ RDT/ cassette	NA

SN	Test Category /Disease	IV Diagnostic test	Test purpose	Specimen type	Assay format	Equipment used
26	Serology/Immunology	Hepatitis B surface antigen (HBsAg)	To screen for acute and chronic HBV infection	Capillary or Venous whole blood	Rapid diagnostic test (RDT)/ cassette	NA
27	Serology/Immunology	Hepatitis C (Anti-HCV antibody)	To screen for HCV infection:	Oral fluid, Capillary whole blood or whole blood	Rapid diagnostic test (RDT)/ cassette	NA
28	Serology/Immunology	H. pylori Ag/Ab	To identify current infection	Stool, serum	Rapid diagnostic test (RDT/ cassette	NA
29	Serology/Immunology	Papilloma virus	For cervical cancer screening	Cervical cells collected in test specific transport fluid	RDT/ test cassette	NA
30	Serology/Immunology	Proteus Weil Felix Test- OX19	Detects typhus and specific rickettsial infections	Serum	RDT/ test cassette	NA
31	Serology/Immunology	Salmonella (Widal Test (H, O))	To detect the presence of typhoid and paratyphoid fever	Serum	RDT/ test cassette	NA
32	Serology/Immunology	rk39 (leishmania)	To aid in the diagnosis of clinically suspected visceral leishmaniasis	Serum Capillary Venous whole blood2	Rapid diagnostic test (RDT)chromatography	NA
33	Serology/Immunology	Qualitative HIV Antibody Test	To diagnose HIV Infection	Oral fluid, Capillary, serum or whole blood	Rapid diagnostic test (RDT)	NA
34	Urinalysis	Urinalysis/dipstick	To detect urinary tract infections, glucose and others	Urine	Multi- parameter strip (dipstick)	N/A
35	Urinalysis	Urine Microscopic	Microscopic urine sediment examination for detection of *S. haematobium*, cells and infectious agents	Urine	Microscopy	Microscope

3.6.3 List of Laboratory Tests at Primary Hospitals

SN	Test Category /Disease	IV Diagnostic test	Test purpose	Specimen type	Assay format	Equipment used
1	Bacteriology & Mycology	Gram staining	As a critical test for rapid and presumptive diagnosis of infective agents directly from specimens	All except urine, stool and blood	Microscopic examination of slides as wet preparations or treated with organism-specific chemical stains (e.g., Gram stain)	Microscope
2	Bacteriology & Mycology	*Vibrio Cholerae* antigen test	For initial detection or exclusion of *cholera* outbreak (not for use in case management	Stool, rectal swab	RDT	NA
3	Bacteriology & Mycology	Wet mount	For the detection of *T.Vaginalis, Candiasis*	Genital discharge, lesions,	Discharge mixed with physiologic saline, examine using low- and high-power magnifications. for BV and a yeast infection	Microscope
4	Bacteriology & Mycology	Indian ink	As a critical test for rapid and presumptive diagnosis of infective agents directly from specimens	CSF, sputum and bronchoalveolar lavage fluid	*Cryptococcus yeast cell* surrounded by a characteristic polysaccharide capsule – Visualized microscopically, India Ink stains the background, revealing the extra cellular capsule	Microscope
5	Bacteriology & Mycology	KOH	For presumptive diagnostic of infective agents directly from specimen	Skin, scalp, nail scrap	Microscopic examination of slides	Microscope
6	Clinical Chemistry	Glucose	To diagnose and screen for diabetes and intermediate hyperglycemia	Serum/Plasma	Optical /Semi-automated/Automated Methods	Semi-automated/ Automated Analyzer

SN	Test Category /Disease	IV Diagnostic test	Test purpose	Specimen type	Assay format	Equipment used
7	Clinical Chemistry	Urea	To assess kidney function	Serum/Plasma	Optical /Semi-automated/Automated Methods	Semi-automated/ Automated Analyzer
8	Clinical Chemistry	Creatinine	To monitor kidney function for management of severe infections	Serum/Plasma	Optical /Semi-automated/Automated Methods	Semi-automated /Automated Analyzer
9	Clinical Chemistry	GOT/AST	To assess liver function	Serum/Plasma	Optical /Semi-automated/Automated Methods	Semi-automated/ Automated Analyzer
10	Clinical Chemistry	GPT/ALT	To assess liver function	Serum/Plasma	Optical /Semi-automated/Automated Methods	Semi-automated/ Automated Analyzer
11	Clinical Chemistry	ALP	To aid in the diagnosis of hepatobiliary diseases and bone disorder	Serum/plasma	Optical /Semi-automated/Automated Methods	Semi-automated/ Automated Analyzer
12	Clinical Chemistry	Total and Direct Bilirubin	To detect or monitor liver disease, bile duct disorders and hemolytic anemia and to differentiate between these causes of jaundice	Serum/Plasma	Optical /Semi-automated/Automated Methods	Semi-automated/ Automated Analyzer
13	Clinical Chemistry	Total Protein	To diagnose nutritional problems, kidney and liver diseases.	Serum/Plasma	Optical /Semi-automated/Automated Methods	Semi-automated/ Automated Analyzer
14	Clinical Chemistry	Albumin	To detect or monitor malnutrition, kidney, liver diseases or mal-absorption	Serum/Plasma	Optical /Semi-automated/Automated Methods	Semi -automated/ Automated Analyzer

SN	Test Category /Disease	IV Diagnostic test	Test purpose	Specimen type	Assay format	Equipment used
15	Clinical Chemistry	GGT	To assess hepatobiliary function	Serum/Plasma	Optical /Semi-automated/Automated Methods	Semi-automated /Automated Analyzer
16	Clinical Chemistry	Uric Acid	To diagnose and monitor gout	Serum/Plasma	Optical /Semi-automated/Automated Methods	Semi-automated /Automated Analyzer
17	HIV	Qualitative HIV virological nucleic acid test (Early Infant Diagnosis for HIV (EID))	For diagnosis of HIV infection in infants < 18 months of age	Capillary whole blood/Venous whole blood/Dried blood spots	Nucleic Acid Amplification Test	Molecular WRD test
18	Immuno-Hematology	COMPLETE BLOOD COUNT (CBC)	To evaluate overall health and to detect a wide range of disorders, including anemia, infections, leukemia, RBC, WBC and platelet abnormalities and primary immune disorders	Capillary blood EDTA venous blood	Automated hematology analyzer	CBC analyzer
19	Immuno-Hematology	Blood Group and Rh	To determine A, B and O groups and Rh type	Capillary blood EDTA venous blood	Slide agglutination test	NA
20	Immuno-Hematology	Blood cross matching	To determine blood compatibility for blood transfusions	Venous whole blood Capillary blood, Serum	Slide and/or tube agglutination test	NA
21	Immuno-Hematology	Direct Coombs test	To aid in the diagnosis of the cause of immune hemolytic anemia	Venous whole blood	Red blood cell agglutination	NA

SN	Test Category /Disease	IV Diagnostic test	Test purpose	Specimen type	Assay format	Equipment used
22	Immuno-Hematology	Indirect Coombs test	To screen for antibodies to red blood cells before a blood transfusion or in pregnancy, To aid in the diagnosis of hemolytic anemia and blood transfusion reaction	Serum	Red blood cell agglutination	NA
23	Immuno-Hematology	Erythrocyte sedimentation rate	it is used as indication for the presence of inflammatory and infectious diseases	Capillary or EDTA venous blood	Sedimentation of red blood	Disposable Plastic Citrated ESR Graduated Pipette Tube
24	Immuno-Hematology	Morphology examination (Peripheral blood)	For the detection of RBC, WBC and platelet abnormalities, malignancies and parasites and for white blood cell differential count	Capillary whole blood Venous whole blood	Manual	Microscope
25	Immuno-Hematology	CD4% & CD8%	For staging advanced HIV disease and monitoring response to ART. (In settings where viral load is not available)	Capillary whole blood Venous whole blood	Point of care	POC
26	Parasitology	Direct microscopy and/or formol-ether concentration test	Microscopic examiation of fresh faeces for detection of trophozoites, ova, cysts, larvae and adult worm of the parasite	Stool/faeces	Wet smear	Microscope
27	Parasitology	Peripheral smear for malaria parasite detection	For the diagnosis of one or more human malaria species (*P. falciparum, P. vivax, P. malariae, P. ovale*) and *Borrela spps*	Capillary/venous blood	Blood Staining	Microscope

SN	Test Category /Disease	IV Diagnostic test	Test purpose	Specimen type	Assay format	Equipment used
28	Parasitology	Wet mount	For the detection of *T. vaginalis*	Urine	Wet smear	Microscope
29	Parasitology	Skin snip	For the detection of microfilariae of *O. volvulus*	Skin snip	Wet smear	Microscope
30	Parasitology	Stained aspirates and smears	For investigation of cutaneous or *visceral leishmania*	Bone marrow, lymph, spleen, liver, tissue aspirate	microscopy	Microscope
31	Serology	HIV rapid test	To diagnose HIV Infection	Oral fluid, Capillary or whole blood	Rapid diagnostic test (RDT)/ Cassette	NA
32	Serology/Immunology	Pregnancy test	To aid in the early detection of pregnancy	Urine (early morning)	Rapid diagnostic test (RDT) (dipstick and cassette), latex agglutination /test strip	NA
33	Serology/Immunology	*Hepatitis B* surface antigen (HBsAg)	To screen for acute and chronic HBV infection	Capillary or Venous whole blood	Rapid diagnostic test (RDT)/ Test Cassette	NA
34	Serology/Immunology	*Hepatitis C* (Anti-HCV antibody)	To screen for HCV infection:	Oral fluid, Capillary blood or whole blood	Rapid diagnostic test (RDT)/ Test Cassette	NA
35	Serology/Immunology	Syphilis (TPHA/RPR/VDRL)	For the diagnosis or as an aid in the diagnosis of *T. pallidum*	Capillary or Venous whole blood	Rapid diagnostic test (RDT)/ Test Cassette	NA
36	Serology/Immunology	*Human Papilloma Virus*	For cervical cancer	Cervical cells collected in test specific transport fluid	Rapid diagnostic test (RDT)/ Test Cassette	NA

SN	Test Category /Disease	IV Diagnostic test	Test purpose	Specimen type	Assay format	Equipment used
37	Serology/Immunology	*H. pylori Ag/Ab*	To identify current infections	Stool	Rapid diagnostic test (RDT/ Test Cassette	NA
38	Serology/Immunology	RF (Rheumatoid Factor)	To diagnose rheumatoid arthritis (RA)	Serum	rapid latex agglutination test	NA
39	Serology/Immunology	*Salmonella* (Widal Test (H, O))	To detect the presence of with typhoid and paratyphoid fever.	Serum	RDT/ Test Cassette	NA
40	Serology/Immunology	ASO (*anti-streptolysin O*)	To diagnose a strep infection	Serum	rapid latex agglutination test	NA
41	Serology/Immunology	Cryptococcal antigen test	Detection of *cryptococcal* capsular polysaccharide antigen (CrAg)	Serum and cerebrospinal fluid	Rapid chromatography/lateral flow/ Test Cassette	NA
42	Serology/Immunology	Proteus Weil Felix Test- *OX19*	Detects typhus and specific *rickettsial* infections	Serum	RDT/ Test Cassette	NA
43	TB	ZN/FM	Diagnosis/Treatment monitoring	Sputum/Body fluids	Microscopic examination of stained slides	Microscope
44	TB	mWRD	Diagnosis	Sputum/Body fluids	Nucleic Acid Amplification Test	mWRD
45	TB	LF-LAM	For the diagnosis of TB at ART sites	Urine	RDT for the detection of lipoarabinomannan (LAM) levels in the urine	NA
46	Urinalysis	Urinalysis/dipstick	To detect urinary tract infections	Urine	Multi- parameter Strip (dipstick)	NA
47	Urinalysis	Urine Microscopic	Microscopic Urine sediment examination for detection of *S. haematobium*, cells and infectious agents	Urine	Microscope	Microscope

3.7 Secondary Level of Healthcare

The secondary level of healthcare comprises general hospitals. General hospitals are organized to provide health care services for referral cases from the primary level in addition to the patients visiting the facility. The arrangement of essential diagnostic tests for these health facilities differ from the primary level laboratories as they are expected to provide broader and advanced diagnostic tests in line with the increased scope of clinical care services, have relatively better infrastructure and budgetary resources.

3.7.1 List of Laboratory Tests at General Hospitals

SN	Test Category/ Disease	IV Diagnostic test	Test purpose	Specimen type	Assay format	Equipment used
1	Bacteriology & Mycology	Wet mount	Microscopic examination of vaginal discharge or scrapings from vulvar lesions	Genital discharge, lesions,	Discharge mixed with physiologic saline, examine using low- and high-power magnifications. for BV and a yeast infection	Microscope
2	Bacteriology & Mycology	Culture and Antimicrobial susceptibility testing (AST)	Initial step in detection and identification of bacterial and fungal species for selection of appropriate antibiotic regimens	Disease-appropriate specimens (e.g., blood, urine, stool, cerebrospinal fluid, etc.)	Culture on growth media plates or broth in an incubator followed by recovery of isolates and species identification (traditional manual techniques or automated equipment)	Traditional manual techniques and Automated
3	Bacteriology & Mycology	Gram staining	As a critical test for rapid and presumptive diagnosis of infective agents directly from specimens	All except urine, stool and blood	Microscopic examination of slides as wet preparations or treated with organism-specific chemical stains (e.g., Gram stain)	Microscope

SN	Test Category/ Disease	IV Diagnostic test	Test purpose	Specimen type	Assay format	Equipment used
4	Bacteriology & Mycology	Indian ink	As a critical test for rapid and presumptive diagnosis of infective agents directly from specimens	CSF, sputum and bronchoalveolar lavage fluid	Cryptococcus yeast cell surrounded by a characteristic polysaccharide capsule Visualized microscopically, India Ink stains the background, revealing the extra cellular capsule	Microscope
5	Bacteriology & Mycology	Vibrio Cholerae antigen test	For initial detection or exclusion of cholera outbreak (not for use in case management	Stool, rectal swab	RDT	NA
6	Bacteriology & Mycology	KOH	For presumptive diagnostic of infective agents directly from specimen	Skin, scalp, nail scrap	Microscopic examination of slides	Microscope
7	Bacteriology & Mycology	ZN/FM	Diagnosis/Treatment monitoring	Sputum/Body fluids	Staining of sputum/body fluid	Microscope
8	Bacteriology & Mycology	Molecular WRD test	For the diagnosis of active TB	Sputum/Body fluids	Nucleic Acid Amplification Test	mWRD
9	Bacteriology & Mycology	LF-LAM	For the diagnosis of active TB in ART sites	Urine	RDT for the detection of lipoarabinomannan (LAM) levels in the urine	NA
10	Clinical Chemistry	Direct and total Bilirubin	To detect or monitor liver disease, bile duct disorders and hemolytic anemia and to differentiate between these causes of jaundice	Serum/Plasma	Automated Methods for basic chemistry parameters, Immunoassay for hormonal tests, Blood gases analyzer for blood gases	Automated Analyzer

SN	Test Category/ Disease	IV Diagnostic test	Test purpose	Specimen type	Assay format	Equipment used
11	Clinical Chemistry	GOT/AST	To assess liver function	Serum/Plasma	Optical /Semi-automated/Automated Methods for basic chemistry parameters, Immunoassay for hormonal tests, Blood gases analyzer for blood gases	Semi-automated/ Automated Analyzer
12	Clinical Chemistry	GPT/ALT	To assess liver function	Serum/Plasma	Optical /Semi-automated/Automated Methods for basic chemistry parameters, Immunoassay for hormonal tests, Blood gases analyzer for blood gases	Semi-automated/ Automated Analyzer
13	Clinical Chemistry	ALP	To aid in the diagnosis of hepatobiliary diseases and bone disorders	Serum/Plasma	Optical /Semi-automated/Automated Methods for basic chemistry parameters, Immunoassay for hormonal tests, Blood gases analyzer for blood gases	Semi-automated/ Automated Analyzer
14	Clinical Chemistry	Glucose	To diagnose and screen for diabetes and intermediate hyperglycemia, to diagnose hypoglycemia	Serum/Plasma	Optical /Semi-automated/Automated Methods for basic chemistry parameters, Immunoassay for hormonal tests, Blood gases analyzer for blood gases	Semi-automated/ Automated Analyzer
15	Clinical Chemistry	Creatinine	To monitor kidney function for management of severe infections	Serum/Plasma	Optical /Semi-automated/Automated Methods for basic chemistry parameters, Immunoassay for hormonal tests, Blood gases analyzer for blood gases	Semi-automated/ Automated Analyzer

SN	Test Category/ Disease	IV Diagnostic test	Test purpose	Specimen type	Assay format	Equipment used
16	Clinical Chemistry	Electrolytes (Na, K, Cl, phosphate)	To detect an acid-base imbalance in blood	Serum/Plasma	ISE	Semi-automated/ Automated Analyzer
17	Clinical Chemistry	Urea	To assess kidney function	Serum/Plasma	Optical /Semi-automated/Automated Methods for basic chemistry parameters, Immunoassay for hormonal tests, Blood gases analyzer for blood gases	Semi-automated/ Automated Analyzer
18	Clinical Chemistry	Cholesterol	To assess risk of cardiovascular disease (CVD)	Serum/Plasma	Optical /Semi-automated/Automated Methods for basic chemistry parameters, Immunoassay for hormonal tests, Blood gases analyzer for blood gases	Semi-automated/ Automated Analyzer
19	Clinical Chemistry	Triglyceride	To assess risk of cardiovascular disease (CVD)	Serum/Plasma	Optical /Semi-automated/Automated Methods for basic chemistry parameters, Immunoassay for hormonal tests, Blood gases analyzer for blood gases	Semi-automated/ Automated Analyzer
20	Clinical Chemistry	Urine chemistry (Creatinine, TP, albumin, UA, Ca, glucose, Na, Cl, K, Phosphate)	To detect and quantify substances in the urine associated with metabolic disorders, renal dysfunction or urinary tract infections.	Urine	Optical /Semi-automated/Automated Methods for basic chemistry parameters, Immunoassay for hormonal tests, Blood gases analyzer for blood gases	Semi-automated/ Automated Analyzer

SN	Test Category/ Disease	IV Diagnostic test	Test purpose	Specimen type	Assay format	Equipment used
21	Clinical Chemistry	Uric Acid	To diagnose and monitor gout	Serum/Plasma	Optical /Semi-automated/Automated Methods for basic chemistry parameters, Immunoassay for hormonal tests, Blood gases analyzer for blood gases	Semi-automated/ Automated Analyzer
22	Clinical Chemistry	GGT	To assess hepatobiliary function, To distinguish between bone and hepatobiliary causes of raised ALP	Serum/Plasma	Optical /Semi-automated/Automated Methods for basic chemistry parameters, Immunoassay for hormonal tests, Blood gases analyzer for blood gases	Semi-automated/ Automated Analyzer
23	Clinical Chemistry	LDL	To assess risk of cardiovascular disease (CVD)	Serum/Plasma	Optical /Semi-automated/Automated Methods for basic chemistry parameters, Immunoassay for hormonal tests, Blood gases analyzer for blood gases	Semi-automated/ Automated Analyzer
24	Clinical Chemistry	HDL	To assess risk of cardiovascular disease (CVD)	Serum/Plasma	Optical /Semi-automated/Automated Methods for basic chemistry parameters, Immunoassay for hormonal tests, Blood gases analyzer for blood gases	Semi-automated/ Automated Analyzer
25	Clinical Chemistry	LDH	To assess metabolic acidosis, diabetic keto-acidosis, sepsis and dehydration	Serum/Plasma	Optical /Semi-automated/Automated Methods for basic chemistry parameters, Immunoassay for hormonal tests, Blood gases analyzer for blood gases	Semi-automated/ Automated Analyzer

SN	Test Category/ Disease	IV Diagnostic test	Test purpose	Specimen type	Assay format	Equipment used
26	Clinical Chemistry	CRP	To detect inflammation as an indicator of various conditions (e.g., cardiovascular disease (CVD) high sensitivity CRP required, sepsis)	Serum/Plasma	Optical /Semi-automated/Automated Methods for basic chemistry parameters, Immunoassay for hormonal tests, Blood gases analyzer for blood gases	Semi-automated/ Automated Analyzer
27	Clinical Chemistry	Albumin	To detect or monitor malnutrition, kidney, liver disease or malabsorption	Serum/Plasma	Optical /Semi-automated/Automated Methods for basic chemistry parameters, Immunoassay for hormonal tests, Blood gases analyzer for blood gases	Semi-automated/ Automated Analyzer
28	Clinical Chemistry	Progesterone	Utilized in fertility diagnosis for the detection of ovulation and assessment of the luteal phase	Serum/Plasma	Optical /Semi-automated/Automated Methods for basic chemistry parameters, Immunoassay for hormonal tests, Blood gases analyzer for blood gases	Semi-automated/ Automated Analyzer
29	Clinical Chemistry	FSH	Used to indicate congenital diseases with chromosome aberrations, polycystic ovaries (PCO), amenorrhea (causes), and menopausal syndrome	Serum/Plasma	Automated Methods for basic chemistry parameters, Immunoassay for hormonal tests, Blood gases analyzer for blood gases	Semi-automated/ Automated Analyzer
30	Clinical Chemistry	TSH	To screen for hypothyroidism and hyperthyroidism	Serum/Plasma	Optical /Semi-automated/Automated Methods for basic chemistry parameters, Immunoassay for hormonal tests,	Semi-automated/ Automated Analyzer

SN	Test Category/ Disease	IV Diagnostic test	Test purpose	Specimen type	Assay format	Equipment used
31	Clinical Chemistry	LH	Used to indicate congenital diseases with chromosome aberrations, polycystic ovaries (PCO), amenorrhea (causes), and menopausal syndrome	Serum/Plasma	Optical /Semi-automated/Automated Methods for basic chemistry parameters, Immunoassay for hormonal tests	Semi-automated/ Automated Analyzer
32	Clinical Chemistry	Total Protein	To diagnose nutritional problems, kidney disease and liver disease.	Serum/Plasma	Optical /Semi-automated/Automated Methods for basic chemistry parameters	Semi-automated/ Automated Analyzer
33	Clinical Chemistry	Troponin	To diagnose myocardial infarction	Serum/Plasma	Optical /Semi-automated/Automated Methods for basic chemistry parameters, Immunoassay for hormonal tests	Semi-automated/ Automated Analyzer
34	Clinical Chemistry	T3/FT3	To screen for hypothyroidism and hyperthyroidism	Serum/Plasma	Optical /Semi-automated/Automated Methods for basic chemistry parameters, Immunoassay for hormonal tests	Semi-automated/ Automated Analyzer
35	Clinical Chemistry	T4/FT4	To screen for hypothyroidism and hyperthyroidism	Serum/Plasma	Optical /Semi-automated/Automated Methods for basic chemistry parameters, Immunoassay for hormonal tests	Semi-automated/ Automated Analyzer
36	Clinical Chemistry	CK-MB	To determine the myocardial infraction	Serum/Plasma	Optical /Semi-automated/Automated Methods for basic chemistry parameters	Semi-automated/ Automated Analyzer

SN	Test Category/ Disease	IV Diagnostic test	Test purpose	Specimen type	Assay format	Equipment used
37	Clinical Chemistry	Hb A1C	To diagnose and monitor treatment of diabetes mellitus	Venous whole blood	Optical /Semi-automated/Automated Methods for basic chemistry parameters, Immunoassay for hormonal tests, Blood gases analyzer for blood gases	Semi-automated/ Automated Analyzer
38	HIV	Qualitative HIV virological nucleic acid test (Early Infant Diagnosis for HIV (EID))	For the diagnosis of HIV infection in infants < 18 months of age	Capillary whole blood/Venous whole blood/Dried blood spots	Nucleic Acid Amplification Test	mWRD
39	Human Papilloma Virus	*Human Papilloma Virus*	Used for cervical cancer screening	Serum/plasma	Rapid chromatography	NA
40	Immuno-Hematology	Complete Blood Count (CBC)	To diagnose and monitor anemia and polycythemia, To monitor the safety of certain drugs, Clinical marker for certain severe infections (e.g., malaria, viral hemorrhagic fevers), Aid in the diagnosis of intravascular hemolysis, renal conditions, rhabdomyolysis (myoglobinuria)	Capillary or venous blood.	Automated hematology analyzer, total and differential counts of white blood cell (WBC), Red blood cell (RBC), platelets.	CBC Analyzer (Five diff)
41	Immuno-Hematology	Blood Group and Rh	To determine A, B and O groups and Rh type	Capillary blood	Slide agglutination test	NA

SN	Test Category/ Disease	IV Diagnostic test	Test purpose	Specimen type	Assay format	Equipment used
42	Immuno-Hematology	Erythrocyte sedimentation rate	To detect the presence of inflammation caused by one or more conditions such as infections, tumors or autoimmune diseases	citrate whole blood	Semi-automated analyzer.	Disposable Plastic Citrated ESR Graduated Pipette Tube
43	Immuno-Hematology	Blood cross matching	To determine blood compatibility for blood transfusions	Capillary and Venous whole blood	Slide and/or tube agglutination test	NA
44	Immuno-Hematology	Prothrombin time and international normalized ratio (PT/INR)	To detect or diagnose a bleeding disorder or thrombotic disorder (prothrombin time (PT), Monitor performance of anticoagulant medications (International normalized ratio (INR))	Citrate plasma	Hand-held or automated coagulation analyzer	Coagulation analyzer
45	Immuno-Hematology	CD4%, CD8%	For staging advanced HIV disease.	Venous whole blood	Flowcytometry	CD4 analyzer
46	Immuno-Hematology	LYMPHOCYTE IMMUNE-PHENOTYPING (CD4%, CD4#, CD3%, CD3#, CD8#, CD8%, CD4/CD8 RATIO & CD45#)	For monitoring response to Antiretroviral therapy. (In settings where viral load is not available)	Venous whole blood	Flowcytometry	CD4 analyzer

SN	Test Category/ Disease	IV Diagnostic test	Test purpose	Specimen type	Assay format	Equipment used
47	Immuno-Hematology	Morphology examination (peripheral blood, bone marrow, Biopsy, ….)	For detection of red blood cell, white blood cell and platelet abnormalities, malignancies and parasites and for white blood cell differential count	Capillary and venous whole blood	Romanowsky stained blood films	Microscope
48	Parasitology	Wet mount	For the detection of *T. vaginalis*	Urine	Wet smear	Microscope
49	Parasitology	Peripheral smear for malaria and other parasite detection	For the diagnosis of one or more human malaria species (*P. falciparum, P. vivax, P. malariae, P. ovale*), *Borrela spps, For detection of trypomastigotes stage of T.b.*	Capillary/venous blood	Blood Staining (Thick and thin films)	Microscope
50	Parasitology	Direct microscopy and formol-ether concentration of faeces for ova or parasite	Microscopy of fresh faeces for detection of trophozoites, ova, cysts & larvae of the parasite	Stool/faeces	Wet smear	Microscope
51	Parasitology	Stained aspirates and smears	For investigation of cutaneous or visceral leishmania	Bone marrow, lymph, spleen, liver, tissue aspirate	Aspirate staining	Microscope
52	Parasitology	Skin snip	For detection of microfilariae of O. volvulus	Skin snip	Wet smear	Microscopy
53	Serology/Immunology	Hepatitis B surface antigen (HBsAg)	Screening for acute and chronic hepatitis B (HBV) infection: infants over 12 months of age, children, adolescents, adults	Whole blood/serum	Rapid diagnostic test (RDT)/cassette	NA

SN	Test Category/ Disease	IV Diagnostic test	Test purpose	Specimen type	Assay format	Equipment used
54	Serology/Immunology	*Hepatitis C* (Anti-HCV antibody)	Screening for HCV infection: infants over 18 months of age, children, adolescents, adults	Whole blood/serum	Rapid diagnostic test (RDT)/cassette	NA
55	Serology/Immunology	Pregnancy test	Pregnancy	Urine	Rapid chromatography/strips	NA
56	Serology/Immunology	HIV rapid test	For the diagnosis of HIV infection: adults, adolescents, children and infants over 18 months of age	Whole blood/serum	Rapid chromatography	NA
57	Serology/Immunology	Syphilis (TPHA/ RPR/VDRL)	For the diagnosis or as an aid in the diagnosis of *T. palladium*	Serum/plasma	Rapid chromatography/ Cassette	NA
58	Serology/Immunology	*H. pylori Ag/Ab*	To identify current infection	Stool, serum	Rapid chromatography/Cassette	NA
59	Serology/Immunology	ASO (Anti-Streptolysin O)	To help determine whether you have had a recent strep infection with the bacteria *group A Streptococcus;* To help diagnose complications resulting from a strep infection such as rheumatic fever or glomerulonephritis, a form of kidney disease	Serum	Rapid chromatography	NA
60	Serology/Immunology	Cryptococcal antigen test	For screening and diagnosis of cryptococcal meningitis in people living with advanced HIV disease	CSF, Serum	Rapid chromatography/ Cassette	NA
61	Serology/Immunology	*Salmonella (Widal Test (H, O))*	Diagnosis of typhoid fever	Serum/plasma	Rapid chromatography/ Cassette	NA

SN	Test Category/ Disease	IV Diagnostic test	Test purpose	Specimen type	Assay format	Equipment used
62	Serology/Immunology	*Proteus Weil Felix Test- OX19*	Diagnosis of typhus fever	Serum/plasma	Rapid chromatography/ Cassette	NA
63	Serology/Immunology	Occult blood	Occult blood in the stool may indicate colon cancer or polyps in the colon or rectum — though not all cancers or polyps' bleed.	Stool	Rapid chromatography	NA
64	Serology/Immunology	Rheumatoid Factor (RF)	RF test is most often used to help diagnose rheumatoid arthritis	Serum/plasma	Rapid chromatography	NA
65	Serology/Immunology	rk39 (leishmania)	Diagnosis of visceral leishmaniasis (VL)	Serum	Rapid chromatography	NA
66	Serology/Immunology	Cancer rapid test (PSA)	For the diagnosis of prostate cancer	Whole blood/serum	Rapid chromatography	NA
67	Urinalysis	Urinalysis/dipstick	To detect urinary tract infections	Urine	Multi- parameter Strip (dipstick	NA
68	Urinalysis	Urine Microscopic	Microscopic Urine sediment examination for detection of *S. haematobium*, cells and infectious agents	Urine	Microscopy	Microscope

3.8 Tertiary Level of Care

The tertiary level of healthcare comprises comprehensive specialized hospitals. The comprehensive specialized hospitals are organized to provide more advanced, comprehensive and specialized healthcare services for all types of referral cases from all levels. The arrangement of essential diagnostic tests for these health facilities differ from the primary and secondary level laboratories as they are expected to provide wider and advanced diagnostic tests to meet the needs of specialized and complex healthcare services, have by far better and more advanced infrastructure, significantly higher budgetary resource and staffed with highly qualified personnel.

3.8.1 List of Laboratory Tests at Comprehensive Specialized Hospitals

SN	Test Category/Disease	IV Diagnostic test	Test purpose	Specimen type	Assay format	Equipment used
1	Bacteriology & Mycology	Culture and Antimicrobial susceptibility testing (AST)	For the detection of bacterial and fungal pathogens	All clinical specimen	Culture	Automated / Manual
2	Bacteriology & Mycology	Wet mount	Microscopic examination of vaginal discharge or scrapings from vulvar lesions	Genital discharge, lesions,	Discharge mixed with physiologic saline, examine using low- and high-power magnifications. for BV and a yeast infection	Microscope
3	Bacteriology & Mycology	Gram staining	As a critical test for rapid and presumptive diagnosis of infective agents directly from specimens	All except urine, stool and blood	Microscopic examination of slides as wet preparations or treated with organism-specific chemical stains (e.g., Gram stain)	Microscope
4	Bacteriology & Mycology	*Vibrio Cholerae* antigen test	For initial detection or exclusion of cholera outbreak (not for use in case management)	Stool, rectal swab	RDT	NA

SN	Test Category/ Disease	IV Diagnostic test	Test purpose	Specimen type	Assay format	Equipment used
5	Bacteriology & Mycology	Cryptococcal antigen	For screening and diagnosis of cryptococcal meningitis	Capillary whole blood Venous whole blood, CSF	Cryptococcal antibody-coated latex particles agglutinate with specimens containing cryptococcal antigen (CrAg)	NA
6	Bacteriology & Mycology	Indian ink	As a critical test for rapid and presumptive diagnosis of infective agents directly from specimens	CSF, sputum and bronchoalveolar lavage fluid	Cryptococcus yeast cell surrounded by a characteristic polysaccharide capsule – Visualized microscopically, India Ink stains the background, revealing the extra cellular capsule	Microscope
7	Bacteriology & Mycology	KOH	For presumptive diagnostic of infective agents directly from specimen	Skin, scalp, nail scrap	Microscopic examination of slides	Microscope
8	Bacteriology & Mycology	Molecular WRD test	Diagnosis	Sputum/Body fluid	Nucleic Acid Amplification Test (Xpert MTB/RIF Assay)	mWRD
9	Bacteriology & Mycology	LF-LAM (lipoarabinomannan)	RDT for the detection of LAM levels in urine for the diagnosis of active TB in PLWHIV	Urine	RDT for the detection of LAM levels in the urine	NA
10	Bacteriology & Mycology	ZN/FM	Diagnosis/Treatment monitoring	Sputum/Body fluid	Microscopic examination of stained slides	Microscope

SN	Test Category/ Disease	IV Diagnostic test	Test purpose	Specimen type	Assay format	Equipment used
11	Clinical Chemistry	Urea	To assess kidney function	Serum/Plasma	Optical Automated Methods for basic chemistry parameters, Immunoassay for hormones and tumor markers, Blood gas analyzers for blood gases	Automated Analyzer
12	Clinical Chemistry	Urine chemistry (Creatinine, TP, albumin, UA, Ca, glucose, Na, Cl, K, Phosphate)	To detect and quantify substances in the urine associated with metabolic disorders, renal dysfunction or urinary tract infections	Urine	Optical /Semi-automated/Automated Methods for basic chemistry parameters, Immunoassay for hormonal and tumour markers, Blood gases analyzer for blood gases	Automated Analyzer
13	Clinical Chemistry	GOT/AST	To assess liver function	Serum/Plasma	Optical /Semi-automated/Automated Methods for basic chemistry parameters, Immunoassay for hormonal and tumour markers, Blood gases analyzer for blood gases	Automated Analyzer
14	Clinical Chemistry	GPT/ALT	To assess liver function	Serum/Plasma	Optical /Semi-automated/Automated Methods for basic chemistry parameters, Immunoassay for hormonal and tumour markers, Blood gases analyzer for blood gases	Automated Analyzer

SN	Test Category/ Disease	IV Diagnostic test	Test purpose	Specimen type	Assay format	Equipment used
15	Clinical Chemistry	ALP	To aid in diagnosis of hepatobiliary diseases and bone disorders	Serum/Plasma	Optical /Semi-automated/Automated Methods for basic chemistry parameters, Immunoassay for hormonal and tumour markers, Blood gases analyzer for blood gases	Automated Analyzer
16	Clinical Chemistry	Direct and total Bilirubin	To detect or monitor liver disease, bile duct disorders and hemolytic anemia, To differentiate between these causes of jaundice	Serum/Plasma	Optical /Semi-automated/Automated Methods for basic chemistry parameters, Immunoassay for hormonal and tumour markers, Blood gases analyzer for blood gases	Automated Analyzer
17	Clinical Chemistry	Creatinine	To monitor kidney function for management of severe infections	Serum/Plasma	Optical /Semi-automated/Automated Methods for basic chemistry parameters, Immunoassay for hormonal and tumour markers, Blood gases analyzer for blood gases	Automated Analyzer
18	Clinical Chemistry	Glucose	To diagnose and screen for diabetes and intermediate hyperglycemia, to diagnose hypoglycemia	Serum/Plasma/CSF	Optical /Semi-automated/Automated Methods for basic chemistry parameters, Immunoassay for hormonal and tumour markers, Blood gases analyzer for blood gases	Automated Analyzer

SN	Test Category/ Disease	IV Diagnostic test	Test purpose	Specimen type	Assay format	Equipment used
19	Clinical Chemistry	Potassium	To monitor fluid, electrolyte and acid-base balance.	Serum/Plasma	Optical /Semi-automated/Automated Methods for basic chemistry parameters, Immunoassay for hormonal and tumour markers, Blood gases analyzer for blood gases	Automated Analyzer
20	Clinical Chemistry	Chloride	To monitor fluid, electrolyte and acid-base balance.	Serum/Plasma	Optical /Semi-automated/Automated Methods for basic chemistry parameters, Immunoassay for hormonal and tumour markers, Blood gases analyzer for blood gases	Automated Analyzer
21	Clinical Chemistry	Magnesium	Diagnosing and monitoring hypomagnesemia and hypermagnesemia	Serum/Plasma	Optical /Semi-automated/Automated Methods for basic chemistry parameters, Immunoassay for hormonal and tumour markers, Blood gases analyzer for blood gases	Automated Analyzer
22	Clinical Chemistry	Calcium	Control parathyroid hormone (PTH), calcitonin, and vitamin D	Serum/Plasma	Optical /Semi-automated/Automated Methods for basic chemistry parameters, Immunoassay for hormonal and tumour markers, Blood gases analyzer for blood gases	Automated Analyzer

SN	Test Category/ Disease	IV Diagnostic test	Test purpose	Specimen type	Assay format	Equipment used
23	Clinical Chemistry	Phosphate	To monitor chronic kidney disease. To prevent and manage tumor lysis syndrome	Serum/Plasma	Optical /Semi-automated/Automated Methods for basic chemistry parameters, Immunoassay for hormonal and tumour markers, Blood gases analyzer for blood gases	Automated Analyzer
24	Clinical Chemistry	GGT	To assess hepatobiliary function, To distinguish between bone and hepatobiliary causes of raised ALP	Serum/Plasma	Optical /Semi-automated/Automated Methods for basic chemistry parameters, Immunoassay for hormonal and tumour markers, Blood gases analyzer for blood gases	Automated Analyzer
25	Clinical Chemistry	Total Protein	To diagnose nutritional problems, kidney disease and liver disease.	Serum/Plasma/CSF	Optical /Semi-automated/Automated Methods for basic chemistry parameters, Immunoassay for hormonal and tumour markers, Blood gases analyzer for blood gases	Automated Analyzer
26	Clinical Chemistry	Albumin	To detect or monitor malnutrition, kidney, liver disease or malabsorption	Serum/Plasma	Optical /Semi-automated/Automated Methods for basic chemistry parameters, Immunoassay for hormonal and tumour markers, Blood gases analyzer for blood gases	Automated Analyzer

SN	Test Category/ Disease	IV Diagnostic test	Test purpose	Specimen type	Assay format	Equipment used
27	Clinical Chemistry	Sodium	To monitor fluid, electrolyte and acid-base balance.	Serum/Plasma	Optical /Semi-automated/Automated Methods for basic chemistry parameters, Immunoassay for hormonal and tumour markers, Blood gases analyzer for blood gases	Automated Analyzer
28	Clinical Chemistry	Uric Acid	To diagnose and monitor gout	Serum/Plasma	Optical /Semi-automated/Automated Methods for basic chemistry parameters, Immunoassay for hormonal and tumour markers, Blood gases analyzer for blood gases	Automated Analyzer
29	Clinical Chemistry	CRP	To detect inflammation as an indicator of various conditions	Serum/Plasma	Optical /Semi-automated/Automated Methods for basic chemistry parameters, Immunoassay for hormonal and tumour markers, Blood gases analyzer for blood gases	Automated Analyzer
30	Clinical Chemistry	Troponin	To diagnose myocardial infarction	Serum/Plasma	Optical /Semi-automated/Automated Methods for basic chemistry parameters, Immunoassay for hormonal and tumour markers, Blood gases analyzer for blood gases	Automated Analyzer

SN	Test Category/ Disease	IV Diagnostic test	Test purpose	Specimen type	Assay format	Equipment used
31	Clinical Chemistry	Cholesterol	To assess risk of cardiovascular disease (CVD)	Serum/Plasma	Optical /Semi-automated/Automated Methods for basic chemistry parameters, Immunoassay for hormonal and tumour markers, Blood gases analyzer for blood gases	Automated Analyzer
32	Clinical Chemistry	FSH	Used to indicate congenital diseases with chromosome aberrations, polycystic ovaries (PCO), amenorrhea (causes), and menopausal syndrome	Serum/Plasma	Optical /Semi-automated/Automated Methods for basic chemistry parameters, Immunoassay for hormonal and tumour markers, Blood gases analyzer for blood gases	Automated Analyzer
33	Clinical Chemistry	LH	Used to indicate congenital diseases with chromosome aberrations, polycystic ovaries (PCO), amenorrhea (causes), and menopausal syndrome	Serum/Plasma	Optical /Semi-automated/Automated Methods for basic chemistry parameters, Immunoassay for hormonal and tumour markers, Blood gases analyzer for blood gases	Automated Analyzer
34	Clinical Chemistry	Estradiol	Utilized clinically in the elucidation of fertility disorders in the hypothalamus-pituitary-gonad axis, gynecomastia, oestrogen-producing ovarian and testicular tumors.	Serum/Plasma	Optical /Semi-automated/Automated Methods for basic chemistry parameters, Immunoassay for hormonal and tumour markers, Blood gases analyzer for blood gases	Automated Analyzer

SN	Test Category/ Disease	IV Diagnostic test	Test purpose	Specimen type	Assay format	Equipment used
35	Clinical Chemistry	Cortisol	Used in the regulation of many essential physiological processes, including energy metabolism, maintenance of electrolyte balance and blood pressure, immunomodulation and stress responses, cell proliferation	Serum/plasma/ urine	Optical /Semi-automated/Automated Methods for basic chemistry parameters, Immunoassay for hormonal and tumour markers, Blood gases analyzer for blood gases	Automated Analyzer
36	Clinical Chemistry	β- HCG	Aid in early detection and monitoring of pregnancy, oncology (to serve the management of patients with trophoblastic diseases).	Serum/Plasma	Optical /Semi-automated/Automated Methods for basic chemistry parameters, Immunoassay for hormonal and tumour markers, Blood gases analyzer for blood gases	Automated Analyzer
37	Clinical Chemistry	Prolactin	Utilized in postpartum to lactation, affects glucose and lipid metabolism	Serum/Plasma	Optical /Semi-automated/Automated Methods for basic chemistry parameters, Immunoassay for hormonal and tumour markers, Blood gases analyzer for blood gases	Automated Analyzer
38	Clinical Chemistry	T3/FT3	To screen for hypothyroidism and hyperthyroidism	Serum/Plasma	Optical /Semi-automated/Automated Methods for basic chemistry parameters, Immunoassay for hormonal and tumour markers, Blood gases analyzer for blood gases	Automated Analyzer

SN	Test Category/ Disease	IV Diagnostic test	Test purpose	Specimen type	Assay format	Equipment used
39	Clinical Chemistry	T4/FT4	To screen for hypothyroidism and hyperthyroidism	Serum/Plasma	Optical /Semi-automated/Automated Methods for basic chemistry parameters, Immunoassay for hormonal and tumour markers, Blood gases analyzer for blood gases	Automated Analyzer
40	Clinical Chemistry	LDH	To assess metabolic acidosis, diabetic keto-acidosis, sepsis and dehydration	Serum/Plasma	Optical /Semi-automated/Automated Methods for basic chemistry parameters, Immunoassay for hormonal and tumour markers, Blood gases analyzer for blood gases	Automated Analyzer
41	Clinical Chemistry	Testosterone	To monitor male secondary sex characteristics	Serum/Plasma	Optical /Semi-automated/Automated Methods for basic chemistry parameters, Immunoassay for hormonal and tumour markers, Blood gases analyzer for blood gases	Automated Analyzer
42	Clinical Chemistry	Triglyceride	To assess risk of cardiovascular disease (CVD)	Serum/Plasma	Optical /Semi-automated/Automated Methods for basic chemistry parameters, Immunoassay for hormonal and tumour markers, Blood gases analyzer for blood gases	Automated Analyzer

SN	Test Category/ Disease	IV Diagnostic test	Test purpose	Specimen type	Assay format	Equipment used
43	Clinical Chemistry	LDL	To assess risk of cardiovascular disease (CVD)	Serum/Plasma	Optical /Semi-automated/Automated Methods for basic chemistry parameters, Immunoassay for hormonal and tumor markers, Blood gases analyzer for blood gases	Automated Analyzer
44	Clinical Chemistry	HDL	To assess risk of cardiovascular disease (CVD)	Serum/Plasma	Optical /Semi-automated/Automated Methods for basic chemistry parameters, Immunoassay for hormonal and tumour markers, Blood gases analyzer for blood gases	Automated Analyzer
45	Clinical Chemistry	TSH	To screen for hypothyroidism and hyperthyroidism	Serum/Plasma	Optical /Semi-automated/Automated Methods for basic chemistry parameters, Immunoassay for hormonal and tumour markers, Blood gases analyzer for blood gases	Automated Analyzer
46	Clinical Chemistry	PTH	To regulate calcium level in circulation, to determine hyperparathyroidism and hypoparathyroidism	Serum/Plasma	Optical /Semi-automated/Automated Methods for basic chemistry parameters, Immunoassay for hormonal and tumour markers, Blood gases analyzer for blood gases	Automated Analyzer

SN	Test Category/ Disease	IV Diagnostic test	Test purpose	Specimen type	Assay format	Equipment used
47	Clinical Chemistry	Amylase/Lipase	To assess acute pancreatitis and other pancreatic disorders	Serum/Plasma	Optical /Semi-automated/Automated Methods for basic chemistry parameters, Immunoassay for hormonal and tumour markers, Blood gases analyzer for blood gases	Automated Analyzer
48	Clinical Chemistry	CK-MB	To determine the myocardial infraction	Serum/Plasma	Optical /Semi-automated/Automated Methods for basic chemistry parameters, Immunoassay for hormonal and tumour markers, Blood gases analyzer for blood gases	Automated Analyzer
49	Clinical Chemistry	Folic Acid	To determine folate deficiency which alter nucleic acid synthesis, methionine regeneration, To assess megaloblastic anemia	Serum/Plasma	Optical /Semi-automated/Automated Methods for basic chemistry parameters, Immunoassay for hormonal and tumour markers, Blood gases analyzer for blood gases	Automated Analyzer
50	Clinical Chemistry	Ferritin	To assess Iron deficiency anemia and hemochromatosis	Serum/Plasma	Optical /Semi-automated/Automated Methods for basic chemistry parameters, Immunoassay for hormonal and tumour markers, Blood gases analyzer for blood gases	Automated Analyzer

SN	Test Category/ Disease	IV Diagnostic test	Test purpose	Specimen type	Assay format	Equipment used
51	Clinical Chemistry	Soluble Transferrin Receptor	To describe the functional iron status. Polycythemia, hemolytic anemia, thalassemia, hereditary spherocytosis, sickle cell anemia, megaloblastic anemia	Serum/Plasma	Optical /Semi-automated/Automated Methods for basic chemistry parameters, Immunoassay for hormonal and tumour markers, Blood gases analyzer for blood gases	Automated Analyzer
52	Clinical Chemistry	Blood gases (blood PH, CO_2, O_2)	To monitor treatment for lung disease. To detect an acid-base imbalance in blood. To evaluate the effectiveness of oxygen therapy	Whole blood	Optical /Semi-automated/Automated Methods for basic chemistry parameters, Immunoassay for hormonal and tumour markers, Blood gases analyzer for blood gases	Automated Analyzer
53	Clinical Chemistry	Hb A1C	To diagnose and monitor diabetes mellitus	Serum/Plasma	Optical /Semi-automated/Automated Methods for basic chemistry parameters, Immunoassay for hormonal and tumour markers, Blood gases analyzer for blood gases	Automated Analyzer
54	Clinical Chemistry	Iron	Used in the diagnosis and treatment of diseases such as iron deficiency anemia and hemochromatosis	Serum/Plasma	Optical /Semi-automated/Automated Methods for basic chemistry parameters, Immunoassay for hormonal and tumour markers, Blood gases analyzer for blood gases	Automated Analyzer

SN	Test Category/ Disease	IV Diagnostic test	Test purpose	Specimen type	Assay format	Equipment used
55	Clinical Chemistry	AFP	Important part in the risk assessment for trisomy 21 in the second trimester of pregnancy together with hCG-β. To detect and monitor testicular cancer. To detect and monitor Hepatocellular cancer	Serum/Plasma	Optical /Semi-automated/Automated Methods for basic chemistry parameters, Immunoassay for hormonal and tumour markers, Blood gases analyzer for blood gases	Automated Analyzer
56	Clinical Chemistry	Vitamin D	To monitor bone-malformation (rickets). An aid in the assessment of bone metabolism	Serum/Plasma	Optical /Semi-automated/Automated Methods for basic chemistry parameters, Immunoassay for hormonal and tumour markers, Blood gases analyzer for blood gases	Automated Analyzer
57	Clinical Chemistry	CA-15	An aid in the early detection of recurrence in previously treated stage II and III breast cancer patients. For monitoring response to therapy in metastatic breast cancer patients	Serum/Plasma	Optical /Semi-automated/Automated Methods for basic chemistry parameters, Immunoassay for hormonal and tumour markers, Blood gases analyzer for blood gases	Automated Analyzer
58	Clinical Chemistry	Vitamin B-12	Used to confirm the diagnosis of vitamin B12 deficiency. To assess megaloblastic anemia	Serum/Plasma	Optical /Semi-automated/Automated Methods for basic chemistry parameters, Immunoassay for hormonal and tumour markers, Blood gases analyzer for blood gases	Automated Analyzer

SN	Test Category/ Disease	IV Diagnostic test	Test purpose	Specimen type	Assay format	Equipment used
59	Clinical Chemistry	CEA	To detect colorectal adenocarcinoma. Occur in non-malignant diseases of the intestine, the pancreas, the liver, and the lungs.	Serum/Plasma	Optical /Semi-automated/Automated Methods for basic chemistry parameters, Immunoassay for hormonal and tumour markers, Blood gases analyzer for blood gases	Automated Analyzer
60	Clinical Chemistry	CA-19	Primarily used in the management of pancreatic cancer. To detect obstructive jaundice as alternative test	Serum/Plasma	Optical /Semi-automated/Automated Methods for basic chemistry parameters, Immunoassay for hormonal and tumour markers, Blood gases analyzer for blood gases	Automated Analyzer
61	Clinical Chemistry	CA-125	An aid in the detection of residual or recurrent ovarian carcinoma	Serum/Plasma	Optical /Semi-automated/Automated Methods for basic chemistry parameters, Immunoassay for hormonal and tumour markers, Blood gases analyzer for blood gases	Automated Analyzer
62	Clinical Chemistry	CA-126	To monitor malignancies of the endometrium, breast, gastrointestinal tract	Serum/Plasma	Optical /Semi-automated/Automated Methods for basic chemistry parameters, Immunoassay for hormonal and tumour markers, Blood gases analyzer for blood gases	Automated Analyzer

SN	Test Category/ Disease	IV Diagnostic test	Test purpose	Specimen type	Assay format	Equipment used
63	Clinical Chemistry	TPSA/FPSA	Aid to detect inflammation or trauma of the prostate. To monitor prostate cancer	Serum/Plasma	Optical /Semi-automated/Automated Methods for basic chemistry parameters, Immunoassay for hormonal and tumour markers, Blood gases analyzer for blood gases	Automated Analyzer
64	HIV	Qualitative HIV virological nucleic acid test (Early Infant Diagnosis for HIV (EID))	For the diagnosis of HIV infection in infants < 18 months of age	Capillary whole blood/Venous whole blood/Dried blood spots	Nucleic Acid Amplification Test (HIV/EID)	mWRD
65	HIV	HIV rapid test	For the diagnosis of HIV infection: adults, adolescents, children and infants over 18 months of age	Whole blood/serum/plasma	Rapid chromatography	NA
66	Immuno-Hematology	Complete Blood Count (CBC)	To diagnose and monitor anemia and polycythemia, To monitor the safety of certain drugs, Clinical marker for certain severe infections red blood cell (RBC), platelets, Aid in the diagnosis of intravascular hemolysis, renal conditions, rhabdomyolysis (myoglobinuria)	Capillary or venous blood.	Automated hematology analyzer, total and differential counts of white blood cell (WBC), Red blood cell (RBC), platelets.	CBC Analyzer
67	Immuno-hematology	Blood Group and Rh	To determine A, B and O groups and Rh type	Capillary blood	Slide agglutination test	NA

SN	Test Category/ Disease	IV Diagnostic test	Test purpose	Specimen type	Assay format	Equipment used
68	Immuno-Hematology	Prothrombin time and international normalized ratio (PT/INR)	To detect or diagnose a bleeding disorder or thrombotic disorder (Prothrombin time)	Citrate plasma	Hand-held or automated coagulation analyzer	Coagulation analyzer
69	Immuno-hematology	LYMPHOCYTE IMMUNE-PHENOTYPING (CD4%, CD4#, CD3%, CD3#, CD8#, CD8%, CD4/CD8 RATIO & CD45#)	For staging advanced HIV disease	Venous whole blood	Flowcytometry	POC
70	Immuno-hematology	CD4%, CD8.	For monitoring response to Antiretroviral therapy. (In settings where viral load is not available)	Venous whole blood	Flowcytometry	POC
71	Immuno-Hematology	Erythrocyte sedimentation rate	The erythrocyte sedimentation rate (ESR) is a non-specific test. It is raised in a wide range of infectious, inflammatory, degenerative, and malignant conditions associated with changes in plasma proteins, particularly increases in fibrinogen, immunoglobulins, and C-reactive protein.	Venous whole blood	Automated/ESR stand	Disposable Plastic Citrated ESR Graduated pipette tube

SN	Test Category/ Disease	IV Diagnostic test	Test purpose	Specimen type	Assay format	Equipment used
72	Immuno-Hematology	Morphology examination (peripheral blood, bone marrow, Biopsy, ….)	For detection of red blood cell, white blood cell and platelet abnormalities, malignancies and parasites and for white blood cell differential count	Capillary and venous whole blood	Romanowsky stained blood films	Microscopy
73	Immuno-hematology	Blood cross matching	To determine blood compatibility for blood transfusions; Rh typing for pregnant women	Whole blood/serum/plasma	Antisera for agglutination	NA
74	Parasitology	Wet mount	For detection of *T. vaginalis*	Urine	Wet smear	Microscope
75	Parasitology	Peripheral smear for malaria and other parasite detection	For diagnosis of one or more human malaria species (*P. falciparum, P. vivax, P. malariae, P. ovale*) and *Borrela spps*, For *filarial* parasite detection, For detection of trypomastigotes stage of *T.b. gambiense*	Capillary/venous blood	Blood Staining	Microscope
76	Parasitology	Peripheral smear for malaria and other parasite detection	For *filarial* parasite detection, For detection of trypomastigotes stage of *T.b. gambiense*	Capillary Blood /CSF	Staining of thick blood film	Microscope
77	Parasitology	Direct microscopy and formol-ether concentration of faeces for ova or parasite	Microscopy of fresh faeces for detection of trophozoites, ova, cysts &larvae of the parasite	Stool/faeces	Wet smear	Microscope
78	Parasitology	Skin snip	For detection of microfilariae of *O. volvulus*	Skin snip	Wet smear	Microscope
79	SARS COV-2 (COVID-19)	COVID-19 testing	Diagnosis of SARS COV-2	Nasopharyngeal/Oro pharyngeal specimens	Nucleic Acid Amplification Test (RT PCR)	Automated

SN	Test Category/ Disease	IV Diagnostic test	Test purpose	Specimen type	Assay format	Equipment used
80	Serology/Immunology	Pregnancy test	Pregnancy, uterine Ca	Urine	Rapid chromatography/Strip test	NA
81	Serology/Immunology	Hepatitis B surface antigen (HBsAg)	Screening for acute and chronic hepatitis B (HBV) infection: infants over 12 months of age, children, adolescents, adults	Serum	Rapid chromatography/ Test Cassette	NA
82	Serology/Immunology	*Hepatitis C* (Anti-HCV antibody)	Screening for HCV infection: infants over 18 months of age, children, adolescents, adults	Serum	Rapid chromatography/ Test Cassette	NA
83	Serology/Immunology	*Human Papilloma Virus*	Used for cervical cancer screening	Serum	Rapid chromatography	NA
84	Serology/Immunology	Cryptococcal antigen test	For screening and diagnosis of cryptococcal meningitis in people living with advanced HIV disease	Serum	Rapid chromatography/ Test Cassette	NA
85	Serology/Immunology	Direct Coombs test	The direct Coombs test is used to test for autoimmune hemolytic anemia	Whole blood/serum/plasma	Agglutination	NA
86	Serology/Immunology	Indirect Coombs test	The indirect Coombs test is used in prenatal testing of pregnant women and in testing prior to a blood transfusion	Whole blood/serum/plasma	Agglutination	NA
87	Serology/Immunology	*H. pylori Ag/Ab*	Look for *H. pylori* bacteria in the digestive tract,	Stool	Rapid chromatography/ Test Cassette	NA
88	Serology/Immunology	*Salmonella (Widal Test (H, O))*	Diagnosis of typhoid fever	Serum	Rapid chromatography/ Test Cassette	NA
89	Serology/Immunology	*Proteus Weil Felix Test- OX19*	Diagnosis of typhus fever	Serum	Rapid chromatography/Test Cassette	NA

SN	Test Category/ Disease	IV Diagnostic test	Test purpose	Specimen type	Assay format	Equipment used
90	Serology/Immunology	Occult blood	Occult blood in the stool may indicate colon cancer or polyps in the colon or rectum though not all cancers or polyps' bleed.	Stool	Rapid chromatography/ Test Cassette	NA
91	Serology/Immunology	ASO (ANTI-STREPTOLYSIN O)	To help determine whether you have had a recent strep infection with the bacteria *group A Streptococcus*; to help diagnose complications resulting from a strep infection such as rheumatic fever or glomerulonephritis, a form of kidney disease	Serum	Rapid chromatography	NA
92	Serology/Immunology	Rheumatoid Factor (RF)	An RF test is most often used to help diagnose rheumatoid arthritis	Serum	Rapid chromatography	NA
93	Serology/Immunology	complement blood test	To measure the levels of a specific type of compliment protein in your blood (eg. C3 proteins)	Serum	Optical /Semi-automated/Automated Methods	Automated Analyzer
94	Urinalysis	Urinalysis/dipstick	To detect urinary tract infections	urine	Multi- parameter Strip (dipstick	N/A
95	Urinalysis	Urine Microscopic	Microscopic Urine sediment examination for detection of *S. haematobium*, cells and infectious agents	Urine	Microscopy	Microscopy
96	Urinalysis	24-hrs urine protein	For the quantitative assessment of 24-hrs urine protein	24-hrs Urine	Optical /Semi-automated/Automated Methods	Automated Analyzer

3.9 Standalone Reference Laboratories

The standalone reference laboratories include the National and Regional Reference Laboratories. These laboratories are organized to provide referral laboratory services that embraces more advanced, comprehensive and specialized laboratory tests. The arrangement of essential diagnostic tests for these reference laboratories differs from the other level laboratories as they have more advanced infrastructure including sophisticated equipment and staffed with highly qualified personnel. Furthermore, they are expected to support health researches including survey and surveillance activities as well as responsible for the detection and characterization of emerging and re-emerging infectious pathogens to guide effective responses to public health emergency events.

3.9.1 List of Laboratory Tests at Regional Reference Laboratories

SN	Test Category/Disease	IV Diagnostic test	Test purpose	Specimen type	Assay format	Equipment used
1	Bacteriology & Mycology	Culture /aerobic and (AST)	Initial step in detection and identification of bacterial and fungal species for selection of appropriate antibiotic regimens	Urine, blood, pus, Stool, Sputum spinal fluid, or discharge from the vagina or penis, etc.	Culture	Traditional manual techniques and Automated
2	Bacteriology & Mycology	Genus and species identification of bacteria and fungi	For the identification of the genus or species of bacteria from cultured isolates	Isolates from bacterial or cultures	A range of biochemical tests that may be performed manually or on automated equipment.	Automated / manual.

SN	Test Category/ Disease	IV Diagnostic test	Test purpose	Specimen type	Assay format	Equipment used
3	Bacteriology & Mycology	Genus and species identification of bacteria *B. anthracis*	For the detection and identification of *B. anthracis*	Serum, Stool, CSF, Nasal swab, sputum, Ascetic fluid, Swab from cutaneous, vesicular lesion	Nucleic acid extraction from specimens followed by RT-PCR	RT- PCR machine
4	Bacteriology & Mycology	Genus and species identification of bacteria Vibrio cholera O1 and O39	For the detection and identification of *V. cholerae 01/0139*	Stool, Rectal swab and water	Stool culture, PCR (from isolates)	Manual / automated
5	Bacteriology & Mycology	Genus and species identification of bacteria Dysentery causative agents like Shigellosis	For the detection and identification dysentery causative agents like Shigellosis	Stool	Stool culture	Microscopy, Bacterial Culture, and Serological test
6	Bacteriology & Mycology	Genus and species identification of bacterial Meningitis (N.menigitidis,S.pneumonae,H.influenza,E.coli)	For the detection and identification causative agents for bacterial meningitis	CSF, Blood	Serological test, culture, PCR	Microscopy(A). Bacterial Culture
7	Bacteriology & Mycology	Genus and species identification of Brucellosis	Genus and species identification of brucellosis	Blood, CSF,	ELISA, PCR	ELISA, PCR
8	Clinical Chemistry	CEA	To detect colorectal adenocarcinoma. Occur in non-malignant diseases of the intestine, the pancreas, the liver, and the lungs.	Serum/Plasma	Optical /Semi-automated/Automated Methods for basic chemistry parameters, Immunoassay for hormonal and tumor markers.	Automated Analyzer

SN	Test Category/ Disease	IV Diagnostic test	Test purpose	Specimen type	Assay format	Equipment used
9	Clinical Chemistry	CA-15	An aid in the early detection of recurrence in previously treated stage II and III breast cancer patients. For monitoring response to therapy in metastatic breast cancer patients	Serum/Plasma	Optical /Semi-automated/Automated Methods for basic chemistry parameters, Immunoassay for hormonal and tumor markers.	Automated Analyzer
10	Clinical Chemistry	CA-19	Primarily used in the management of pancreatic cancer. To detect obstructive jaundice as alternative test	Serum/Plasma	Optical /Semi-automated/Automated Methods for basic chemistry parameters, Immunoassay for hormonal and tumor markers.	Automated Analyzer
11	Clinical Chemistry	CA-125	An aid in the detection of residual or recurrent ovarian carcinoma. To monitor malignancies of the endometrium, breast, gastrointestinal tract	Serum/Plasma	Optical /Semi-automated/Automated Methods for basic chemistry parameters, Immunoassay for hormonal and tumor markers.	Automated Analyzer
12	Clinical Chemistry	TPSA/FPSA	Aid to detect inflammation or trauma of the prostate. To monitor prostate cancer	Serum/Plasma	Optical /Semi-automated/Automated Methods for basic chemistry parameters, Immunoassay for hormonal and tumor markers.	Automated Analyzer
13	Clinical Chemistry	GGT	To assess hepatobiliary function. To distinguish between bone and hepatobiliary causes of raised ALP	Serum/Plasma	Optical /Semi-automated/Automated Methods for basic chemistry parameters, Immunoassay for hormonal and tumor markers.	Automated Analyzer

SN	Test Category/ Disease	IV Diagnostic test	Test purpose	Specimen type	Assay format	Equipment used
14	Clinical Chemistry	β- HCG	Aid in early detection and monitoring of pregnancy, oncology (to serve the management of patients with trophoblastic diseases).	Serum/Plasma	Optical /Semi-automated/Automated Methods for basic chemistry parameters, Immunoassay for hormonal and tumor markers.	Automated Analyzer
15	Clinical Chemistry	T3/FT3	To screen for hypothyroidism and hyperthyroidism	Serum/Plasma	Optical /Semi-automated/Automated Methods for basic chemistry parameters, Immunoassay for hormonal and tumor markers.	Automated Analyzer
16	Clinical Chemistry	T4/FT4	To screen for hypothyroidism and hyperthyroidism	Serum/Plasma	Optical /Semi-automated/Automated Methods for basic chemistry parameters, Immunoassay for hormonal and tumor markers.	Automated Analyzer
17	Clinical Chemistry	Amylase/Lipase	To assess acute pancreatitis and other pancreatic disorders	Serum/Plasma	Optical /Semi-automated/Automated Methods for basic chemistry parameters, Immunoassay for hormonal and tumor markers.	Automated Analyzer
18	Clinical Chemistry	Iron	Used in the diagnosis and treatment of diseases such as iron deficiency anemia and hemochromatosis	Serum/Plasma	Optical /Semi-automated/Automated Methods for basic chemistry parameters, Immunoassay for hormonal and tumor markers.	Automated Analyzer

SN	Test Category/ Disease	IV Diagnostic test	Test purpose	Specimen type	Assay format	Equipment used
19	Clinical Chemistry	Hb A1C	To diagnose and monitor diabetes mellitus	Serum/Plasma	Optical /Semi-automated/Automated Methods for basic chemistry parameters, Immunoassay for hormonal and tumor markers.	Automated Analyzer
20	Clinical Chemistry	Estradiol	Utilized clinically in the elucidation of fertility disorders in the hypothalamus-pituitary-gonad axis, gynecomastia, oestrogen-producing ovarian and testicular tumors.	Serum/Plasma	Optical /Semi-automated/Automated Methods for basic chemistry parameters, Immunoassay for hormonal and tumor markers.	Automated Analyzer
21	Clinical Chemistry	Cortisol	Used in the regulation of many essential physiological processes, including energy metabolism, maintenance of electrolyte balance and blood pressure, immunomodulation and stress responses, cell proliferation	Serum/plasma/ urine	Optical /Semi-automated/Automated Methods for basic chemistry parameters, Immunoassay for hormonal and tumor markers.	Automated Analyzer
22	Clinical Chemistry	Vitamin B-12	Used to confirm the diagnosis of vitamin B12 deficiency. To assess megaloblastic anemia	Serum/Plasma	Optical /Semi-automated/Automated Methods for basic chemistry parameters, Immunoassay for hormonal and tumor markers.	Automated Analyzer
23	Clinical Chemistry	Folic Acid	To determine folate deficiency which alter nucleic acid synthesis, methionine regeneration. To assess megaloblastic anemia	Serum/Plasma	Optical /Semi-automated/Automated Methods for basic chemistry parameters, Immunoassay for hormonal and tumor markers.	Automated Analyzer

SN	Test Category/ Disease	IV Diagnostic test	Test purpose	Specimen type	Assay format	Equipment used
24	Clinical Chemistry	Ferritin	To assess Iron deficiency anemia and hemochromatosis	Serum/Plasma	Optical /Semi-automated/Automated Methods for basic chemistry parameters, Immunoassay for hormonal and tumor markers.	Automated Analyzer
25	Clinical Chemistry	Soluble Transferrin Receptor	To describe the functional iron status. Polycythemia, hemolytic anemia, thalassemia, hereditary spherocytosis, sickle cell anemia, megaloblastic anemia	Serum/Plasma	Optical /Semi-automated/Automated Methods for basic chemistry parameters, Immunoassay for hormonal and tumor markers.	Automated Analyzer
26	Clinical Chemistry	CK-MB	To determine myocardial infraction	Serum/Plasma	Optical /Semi-automated/Automated Methods for basic chemistry parameters, Immunoassay for hormonal and tumor markers.	Automated Analyzer
27	Clinical Chemistry	CK/CPK	To determine the myocardial infraction	Serum/Plasma	Optical /Semi-automated/Automated Methods for basic chemistry parameters, Immunoassay for hormonal and tumor markers.	Automated Analyzer
28	Clinical Chemistry	Testosterone	To monitor male secondary sex characteristics	Serum/Plasma	Optical /Semi-automated/Automated Methods for basic chemistry parameters, Immunoassay for hormonal and tumor markers.	Automated Analyzer

SN	Test Category/ Disease	IV Diagnostic test	Test purpose	Specimen type	Assay format	Equipment used
29	Clinical Chemistry	PTH	To regulate calcium level in circulation, to determine hyperparathyroidism and hypoparathyroidism	Serum/Plasma	Optical /Semi-automated/Automated Methods for basic chemistry parameters, Immunoassay for hormonal and tumor markers.	Automated Analyzer
30	Clinical Chemistry	Prolactin	Utilized in postpartum to lactation, affects glucose and lipid metabolism	Serum/Plasma	Optical /Semi-automated/Automated Methods for basic chemistry parameters, Immunoassay for hormonal and tumor markers.	Automated Analyzer
31	Clinical Chemistry	Vitamin D	To monitor bone-malformation (rickets). An aid in the assessment of bone metabolism		Optical /Semi-automated/Automated Methods for basic chemistry parameters, Immunoassay for hormonal and tumor markers.	Automated Analyzer
32	Hepatitis B	Viral Load/Quantitative	Treatment Monitoring	Plasma/Serum	Nucleic Acid Amplification Test (RT PCR)	Abbott/Roche
33	HIV	Viral Load/Quantitative	Treatment Monitoring	Plasma	Nucleic Acid Amplification Test (RT PCR)	Abbott/Roche
34	HIV	Qualitative HIV virological nucleic acid test (Early Infant Diagnosis for HIV (EID))	Diagnosis	Dry Blood Spot (DBS)	Nucleic Acid Amplification Test (RT PCR)	Abbott/Roche

SN	Test Category/ Disease	IV Diagnostic test	Test purpose	Specimen type	Assay format	Equipment used
35	Human papilloma virus	Molecular testing	For the diagnosis of human papilloma virus	Cervical swab	Nucleic Acid Amplification Test (RT PCR)	Abbott/Roche
36	Immuno-hematology	CBC	To evaluate overall health and to detect a wide range of disorders, including anemia, infections, leukemia's, red blood cell, white blood cell and platelet abnormalities and primary immune disorders	EDTA whole blood.	Fully Automated hematology analyzer	Fully Automated hematology analyzer
37	Immuno-hematology	Lymphocyte immune-phenotyping (CD4%, CD4#, CD3%, CD3#, CD8#, CD8%, CD4/CD8 ratio & CD45#)	Used to monitor immune deficiency therapy.	EDTA blood	Automated flow cytometer	Automated flow cytometer
38	Immuno-hematology	D-Dimer	To diagnose disseminated intravascular coagulation	Citrate plasma	Fully Automated coagulation analyzer	Fully Automated hematology analyzer
39	Immuno-hematology	Sickle cell testing	To aid in the diagnosis of sickle cell anemia, sickle	Venous EDTA whole blood	Sodium metabisulfite slide test, Hemoglobin Solubility	Fully Automated hematology analyzer
40	Molecular test	Genus and species identification of *Pertussis*	Genus and species identification for bacterial whooping cough	Bacterial isolate, Nasopharyngeal	RT PCR	RT-PCR

SN	Test Category/ Disease	IV Diagnostic test	Test purpose	Specimen type	Assay format	Equipment used
41	Parasitology	Molecular test for *malaria*	PCR (gold standard) for *malaria* confirmation and species determination.	EDTA Blood	PCR	PCR machine
42	Parasitology	Culture and PCR for *Leishmaniases/for endemic regions*	For the investigation of cutaneous or visceral *leishmaniasis*	Bone marrow, lymph, spleen, liver, tissue.	Culture and PCR	PCR machine
43	Parasitology	Others Molecular tests	For species determinations & conformation of parasites	Blood, CSF, any body fluids	Culture and PCR	PCR machine
44	SARS COV-2 (COVID-19)	COVID-19 testing molecular	Diagnosis	Nasopharyngeal/Oro pharyngeal specimens	Nucleic Acid Amplification Test (RT PCR)	Automated/ Manual
45	TB	Molecular WRD test	Diagnosis	Sputum	Nucleic Acid Amplification Test	mWRD
46	TB	Mycobacterium tuberculosis bacteria culture	Diagnosis and Treatment monitoring	Sputum/Body fluid	Bacterial Culture (LJ and MGIT)	BD MIGIT 960/Manual
47	TB	Drug susceptibility testing with MTB culture	To detect resistance to first-line	Bacterial culture of MTB	Bacterial Culture (LJ and MGIT)	BD MIGIT 960/Manual
48	TB	MTB DNA mutations associated with resistance	For the detection of resistance for second-line anti-TB medicines	Sputum/Bacterial culture of MTB	Molecular line probe assay (LPA)	Twincubator
49	Other newly emerging tests of clinical and public health importance				Latest method and technology	

3.9.2 List of Laboratory Tests at National Reference Laboratories

SN	Test Category/Disease	IV Diagnostic test	Test purpose	Specimen type	Assay format	Equipment used
1	Bacteriology & Mycology	Genus and species identification of bacteria and fung	For the identification of the genus or species of bacteria or fungi from cultured isolates	Isolates from bacterial or fungal cultures	A range of biochemical tests that may be performed manually or on automated equipment.	Automated / manual.
2	Bacteriology & Mycology	Culture and Antimicrobial susceptibility testing (AST)	For the detection of bacterial and fungal bloodstream infections (sepsis)	Bacterial isolate, Venous whole blood collected aseptically.	Blood culture bottle in an incubator followed by recovery of isolates.	Automated /manual
3	Bacteriology & Mycology	Genus and species identification of bacteria *Vibrio cholera O1 and O39*	For the detection and identification of *V. Cholera* 01/0139	Bacterial isolate, Stool, Rectal swab and water	Stool culture, PCR (from isolates)	RT- PCR machine
4	Bacteriology & Mycology	Genus and species identification of bacteria Dysentery causative agents like *Shigellosis*	For the detection and identification of dysentery causing agents like *Shigellosis*	Bacterial isolate, Stool	Stool culture	Microscopy, Bacterial Culture, and Serological test
5	Bacteriology & Mycology	Genus and species identification of bacterial Meningitis (*N.menigitidis,S.pneumonae,H.influenza,E.coli)*	For the detection and identification of bacterial meningitis causing agents	Bacterial isolate, CSF, Blood	Culture, PCR	Bacterial Culture, RT-PCR

SN	Test Category/ Disease	IV Diagnostic test	Test purpose	Specimen type	Assay format	Equipment used
6	Bacteriology & Mycology	Culture anaerobic	Initial step in detection and identification of bacterial and fungal species for selection of appropriate antibiotic regimens	Bacterial isolate, normally sterile body fluids, Surgical specimens from sites that normally are sterile, Deep abscess contents taken aseptically, Aspirates from deep wounds	Culture	Anaerobic chamber and incubator.
7	Bacteriology & Mycology	Genus and species identification of bacteria *B. anthracis*	For the detection and identification of *B. anthracis*	Bacterial isolate Serum, Stool, CSF, Nasal swab, sputum, Ascetic fluid, Swab from cutaneous, vesicular lesion	Nucleic acid extraction from specimens followed by RT-PCR	RT- PCR machine
8	Bacteriology & Mycology	Genus and species identification of Brucellosis	Genus and species identification of brucellosis	Bacterial isolate, Blood, CSF,	ELISA, RT-PCR	ELISA, RT-PCR
9	Bacteriology & Mycology	Genus and species identification of Pertussis	Checks for bacterial whooping cough	Bacterial isolate, Nasopharyngeal	RT PCR	RT-PCR
10	Bacteriology & Mycology	Fungal culture	Checks for the growth of fungal isolates	Fungal isolate, Skin, scalp, nail scraping	Culture	Manual

SN	Test Category/ Disease	IV Diagnostic test	Test purpose	Specimen type	Assay format	Equipment used
11	Clinical chemistry	T3/FT3	To screen for hypothyroidism and hyperthyroidism	Serum/Plasma	Optical /Semi-automated/Automated Methods for basic chemistry parameters, Immunoassay for hormonal and tumor markers.	Semi-automated/Automated Analyzer
12	Clinical chemistry	T4/FT4	To screen for hypothyroidism and hyperthyroidism	Serum/Plasma	Optical /Semi-automated/Automated Methods for basic chemistry parameters, Immunoassay for hormonal and tumor markers.	Semi-automated/Automated Analyzer
13	Clinical chemistry	TSH	To screen for hypothyroidism and hyperthyroidism	Serum/Plasma	Optical /Semi-automated/Automated Methods for basic chemistry parameters, Immunoassay for hormonal and tumor markers.	Semi-automated/Automated Analyzer
14	Clinical chemistry	FSH	Used to indicate congenital diseases with chromosome aberrations, polycystic ovaries (PCO), amenorrhea (causes), and menopausal syndrome	Serum/Plasma	Optical /Semi-automated/Automated Methods for basic chemistry parameters, Immunoassay for hormonal and tumor markers.	Semi-automated/Automated Analyzer

SN	Test Category/ Disease	IV Diagnostic test	Test purpose	Specimen type	Assay format	Equipment used
15	Clinical chemistry	LH	Used to indicate congenital diseases with chromosome aberrations, polycystic ovaries (PCO), amenorrhea (causes), and menopausal syndrome	Serum/Plasma	Optical /Semi-automated/Automated Methods for basic chemistry parameters, Immunoassay for hormonal and tumor markers.	Semi-automated/Automated Analyzer
16	Clinical chemistry	AFP	Important part in the risk assessment for trisomy 21 in the second trimester of pregnancy together with hCG-β. To detect and monitor testicular cancer. To detect and monitor Hepatocellular cancer	Serum/Plasma	Optical /Semi-automated/Automated Methods for basic chemistry parameters, Immunoassay for hormonal and tumor markers.	Semi-automated/Automated Analyzer
17	Clinical chemistry	Iron	Used in the diagnosis and treatment of diseases such as iron deficiency anemia and hemochromatosis	Serum/Plasma	Optical /Semi-automated/Automated Methods for basic chemistry parameters, Immunoassay for hormonal and tumor markers.	Semi-automated/Automated Analyzer
18	Clinical chemistry	Soluble Transferrin Receptor	To describe the functional iron status. Polycythaemia, hemolytic anemia, thalassemia, hereditary spherocytosis, sickle cell anaemia, megaloblastic anemia	Serum/Plasma	Optical /Semi-automated/Automated Methods for basic chemistry parameters, Immunoassay for hormonal and tumor markers.	Semi-automated/Automated Analyzer

SN	Test Category/ Disease	IV Diagnostic test	Test purpose	Specimen type	Assay format	Equipment used
19	Clinical chemistry	CEA	To detect colorectal adenocarcinoma. Occur in non-malignant diseases of the intestine, the pancreas, the liver, and the lungs.	Serum/Plasma	Optical /Semi-automated/Automated Methods for basic chemistry parameters, Immunoassay for hormonal and tumor markers.	Semi-automated/Automated Analyzer
20	Clinical chemistry	CA-15	An aid in the early detection of recurrence in previously treated stage II and III breast cancer patients. For monitoring response to therapy in metastatic breast cancer patients	Serum/Plasma	Optical /Semi-automated/Automated Methods for basic chemistry parameters, Immunoassay for hormonal and tumor markers.	Semi-automated/Automated Analyzer
21	Clinical chemistry	CA-19	Primarily used in the management of pancreatic cancer. To detect obstructive jaundice as alternative test	Serum/Plasma	Optical /Semi-automated/Automated Methods for basic chemistry parameters, Immunoassay for hormonal and tumor markers.	Semi-automated/Automated Analyzer
22	Clinical chemistry	CA-125	An aid in the detection of residual or recurrent ovarian carcinoma. To monitor malignancies of the endometrium, breast, gastrointestinal tract	Serum/Plasma	Optical /Semi-automated/Automated Methods for basic chemistry parameters, Immunoassay for hormonal and tumor markers.	Semi-automated/Automated Analyzer

SN	Test Category/ Disease	IV Diagnostic test	Test purpose	Specimen type	Assay format	Equipment used
23	Clinical chemistry	Hb A1C	To diagnose and monitor diabetes mellitus	Serum/Plasma	Optical /Semi-automated/Automated Methods for basic chemistry parameters, Immunoassay for hormonal and tumor markers.	Semi-automated/Automated Analyzer
24	Clinical chemistry	Cholesterol	To assess risk of cardiovascular disease (CVD)	Serum/Plasma	Optical /Semi-automated/Automated Methods for basic chemistry parameters, Immunoassay for hormonal and tumor markers.	Semi-automated/Automated Analyzer
25	Clinical chemistry	Triglyceride	To assess risk of cardiovascular disease (CVD)	Serum/Plasma	Optical /Semi-automated/Automated Methods for basic chemistry parameters, Immunoassay for hormonal and tumor markers.	Semi-automated/Automated Analyzer
26	Clinical chemistry	LDL	To assess risk of cardiovascular disease (CVD)	Serum/Plasma	Optical /Semi-automated/Automated Methods for basic chemistry parameters, Immunoassay for hormonal and tumor markers.	Semi-automated/Automated Analyzer

SN	Test Category/ Disease	IV Diagnostic test	Test purpose	Specimen type	Assay format	Equipment used
27	Clinical chemistry	HDL	To assess risk of cardiovascular disease (CVD)	Serum/Plasma	Optical /Semi-automated/Automated Methods for basic chemistry parameters, Immunoassay for hormonal and tumor markers.	Semi-automated/Automated Analyzer
28	Clinical chemistry	LDH	To assess metabolic acidosis, diabetic keto-acidosis, sepsis and dehydration	Serum/Plasma	Optical /Semi-automated/Automated Methods for basic chemistry parameters, Immunoassay for hormonal and tumor markers.	Semi-automated/Automated Analyzer
29	Clinical chemistry	TPSA/FPSA	Aid to detect inflammation or trauma of the prostate. To monitor prostate cancer	Serum/Plasma	Optical /Semi-automated/Automated Methods for basic chemistry parameters, Immunoassay for hormonal and tumor markers.	Semi-automated/Automated Analyzer
30	Clinical chemistry	GGT	To assess hepatobiliary function. To distinguish between bone and hepatobiliary causes of raised ALP	Serum/Plasma	Optical /Semi-automated/Automated Methods for basic chemistry parameters, Immunoassay for hormonal and tumor markers.	Semi-automated/Automated Analyzer
31	Clinical chemistry	CK-MB	To determine the myocardial infraction	Serum/Plasma	Optical /Semi-automated/Automated Methods for basic chemistry parameters, Immunoassay for hormonal and tumor markers.	Semi-automated/Automated Analyzer

SN	Test Category/ Disease	IV Diagnostic test	Test purpose	Specimen type	Assay format	Equipment used
32	Clinical chemistry	CK/CPK	To determine the myocardial infraction	Serum/Plasma	Optical /Semi-automated/Automated Methods for basic chemistry parameters, Immunoassay for hormonal and tumor markers.	Semi-automated/Automated Analyzer
33	Clinical chemistry	Amylase/Lipase	To assess acute pancreatitis and other pancreatic disorders	Serum/Plasma	Optical /Semi-automated/Automated Methods for basic chemistry parameters, Immunoassay for hormonal and tumor markers.	Semi-automated/Automated Analyzer
34	Clinical chemistry	Ferritin	To assess Iron deficiency anemia and hemochromatosis	Serum/Plasma	Optical /Semi-automated/Automated Methods for basic chemistry parameters, Immunoassay for hormonal and tumor markers.	Semi-automated/Automated Analyzer
35	Clinical chemistry	Estradiol	Utilized clinically in the elucidation of fertility disorders in the hypothalamus-pituitary-gonad axis, gynecomastia, oestrogen-producing ovarian and testicular tumors.	Serum/Plasma	Optical /Semi-automated/Automated Methods for basic chemistry parameters, Immunoassay for hormonal and tumor markers.	Semi-automated/Automated Analyzer

SN	Test Category/ Disease	IV Diagnostic test	Test purpose	Specimen type	Assay format	Equipment used
36	Clinical chemistry	Cortisol	Used in the regulation of many essential physiological processes, including energy metabolism, maintenance of electrolyte balance and blood pressure, immunomodulation and stress responses, cell proliferation	Serum/plasma/ urine	Optical /Semi-automated/Automated Methods for basic chemistry parameters, Immunoassay for hormonal and tumor markers.	Semi-automated/Automated Analyzer
37	Clinical chemistry	β- HCG	Aid in early detection and monitoring of pregnancy, oncology (to serve the management of patients with trophoblastic diseases).	Serum/Plasma	Optical /Semi-automated/Automated Methods for basic chemistry parameters, Immunoassay for hormonal and tumor markers.	Semi-automated/Automated Analyzer
38	Clinical chemistry	Testosterone	To monitor male secondary sex characteristics	Serum/Plasma	Optical /Semi-automated/Automated Methods for basic chemistry parameters, Immunoassay for hormonal and tumor markers.	Semi-automated/Automated Analyzer
39	Clinical chemistry	PTH	To regulate calcium level in circulation, to determine hyperparathyroidism and hypoparathyroidism	Serum/Plasma	Optical /Semi-automated/Automated Methods for basic chemistry parameters, Immunoassay for hormonal and tumor markers.	Semi-automated/Automated Analyzer

SN	Test Category/ Disease	IV Diagnostic test	Test purpose	Specimen type	Assay format	Equipment used
40	Clinical chemistry	Vitamin B-12	Used to confirm the diagnosis of vitamin B12 deficiency. To assess megaloblastic anemia	Serum/Plasma	Optical /Semi-automated/Automated Methods for basic chemistry parameters, Immunoassay for hormonal and tumor markers.	Semi-automated/Automated Analyzer
41	Clinical chemistry	Folic Acid	To determine folate deficiency which alter nucleic acid synthesis, methionine regeneration. To assess megaloblastic anemia	Serum/Plasma	Optical /Semi-automated/Automated Methods for basic chemistry parameters, Immunoassay for hormonal and tumor markers.	Semi-automated/Automated Analyzer
42	Clinical chemistry	Phenobarbital	Essential to achieve maximal seizure control	Serum/Plasma	Optical /Semi-automated/Automated Methods for basic chemistry parameters, Immunoassay for hormonal and tumor markers.	Semi-automated/Automated Analyzer
43	Clinical chemistry	Phenytoin	For seizure control	Serum/Plasma	Optical /Semi-automated/Automated Methods for basic chemistry parameters, Immunoassay for hormonal and tumor markers.	Semi-automated/Automated Analyzer

SN	Test Category/ Disease	IV Diagnostic test	Test purpose	Specimen type	Assay format	Equipment used
44	Clinical chemistry	Lithium	To ensure compliance and to avoid toxicity in the treatment of manic-depressive psychosis.	Serum/Plasma	Optical /Semi-automated/Automated Methods for basic chemistry parameters, Immunoassay for hormonal and tumor markers.	Semi-automated/Automated Analyzer
45	Clinical chemistry	Valproic acid	For the treatment of primary and secondary generalized seizures	Serum/Plasma	Optical /Semi-automated/Automated Methods for basic chemistry parameters, Immunoassay for hormonal and tumor markers.	Semi-automated/Automated Analyzer
46	Clinical chemistry	Protein electrophoresis	Used to direct detect accurate relative quantification of individual protein fractions.	Urine/serum	Optical /Semi-automated/Automated Methods for basic chemistry parameters, Immunoassay for hormonal and tumor markers.	Semi-automated/Automated Analyzer
47	Clinical chemistry	Hemoglobin variant	Used for the separation of the normal hemoglobin (A, F and A2) and for the detection of the major hemoglobin variants (especially S, C, E or D)	Whole blood	Optical /Semi-automated/Automated Methods for basic chemistry parameters, Immunoassay for hormonal and tumor markers.	Semi-automated/Automated Analyzer
48	Clinical chemistry	Capillary immunotyping	For the detection and the characterization of monoclonal proteins (immunotyping)	Urine/serum	Optical /Semi-automated/Automated Methods for basic chemistry parameters, Immunoassay for hormonal and tumor markers.	Semi-automated/Automated Analyzer

SN	Test Category/ Disease	IV Diagnostic test	Test purpose	Specimen type	Assay format	Equipment used
49	Clinical chemistry	Prolactin	Utilized in postpartum to lactation, affects glucose and lipid metabolism	Serum/Plasma	Optical /Semi-automated/Automated Methods for basic chemistry parameters, Immunoassay for hormonal and tumor markers.	Semi-automated/Automated Analyzer
50	Clinical chemistry	Carbamazepine	Used in particular for the treatment of trigeminal neuralgia, all forms of partial epilepsy, generalized tonic-clonic seizures, and simple and complex partial seizures	Serum/Plasma	Optical /Semi-automated/Automated Methods for basic chemistry parameters, Immunoassay for hormonal and tumor markers.	Semi-automated/Automated Analyzer
51	Genomic Sequencing	Genomic Sequencing	Detection of Down Syndrome, tumor and multiple pathogens	Cells, tissue, formalin-fixed and paraffin-embedded (FFPE) tissue, and liquid biopsies	Whole-genome sequencing (WGS)	
52	Hepatitis B	Viral Load/Quantitative	Treatment Monitoring	Plasma/Serum	Nucleic Acid Amplification Test (RT PCR)	Abbott/Roche
53	Hepatitis C	Viral Load/Quantitative	Treatment Monitoring	Plasma/Serum	Nucleic Acid Amplification Test (RT PCR)	Abbott/Roche
54	HIV	Viral Load/Quantitative	Treatment Monitoring	Plasma	Nucleic Acid Amplification Test (RT PCR)	Abbott/Roche
55	HIV	Early Infant Diagnosis for HIV (EID)	Diagnosis	Dry Blood Spot (DBS)	Nucleic Acid Amplification Test (RT PCR)	Abbott/Roche
56	HIV	Drug resistance	Treatment Monitoring	Plasma/Serum/Body fluids	Genotypic/Phenotypic	Sanger/Illumina

SN	Test Category/ Disease	IV Diagnostic test	Test purpose	Specimen type	Assay format	Equipment used
57	HUMAN PAPILLOMA VIRUS	Molecular testing	For diagnosis of HUMAN PAPILLOMA VIRUS	Cervical swab	Nucleic Acid Amplification Test (RT PCR)	Abbott/Roche
58	Immuno-Hematology	Lymphocyte immunophenotyping (CD4%, CD4#, CD3%, CD3#, CD8#, CD8%, CD4/CD8 ratio & CD45#)	Used to monitor Immuno deficiency therapy.	EDTA whole blood	Automated Flow cytometer	Fully automated coagulation analyzer
59	Immuno-Hematology	COMPLETE BLOOD COUNT (CBC) with Reticulocyte count.	To evaluate overall health and to detect a wide range of disorders, including anemia, infections, leukemia's, red blood cell, white blood cell and platelet abnormalities and primary immune disorders	EDTA	Fully automated hematology analyzer	Fully automated hematology analyzer
60	Immuno-Hematology	Haemoglobinopathies screening/testing (in high prevalence areas)	To diagnose hemoglobin defect.	DBS and whole blood	Isoelectric focusing (IEF) and High-performance liquid chromatography (HPLC)	Fully automated coagulation analyzer
61	Immuno-Hematology	Immuno- phenotyping	For the diagnosis of hematological malignancy.	EDTA Whole blood	Automated Flowcytometry Analyzer	Fully automated coagulation analyzer
62	Immuno-Hematology	Flowcytometry cross-matching (FCXM) for transplantation	For organ transplanting purpose	Tissue.	Automated Flowcytometry Analyzer	Fully automated coagulation analyzer

SN	Test Category/ Disease	IV Diagnostic test	Test purpose	Specimen type	Assay format	Equipment used
63	Immuno-Hematology	BCR-ABL Assay for CML diagnosis	For the diagnosis of chronic myeloid leukemia, for targeted cancer therapy	Whole blood/ bonne marrow	RT-qPCR	Fully automated coagulation analyzer
64	Immuno-Hematology	Immunocytochemistry, Immunohistochemistry	For diagnosis of Hematological malignancies	Whole blood/ tissue	Automated Stainer and magnifier analyzer.	Fully automated coagulation analyzer
65	Immuno-Hematology	Cytochemical staining Immunoglobulin assay	For the diagnosis of Hematological malignancies	Whole blood/ tissue	Manual staining and observing under digital Electron microscopy	Fully automated coagulation analyzer
66	Immuno-Hematology	Cytogenetic staining	For the diagnosis of hematological malignancies	Whole blood/ tissue	Manual staining and observing under digital Electron microscopy	Fully automated coagulation analyzer
67	Immuno-Hematology	Sickle cell testing	To aid in the diagnosis of sickle cell anemia, sickle	EDTA whole blood	Sodium metabisulfite slide test, Hemoglobin solubility	Fully automated coagulation analyzer
68	Parasitology	Molecular test for *malaria*	PCR (gold standard) for *malaria* confirmation and species determination.	EDTA Blood	PCR	PCR machine
69	Parasitology	Culture and PCR for Leishmaniases/for endemic regions	For the investigation of cutaneous or visceral *leishmaniasis*	bone marrow, lymph, spleen, liver, tissue.	Culture and PCR	Manual
70	Parasitology	Molecular test for *O. volvulus*	For the detection of microfilariae of *O. volvulus*	Skin snip	PCR	PCR Machine

SN	Test Category/ Disease	IV Diagnostic test	Test purpose	Specimen type	Assay format	Equipment used
71	Parasitology	Others Molecular tests	For species determinations & conformation of parasites	Blood, CSF, any body fluids	culture & PCR	PCR machine
72	SARS COV-2 (COVID-19)	COVID-19 testing	Diagnosis	Nasopharyngeal/Oro pharyngeal specimens	Nucleic Acid Amplification Test (RT PCR)	Automated/Manual
73	TB	Molecular WRD test	Diagnosis	Sputum	Nucleic Acid Amplification Test (Xpert MTB/RIF Assay)	Molecular WRD test
74	TB	Mycobacterium tuberculosis bacteria culture	Diagnosis and Treatment monitoring	Sputum/Body fluid	Bacterial Culture (LJ and MGIT)	BD MIGIT 960/Manual
75	TB	Drug susceptibility testing with MTB culture	To detect resistance to first-line and/or second line anti-TB medicines	Bacterial culture of MTB	Bacterial Culture (LJ and MGIT)	BD MIGIT 960/Manual
76	TB	MTB DNA mutations associated with resistance	For the detection of resistance for second line anti-TB medicines	Sputum/Bacterial culture of MTB	Molecular line probe assay (LPA)	Twincubator
77	Other newly emerging tests of clinical and public health importance					Latest method and technology

Implementation Strategies and Revision Requirements

3.10 Implementation Strategies

For effective implementation of the NELDL, designing suitable implementation arrangements, monitoring and evaluation framework are mandatory. The following recommendations are forwarded to facilitate the effective implementation of the NELDL at all levels of the Ethiopian health laboratory system. As is true for all development programs and initiatives the implementation should be adequately resourced and be based on well aligned and mutually reinforcing plan of actions with clear roles and responsibilities assigned to all involved stakeholders and partners. Above all, unwavering commitment, strong leadership and coordination of activities at all levels of the health system remain the key to success.

3.10.1 Implementation Arrangements

The implementation arrangement of this NELDL will involve all levels of the government structures for leadership and management of the healthcare system

MOH

- Develop strategies and guide for the seamless implementation of the NELDL.
- Mobilize resources required for the comprehensive implementation of the NELDL.
- Oversee and monitor the proper implementation of the NELDL.

EPHI

- Develop and adopts the NELDL as standard list of laboratory diagnostic tests to be implemented across all health facilities nationwide.
- Develop additional documents as needed to facilitate the implementation of the NELDL
- Evaluate and validate methods and technologies, and define algorithms to support the introduction and effective use of diagnostic tests.
- Implement capacity building programs to enhance the implementation of the NELDL.
- Develop standard specifications for test kits and associated supplies including instruments to be used at the different tiers of the healthcare system.

- In collaboration with stakeholders, establish reliable system for collection of data/information on the needs of healthcare facilities for different tests and associated commodities (Annual testing needs or volumes)
- Strengthen supporting systems for specimen referral linkage and testing services (laboratory referral networks, transportation and result delivery systems).
- Strengthen system for laboratory equipment management at all levels of the healthcare system (installation, preventive and curative maintenance services including management/enforcement of Service Level Agreements established with various manufacturers/suppliers).
- Monitor and evaluate the implementation of the NELDL' develop and implement continuous improvement plans.

EPSS

- Lead and coordinate annual quantification exercises for the procurement of laboratory commodities including instruments to support the implementation of the NELDL.
- Timely procure and ensure the availability of adequate stock of reagents, consumable supplies and equipment.
- Implement reliable system for the real-time collection of data on stock status and consumption of reagents and consumable supplies at all healthcare facilities.
- Monitor and evaluate the effectiveness of the supply chain system for the provision of uninterrupted diagnostic testing services across all healthcare facilities nationwide.

EFDA

- Provide regulatory oversight and implement appropriate measures to enforce and ensure adherence to the effective use of the NELDL by all healthcare facilities.

Regional Health Bureau

- Implement capacity building programs to enhance the implementation of the NELDL
- Orient Zonal/Woreda health departments and healthcare facilities on NELDL implementation requirements.
- Mobilize and allocate the necessary resources

- In collaboration with EPHI, strengthen supporting systems for specimen referral linkage and testing services (laboratory referral networks, transportation and result delivery systems).
- Oversee and monitor the proper implementation of the NELDL within the region.

Regional Public Health Institutes/Regional Reference Laboratories

- Conduct facility readiness assessments on infrastructure, equipment, staffing, etc.
- Develop regional phase-in plans according to facility tier level and diagnostic needs.
- Undertake capacity building activities to enhance the implementation of the NELDL.
- Strengthen regional supporting systems for specimen referral linkage and testing services (laboratory referral networks, transportation and result delivery systems).
- Follow up on equipment management system at all healthcare facilities in the region (installation, preventive and curative maintenance services)
- Closely monitor and evaluate the performance of NELDL implementation in the region; develop and implement continuous improvement plans with regular reporting to the EPHI.

Health Facilities

- Train laboratory managers and staff on the NELDL and testing algorithms.
- Audit current lab testing capacity (available HR, equipment and other infrastructure) practices and commodity needs for the implementation of NELDL at the facility.
- Phase in implementation of NELDL starting with higher tier facilities.
- Allocated adequate resources for the implementation of the NELDL.
- Update lab testing menus, SOPs, quality systems to incorporate NELDL.
- Implement specimen referral system in line with the national and regional arrangements.
- Provide regular reports on consumptions of reagents and consumable supplies in line with the reporting requirements of the facility.
- Estimate annual test volumes and the required quantities of reagents and consumable supplies and have them handy to share with all in need when requested.
- Periodically review the implementation of the NELDL at the facility including through internal customer satisfaction assessments and share reports with all concerned.

3.10.2 Monitoring and Evaluation Framework

Purpose of the M&E Framework

The purpose of the framework is to measure and monitor the effectiveness, efficiency and impact of the implementation of the National Essential Laboratory Diagnostics List (NELDL). As such, the framework presents a crucial tool for all involved in and responsible for the implementation of the NELDL at various leadership and management levels of the national health laboratory system. Furthermore, it is absolutely vital that all operational plans developed for the implementation of the NELDL at health facilities across all tiers of the healthcare service delivery system shall incorporate this fundamental M&E framework.

Information obtained from extensive review of the national health laboratory capacity building strategies, and global experiences and benchmarks from the implementations of NELDLs have served as critical inputs for the creation of this important M&E framework with clear key result areas and related indicators.

Result Based Framework

Result-Based Monitoring and Evaluation Framework has been adopted to serve as a valuable tool for assessing the progress and impact of the National Essential Laboratory Diagnostic List implementation. Regularly tracking the selected indicators and adapting strategies based on evaluation findings will help improve diagnostic services and, ultimately, enhance overall healthcare outcomes.

And also, Results-Based Framework (RBF) is a strategic approach used to monitor and evaluate the achievement of specific outcomes and impacts in a program or project implementation. It's often structured around Key Result Areas (KRAs) to guide the assessment of progress and effectiveness.

For this document, three key result areas are selected to provide a clear and systematic way to measure progress and ensure that resources are effectively directed toward achieving the desired outcomes and impacts.

Key Result Areas (KRAs) for Monitoring and Evaluating the Implementation of the National Essential Laboratory Diagnostic List (ELDL):

I. **Accessibility and Equitable Distribution of Essential Diagnostics**:

This KRA focuses on ensuring that essential diagnostic tests are accessible and evenly distributed across different regions and healthcare facilities in Ethiopia. Key aspects to assess include:

a. Geographical Coverage: Measure the presence and availability of essential diagnostic tests in healthcare facilities across urban and rural areas, including remote geographic locations.

b. Health Facility Capacities: Evaluate the readiness and capacity of healthcare facilities to provide essential diagnostic services, especially in underserved areas.

c. Affordability and Accessibility: Assess the affordability of essential diagnostics for patients, particularly for vulnerable populations, and explore mechanisms to make them more accessible and accessible.

II. Quality of Diagnostic Services:

This KRA aims to ensure that essential diagnostic services provided as part of the implementation of the NELDL meet high-quality standards and produce accurate results. Key aspects to assess include:

a. Laboratory Accreditation: Monitor the accreditation status of laboratories conducting essential diagnostic tests, promoting adherence to international quality standards.

b. Proficiency Testing: Evaluate the proficiency of laboratory personnel and the accuracy of diagnostic results through regular proficiency testing programs.

c. Quality Assurance and Quality Control Practices: Assess the implementation of quality assurance and quality control measures to maintain the accuracy and reliability of diagnostic tests.

III. Patient Outcomes and Improved Healthcare Management:

This KRA focuses on evaluating the impact of the implementation of the NELDL on patient outcomes and overall healthcare management in Ethiopia. Key aspects to assess include:

a. Reduction of Diagnostic Delays: Evaluate whether the implementation of the NELDL contributes to reducing delays in the diagnosis and initiation of treatment, leading to improved health outcomes.

c. Public Health Impact: Assess the contribution of the implementation of the NELDL to performance improvement of public health indicators, particularly those designed to measure the effectiveness of s disease surveillance, control, and prevention efforts.

These three key result areas cover crucial aspects of the ELDL implementation in Ethiopia, including accessibility, quality, and impact on patient outcomes. To ensure effective monitoring and evaluation, specific and measurable indicators should be defined for each KRA, and data collection methods should be established to track progress over time. Additionally, involving relevant stakeholders, including government agencies, healthcare providers, and civil society organizations, will be essential for the successful implementation and continuous improvement of ELDL in Ethiopia.

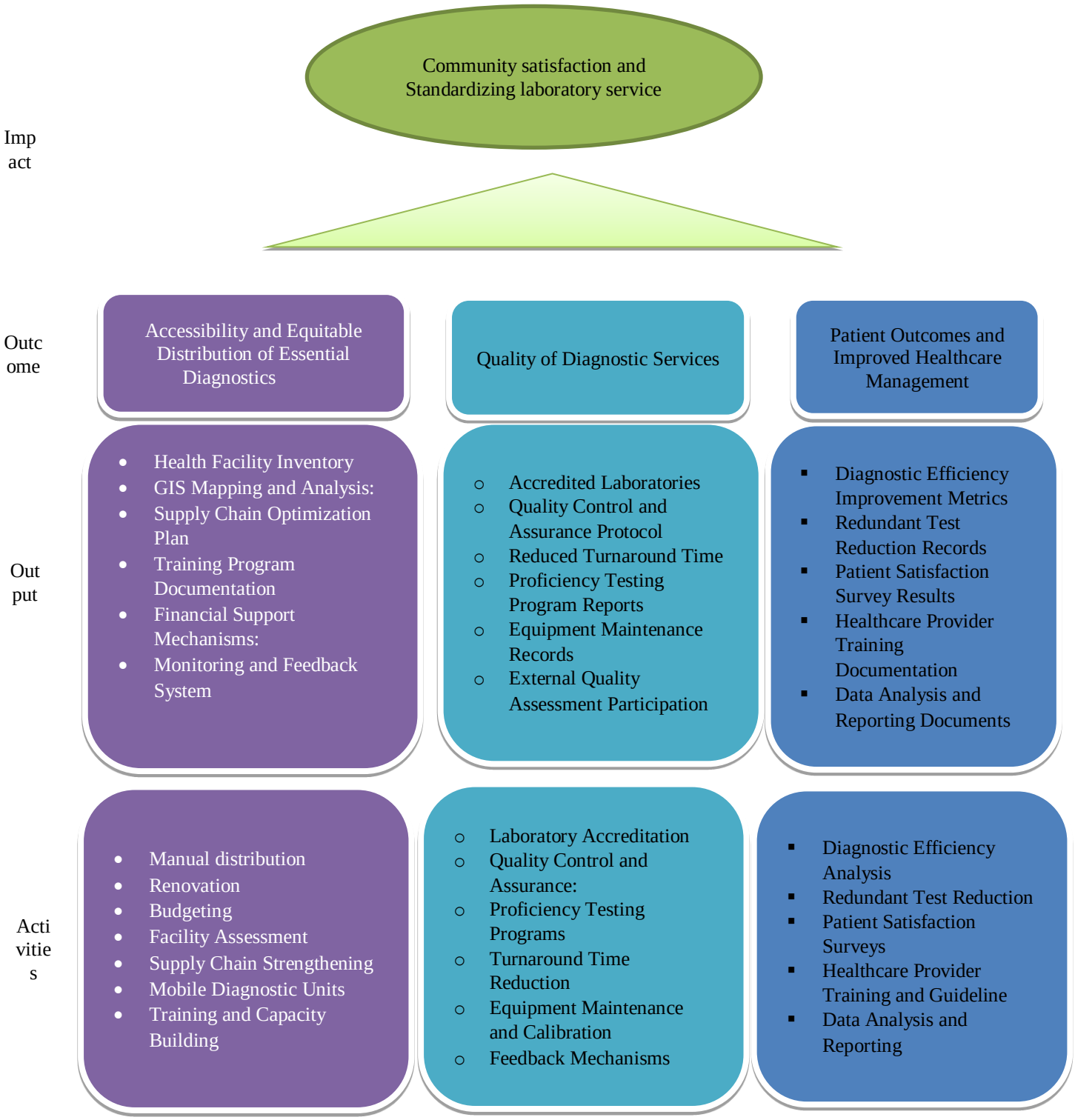

Figure 3: The Results Chain

Table 2: Indicator Matrix

No	Key result Area	Indicators	Description of indicators	Disaggregation	Data Source	Means of Verification
1.	Accessibility and Equitable Distribution of Essential Diagnostics	Percentage of medical facilities with access to ELDL's essential diagnostic tests.	Number of medical facilities with access to the ELDL's essential diagnostic tests/ Total # of medical facilities *100	Region, facility type, facility size ,	-National Health Facility Inventory and Records. -Ministry of Health reports on diagnostic services availability. -Healthcare cost data and patient surveys. -Geographic Information Systems (GIS) data for travel time calculations.	Inventory and Procurement Records, Health report, survey and HIS
2.		The proportion of health facilities providing ELDL-recommended tests in each region.	Number of health facilities providing ELDL- recommended tests in each region / Total number of facilities in the region *100	Region, facility type(pr/go), facility level		Health Facility Surveys, record & report, Site Visits and Inspections
3.		Average Cost-to-patient for ELDL-recommended testing	Total Cost Incurred by Patients for ELDL-Recommended Tests / Total Number of Patients Tested	Type of test, location , facility type (priv/gov), health care setting (Hosps, HCs, Clinics)		Billing and Financial Records, Patient Surveys, Cost Analysis Tools, reports
4.		Travel time and distance to the closest medical facility that performs necessary diagnostic testing, especially in rural and underserved locations.	Travel Time (in minutes) = Distance / Travel Speed NB: - Use GIS tools to calculate the distance (in kilometers or miles) from the origin point to each destination point -Determine which medical facility is the closest to the origin point based on either travel time or travel distance,	Location, type of test, mode of transport, age , sex, socioeconomic status		GIS, GPS data and mapping, facility records, survey and interview

No	Key result Area	Indicators	Description of indicators	Disaggregation	Data Source	Means of Verification
			depending on the specific analysis.		-Health facility surveys focusing on equity and access. -Referral records and health facility reports. -Supply chain management records and inventory report	
5.		Number of necessary diagnostic procedures offered by public as opposed to private healthcare facilities.	Number of Necessary Diagnostic Procedures Offered by Public Facilities - Number of Necessary Diagnostic Procedures Offered by Private Facilities	Type of Diagnostic, location, age gender,		Private Healthcare Provider Surveys, facility records , health report, patient survey
6.		Proportion of health facilities able to perform necessary diagnostic tests inside rather than referring to other hospitals	Number of facilities that perform necessary diagnostic tests inside rather than having to send patients to other hospitals/ Total number of facilities perform necessary diagnostic tests *100	Region, facility, availability of testes, age , sex , socioeconomic status		Reports, records, HIS, surveys
7.		Percentage of health facilities with a functional supply chain for essential diagnostic tests	Number of health facilities with a functional supply chain for essential diagnostic tests/ Total # of facilities perform necessary diagnostic tests * 100	Region, type of test, type of facility		Supply chain records , surveys and assessment
8.	Quality and Accuracy of Diagnostic Services.	Percentage of accredited laboratories performing essential diagnostic tests,	Number of accredited laboratories performing essential diagnostic tests/ Total # of accredited laboratories *100	Region , test type, facilities	-Laboratory accreditation records and reports. -Incident reports and error tracking systems.	Accreditation report, health report, websites, surveys
9.		Proficiency testing score of laboratory personnel involved in conducting ELDL-recommended tests.	Number of Correctly Handled Tests / Total Number of Tests in Proficiency Testing x 100	Region, type of test, laboratory level , time		Proficiency Testing Program Records, reports

No	Key result Area	Indicators	Description of indicators	Disaggregation	Data Source	Means of Verification
10.		Average turnaround time for essential diagnostic tests,	Total Turnaround Time for essential diagnostic tests conducted during a specific period / Total Number of all essential diagnostic tests conducted during the same period	Time , region , test type, facility level	-Laboratory quality control and assurance documentation. -Laboratory records and workflow data. -Proficiency testing program records. -Laboratory error logs and incident reports. -Training records and healthcare provider surveys.	Facility records, LIS, health reports, facility and laboratory assessment
11.		Proportion of sample contamination or pre-analytical errors for essential diagnostic tests.	Number of Erroneous or Contaminated Samples / Total Number of Samples Processed * 100	Type of Erroneous Diagnostic Tests, time, region, facility level		Laboratory Quality Control and Assurance Records, Surveys and Incident Reporting
12.		Number of laboratory personal trained in proper sample collection and handling techniques for ELDL-recommended tests.	Total Count of Trained Laboratory Personnel	Region , time , Type of ELDL-Recommended Test, laboratory level		Training report &records, assessment
13.		Percentage of essential diagnostic tests conducted in accredited laboratories	Number of essential diagnostic tests conducted in accredited laboratories/ Total number of accredited laboratories*100	Type of test, region , time , laboratory level		LIS, accreditation report, assessment
14.		Number of laboratory personnel trained in handling specific diagnostic tests required during different types of public health emergencies.	Total Count of Trained Laboratory Personnel	type of Public Health Emergency, time, region , Laboratory Personnel Roles		Training records &reports, assessment

No	Key result Area	Indicators	Description of indicators	Disaggregation	Data Source	Means of Verification
15.	Patient Outcomes and Improved Healthcare Management	Rate of change in the number of unnecessary or redundant diagnostic tests conducted due to ELDL implementation.	(Number of Unnecessary Tests Before ELDL - Number of Unnecessary Tests After ELDL) / Number of Unnecessary Tests Before ELDL *100	Diagnostic tests list, region, facilities level, time period	Healthcare cost data and utilization statistics	Reports, assessments, cost analysis , Comparative Analysis
16.		Percentage of healthcare providers accessing and utilizing clinical guidelines based on the ELDL recommendations.	Number of Healthcare Providers Accessing and Utilizing Guidelines / Total Number of Healthcare Providers* 100	Region, Facilities level , Type of healthcare providers, Type of Clinical Guideline		Training and Education Records, facility report, Healthcare Provider Surveys, clinical guideline records
17		Utilization rate of ELDL-recommended diagnostics for disease surveillance during and after public health emergencies.	Number of ELDL-Recommended Diagnostic Tests Conducted for Disease Surveillance / Total Number of Diagnostic Tests Required for Disease Surveillance* 100	Type of emergency, region , time , facility level		Emergency Response Plans, surveillance report, facility report

Monitoring and Evaluation Plan

Monitoring Plan

It is important to be explicit about the availability, effectiveness, and quality monitoring plan for the essential diagnostic list and strategy. The overall national monitoring cycle should be linked and consistent with the NELDL's monitoring plan. Making the utilization of the NELDL an integral element of the facilities' performance audit procedures would make it easier to track and evaluate each region's performance across the nation on a regular basis. The KRAs and KPIs listed in this document should be the main topics of the monitoring plan. It should be emphasized that relevant institutions must set goals for these KPIs during planning, and the KPIs are then monitored in relation to these goals. There is a requirement to establish baseline values for each KPI that act as a reference for continuous monitoring of intervention.

Since the NELDL strategy is being implemented as part of institutional initiatives, it should be reviewed annually by the institution that is responsible for the coordination of implementation activities. On the other hand, based on the advancements made in comparison to the goals and by conducting extensive health facility assessments across the nation, the overall implementation of the NELDL should be annually evaluated at the national level with the involvement of all stakeholders and partners. Additionally, regular consultative forums should be set up where performances can be reviewed, gaps identified and corrective action plans developed for continuous process improvement and performance.

Evaluation Plan

Implementation of the strategy should be monitored on a regular basis to ensure that all institutions and facilities are following it faithfully. Process evaluation can be carried out so that it gives the chance to spot problems, look at implementation choices, and then take appropriate corrective actions.

Revising the NELDL strategy should be informed by a thorough evaluation. To evaluate the effects of the implementation of the NELDL on healthcare outcomes, service quality, and cost-effectiveness, it is important to conduct frequent reviews and evaluations (e.g., annually or every two years) of the healthcare service delivery system.

Evaluation activities may include qualitative assessments such as Service Availability and Readiness Assessment (SARA) or Service Provision Assessment (SPA), case studies, and cost-

benefit analyses. These evaluations should focus on processes, outcomes and impacts of the strategy. An extensive analysis should guide the revision of the NELDL strategy. The method, results, effectiveness and impacts of the approach should be the main subjects of these evaluations.

Data Sources, Reporting and Management

In the context of monitoring and evaluation (M&E), a data source refers to the origin or location from where data is collected, generated, or obtained for the purpose of assessing and measuring the performance, progress, and impacts of a program, project, policy, or initiative. Data sources provide the raw information and evidence needed to conduct M&E activities.

Data Sources for the National Essential Laboratory Diagnostic List (NELDL) are:

- Health Facility Records: Data from healthcare facilities regarding the availability of diagnostic tests, equipment, and trained personnel. This includes test menu for essential diagnostic tests.
- Patient Records: Information on patient diagnoses, treatments, and outcomes, which can be anonymous and aggregated for analysis.
- Laboratory Records: Data from laboratories conducting diagnostic tests, including test results, error reports, proficiency testing performance results, and quality control records.
- Laboratory Quality Management System (LQMS) implementation and Accreditation: Laboratory Quality Manual, documented implementation processes and practices, and certificate of accreditation.
- Training Records: Records of healthcare provider training programs (in-service laboratory trainings, Continuous Professional Development/CPD and other accredited trainings), including assessments and certifications.
- Patient Satisfaction Surveys: Feedback and responses from patient satisfaction surveys regarding the quality of diagnostic services provided as part of the implementation of the NELDL.
- Geographic Information Systems (GIS): Geographic data used to map the distribution and referral networks of healthcare facilities, accessibility, and gaps in diagnostic services including existing systems for specimen transportation and result delivery.

- Supply Chain Management Records: Data related to the procurement, distribution, and availability of diagnostic tests and equipment.
- External Quality Assessment Programs: Data from external quality assessment programs assessing the accuracy and reliability of diagnostic results.

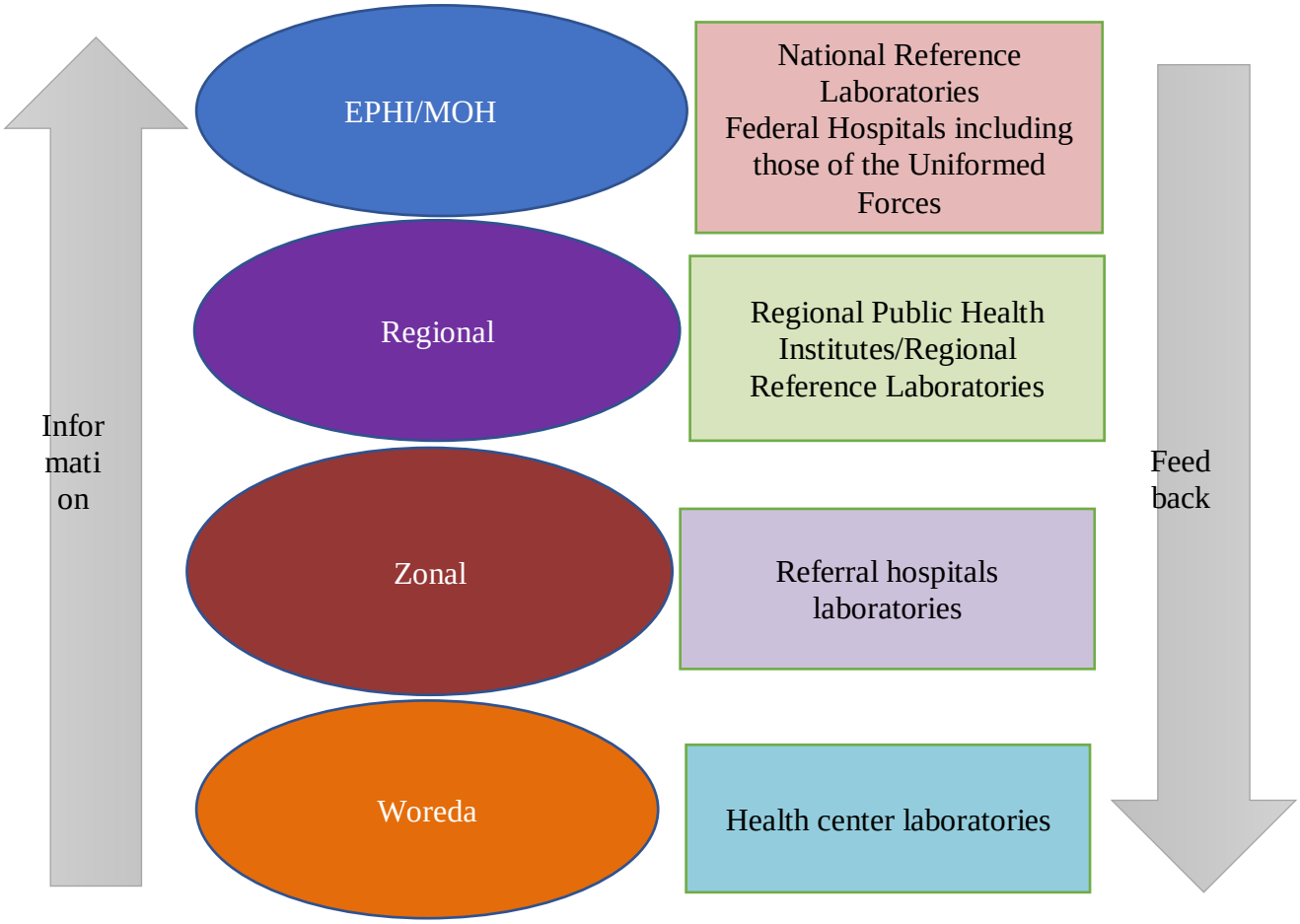

Figure 4: Information/ Data Exchange

3.11 Revision Requirement of the NELDL

Review Frequency

- The NELDL should be reviewed regularly, preferably every 2-3 years, to ensure it remains up-to-date. More frequent reviews may be warranted when new tests or technologies emerge.

Triggers for Revision

- Changes in disease burden, epidemiology, or public health priorities.
- Introduction of new diagnostics or global guidance.
- Changes in clinical recommendations for diagnosis and management of diseases.
- Significant shifts in population demographics or health system structure.
- Issues with availability or costs of listed tests.
- Feedback from clinical healthcare providers and laboratories indicating need for revision.

Review Process

- A multidisciplinary committee should be involved, including lab experts, clinicians, public health professionals.
- Review existing lists, disease data, utilization data, budgets, and global recommendations.
- Draft changes through a consultative process involving key stakeholders and partners.
- Revise lists based on feedback and finalize with approval from Ministry of Health.

Dissemination

- Communicate and distribute the updated NELDL widely to all laboratories, facilities, and health professionals.
- Conduct trainings or orientation workshops as found necessary to support transition to the updated NELDL.

By institutionalizing a regular review and responsive revision process that involves the participation and contributions of all stakeholders and partners, the NELDL can remain a highly relevant, up-to-date resource material for continuous optimization and improvement of laboratory diagnostic services for patient care and public health needs.

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