



MINISTRY OF HEALTH



NATIONAL TUBERCULOSIS, LEPROSY
AND LUNG DISEASE PROGRAM

NATIONAL TUBERCULOSIS REFERENCE LABORATORY **OPERATIONAL PLAN**

2023 - 2028



NATIONAL TUBERCULOSIS REFERENCE LABORATORY OPERATIONAL PLAN

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REPUBLIC OF KENYA

MINISTRY OF HEALTH



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ACRONYMS AND ABBREVIATIONS

ASLM	African Society for Laboratory Medicine	NHS	National Health System
BSL	Biosafety Level	NTP	National Tuberculosis, Leprosy and Lung Disease Control Programme
CDC	Centres for Disease Control	NTRL	National Tuberculosis Reference Laboratory
DRS	Drug Resistance Survey	OR	Operational Research
DST	Drug Susceptibility Testing	PCR	Polymerase Chain Reaction
DHIS-2	District Health Information System 2	PT	Proficiency Testing
ECSA-HC	East Central and Southern Africa Health Community	QC	Quality Control
EQA	External Quality Assessment	RIF	Rifampicin
FM	Fluorescent Microscopy Technique	SLIPTA	Stepwise Laboratory Improvement Process Towards Accreditation
HDI	Health Development Index	SLMTA	Strengthening Laboratory Management Towards Accreditation
HIV	Human Immuno-deficiency Virus	SRL	Supranational Reference Laboratory
HR	Human Resource	TA	Technical Assistance
TB-LAM	Lateral Flow-Lipoarabinomannan Assay	TB	Tuberculosis
LIMS	Laboratory Information Management System	TWG	Technical Working Group
LPA	Line Probe Assay	DTU	Diagnostic and Treatment unit
LQMS	Laboratory Quality Management System	US	Treatment Unit
MDR	Multi Drug Resistant	WHO	World Health Organization
MGIT	Mycobacterium Growth Indicator Tube	ZN	Ziehl Neelsen Technique

FOREWORD

The purpose of the National Tuberculosis Reference Laboratory (NTRL) Operational Plan for the period 2023/24-2027/28 is to align and guide the operationalization of the diagnostic components within the National Tuberculosis Leprosy and Lung Disease Program National Strategic Plan and TB diagnostic components of Division of Laboratory Services - National Strategic Plan. This will be achieved by defining objectives, interventions, major actions, and sub-activities. Additionally, this operational plan will establish a Monitoring & Evaluation (M&E) framework with annual targets that the NTRL will implement to work towards achieving the strategic objectives outlined in the NTLP and DLS strategic plans.

Through the development of this Operational Plan for TB Laboratory Diagnosis, the NTRL has taken steps to harmonize key strategic plans from NTLP and DLS. This harmonization enables the optimization of resources to efficiently serve the TB lab diagnostic network across the country. This plan represents a significant stride towards aligning both government and external partners' initiatives and activities with a focus on sustainable nationwide impact.

The creation of this costed operational plan ensures that the NTRL's policy statements and strategic objectives are translated into integrated actions. These actions will be executed at a pace consistent with the country's End TB strategies and financial resources. Furthermore, this operational plan will serve as a guiding framework for the NTRL's day-to-day operational direction in conjunction with the DLS and NTLP Strategic plans for the next five years, covering the period from 2023/24 to 2027/28. The objective is to engage all stakeholders involved in TB laboratory diagnostic work, facilitating collaborative planning and effective coordination of TB lab diagnostic network activities to meet the desired expectations.

As a ministry, we strongly encourage all stakeholders to support the implementation of this operational plan, enabling the NTRL to fulfill its mandate of improving access to and the quality of laboratory Tuberculosis diagnosis in the country in a robust and sustainable manner.



Mary Muthoni Muriuki, HSC

Principal Secretary

State Department for Public Health and Professional Standards - Ministry of Health



EXECUTIVE SUMMARY

The NTRL 2023/24 – 2027/28 Operational Plan provides the framework to guide the lab in the achievement of its vision guide the organization in the achievement of its Vision "To be a centre of excellence in provision of quality TB Laboratory testing services" and Mission, "To provide effective leadership for efficient, accessible, responsive and quality TB Laboratory network services" that contribute towards achieving resilient and sustainable systems aimed at ending TB.

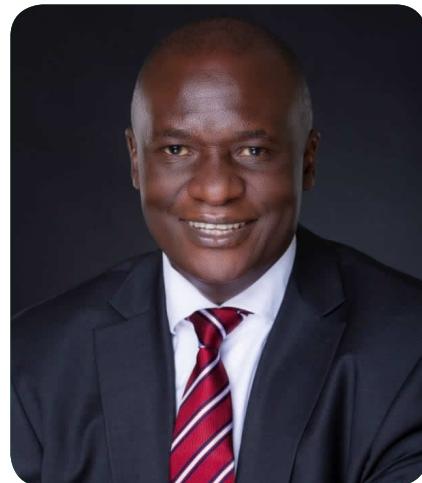
The Operational Plan has been prepared through a participatory process involving various stakeholders in the space of TB Laboratory diagnosis, while recognizing and putting in place initiatives that will effectively respond to the needs and expectations of TB laboratory diagnostic network in Kenya. Chapter One provides an overview of the country's demographics, organization of health services and the laboratory services that enable diagnosis of TB disease. Chapter Two provides the NTRL and the TB laboratory diagnostic network background, legal frameworks and various roles of specific network labs. The strategic intent and desire to achieve accurate and timely laboratory diagnosis for all TB patients by optimizing the contribution of all stakeholders for an effective and efficient lab diagnostic pathway.

This being the 1st Operational Plan by the NTRL in the recent past, Chapter Three provides a situational analysis obtained through the review of performance of the entire diagnostic network referenced from various performance review activities both at the NTP and NPHLS. It summarizes the achievements, challenges and lessons learnt. It is also an analysis of Strengths, Weaknesses, Opportunities and Threats (SWOT), as part of the current situation analysis.

Chapter Four provides a highlight of the key result areas identified as per the Global 2030 EndTB Strategy. These result areas provide anchorage to the Strategic Interventions, Major actions and sub activities as the main Strategic Objectives of the 5-year Operational Plan.

Key result areas

- Increase access to mWRDs for TB diagnosis
- Increase 1st and 2nd line TB DST Coverage
- Strengthen Quality Management of TB laboratory services
- Strengthen management & coordination of the TB Lab diagnostic network



Chapter Five provides monitoring and evaluation strategies to support efficient and effective implementation of the plan. The NTRL is to make monitoring and evaluation an integral part of the entire process of implementation of this Operational Plan. However, from the review of the previous strategic plan, on monitoring and evaluation, the stakeholders recommended that the lab develop a performance management framework. It is also recommended that the Key Performance Indicators to be smart rather than looking like anecdotes.

The methodology we adopted was that the key gaps identified through the various review processes were adopted as part of the Strategic issues which we put on the feasibility vs impact tool that later led to issue prioritization and hence were used the strategic objectives for the operational plan.

Chapter Six provides highlights of the financial resources required for implementing the strategic interventions and activities that are outlined in the implementation matrix. The total amount required to implement this Operational Plan for 2023/24 – 2027/28 is KES/USD 1,096,158,227.00/7,741,069.00. Our working assumption here is that these resources will gradually be utilized in the 5-year implementation period in a more practical and manageable manner of 15%, 20%, 25%, 30% and 10% absorption rates across year 1 to year 5.

It is our collective belief as a Ministry that the implementation of this Operational Plan will steer the country towards the overall goal of TB eradication, as improved diagnosis and management play a crucial role in interrupting the chain of TB transmission and ultimately eliminating the disease burden.



Dr. Patrick Amoth, EBS

Ag. Director General for Health

WORD FROM THE HEAD OF PROGRAM

It is with great pleasure that I extend my heartfelt appreciation and gratitude to the dedicated individuals involved in developing the Tuberculosis (TB) Reference Laboratory Operational Plan. Their tireless efforts in pursuing excellence in TB diagnostics and management are highly commendable. TB remains a significant public health challenge in Kenya, affecting diverse communities and socioeconomic backgrounds. To address this burden, the Ministry has prioritized strengthening diagnostic services for early detection and effective treatment.



The development of the TB Reference Laboratory Operational Plan is a crucial step toward achieving Global EndTB objectives. By leveraging advanced stakeholder engagement and collective responsibility towards its implementation, this plan will enhance the quality and efficiency of TB diagnosis, monitoring, and treatment in Kenya. The collaboration of national and international partners has been vital in analysis of the current performance status providing appropriate interventions, major actions to meet the desired strategic objectives.

The NTLD-P extends deep gratitude to the dedicated team of laboratory professionals for their unwavering commitment to providing accurate and timely TB diagnostic services. Their proficiency will contribute to early detection and prompt initiation of treatment, thus preventing further transmission within communities. The NTLD-P encourages the team to maintain the highest standards of professionalism, integrity, and compassion while prioritizing continuous learning and skills development to support the implementation of this Operational Plan.

With the TB Laboratory serving as a beacon of excellence in diagnostics, research, and capacity building, significant strides can be made in reducing the burden of TB and improving the health outcomes of affected individuals. The ultimate goal is to achieve a TB-free Kenya, and together, this can be accomplished.

A handwritten signature in black ink, appearing to read "IK".

Dr. Immaculate Kathure

Ag. Head, Division of National Tuberculosis Leprosy and Lung Disease - Program

ACKNOWLEDGEMENT

The development of this plan to guide strategic operations of the TB reference laboratory and lab network in Kenya would not have been possible without the contributions and support of various individuals and organizations. The National Tuberculosis Reference Laboratory (NTRL) would like to thank everyone who participated in the review of various reports, data sources and the development of this document. In particular, the NTRL would like to acknowledge all the individuals who participated in providing technical assistance and having worked tirelessly towards the realization of this key strategic document for its operations.

The National Tuberculosis & Leprosy Disease Program (NTLD-P) in Kenya has played a vital role in collaborating with and supporting the laboratory. Their expertise and provision of necessary resources have been instrumental in its success. Additionally, the dedicated staff of the laboratory deserves deep gratitude for their tireless efforts in ensuring the availability of the necessary information to enable the development of this plan. Their professionalism, expertise, and dedication are crucial to the laboratory's onward success and the provision of quality TB lab services in the course of this plan's implementation.

Special appreciation to the National and County Governments, DLS through NPHL, WHO, Supra Reference Laboratory Uganda, Global Fund through the Division of National Tuberculosis Leprosy and Lung Disease program (DNTLD-P), AMREF Health Africa, KEMRI, CDC, Walter Reed Kericho and Center for Health Solutions-Kenya (TB ARC II) for financial assistance in the development and the printing of this Operational Plan.

Finally on behalf of the writing team, I wish to thank the SRL Uganda team and Oduor Otieno F. from SYSTEMS Evaluation Ltd, for their leadership during the development process of this Operational Plan.

Your support, encouragement, and collaboration are deeply appreciated. Together, with all the stakeholders in TB disease program the implementation of this operational plan will greatly contribute to the overall health and well-being of the people of Kenya.



Nellie Mukiri,

Laboratory Manager, NTRL







1

Chapter One

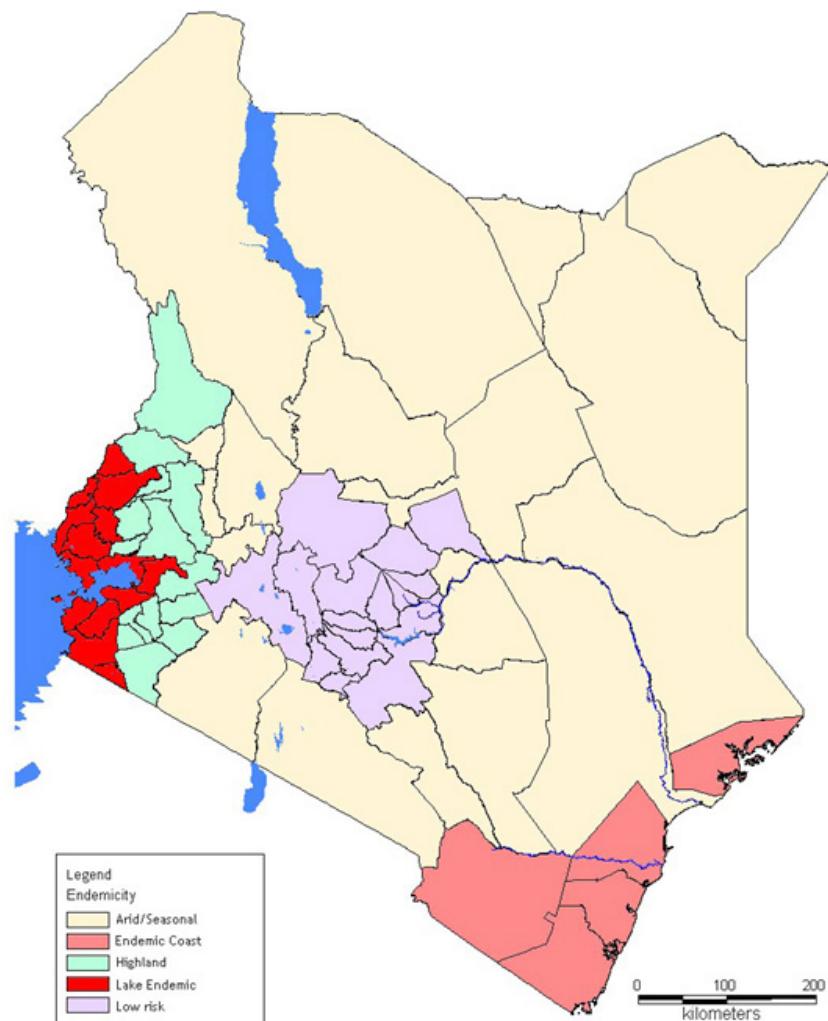
1.1 Introduction

Tuberculosis (TB) remains one of the top infectious killers in the world. In 2021, an estimated 10.6 million people (9.9–11 million) fell ill with TB(ref). Twenty five percent of the global burden of TB was in the World Health Organization (WHO) African Region (AFRO). However, according to the Global TB Report 2022, as few as 6.4 million TB patients were diagnosed and reported to the national programmes. Additionally, 2021 saw the burden of drug-resistant TB increase by 3% from 2020, with 450,000 cases of multidrug- or rifampicin-resistant (MDR/RR)-TB reported. The success rate for people treated for TB in 2020 was 86% globally, the same level as 2019, suggesting that the quality of care was maintained in the first year of the COVID-19 pandemic.

Kenya is one of the 30 high TB burden countries globally, with an estimated incidence of 133,000 cases in 2021 (2022, Global TB report). The country has made progress in reducing TB incidence, with a 9% decline in incidence between 2015 and 2021. In addition, Kenya is among the three high TB burden countries that have attained the first milestones of the END TB strategy for both a 95% reduction in TB incidence and TB deaths.

1.2 The Country Context: Geography, Administration and Governance

Figure 1: Map of Kenya

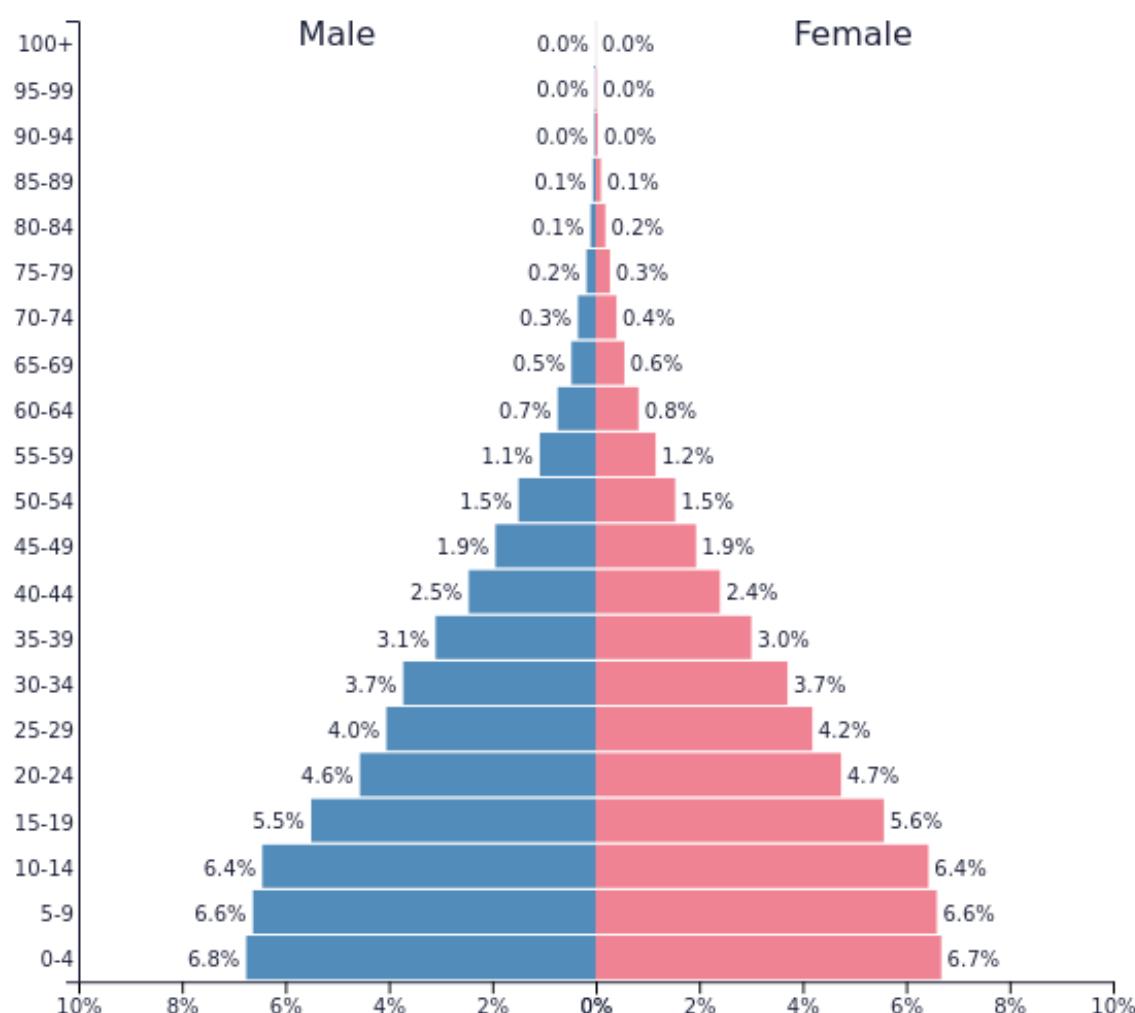


Kenya is one of the countries in Eastern Africa bordered by Ethiopia to the North, Somalia to the North East, Tanzania to the South, Uganda to the West, the Indian Ocean to the East and South Sudan to the North West. It has a total area of approximately 582,646 square kilometers (225,000 square miles) and is divided into 47 administrative counties. Kenya's climate is primarily tropical, with a diverse range of weather patterns because of its location on the equator. Temperatures vary depending on location; generally, they are warm at low- to mid-altitude and very hot at high altitudes. Arid and Semi-Arid Lands (ASALs) spread across 29 counties, located primarily in the northern, eastern, and southern parts of the country. The central and western highlands are characterized by temperate and forested hilly climate and are the most productive agriculturally and, consequently, most densely populated areas. The urban population accounts for 27% of the total population, with an urbanization rate of 4.23%.

Kenya is a presidential democratic republic in which elected officials represent the people and the president as the head of state and government. The government consists of ministries headed by Cabinet Secretaries and run by Principal Secretaries. Kenya promulgated a new constitution in 2010, which administratively divided the country into two arms of governments: The National Government and 47 County governments.

1.3 Demography

Figure 2: Population Pyramid of Kenya, 2019



According to the 2019 National Population and Housing Census, Kenya's population was estimated at 49.6 million people, translating to an average national population density of 82 persons per square kilometer. It is projected that the population will increase to approximately 52 million by 2023 at an annual growth rate of 2.2%. The population's median age is 20 years (male: 19.9 years and female: 20.2 years). People aged between 0-14 years account for 39.03% of the population, 15-24 years for 19.61%, 25-54 years for 34.27%, 55-64 years for 4%, and 65 years and over for 3.08%, as shown in figure 2. In 2018, the birth rate was 22.6 births/1,000, a death rate of 6.7 deaths/1,000, and a life expectancy of 64.6 years.

Kenya National Bureau of statistics, Census Report 2019 12 Governments as shown on fig. 1. The county governments are further divided into 290 sub-counties and further into wards. Under devolution, the national government retained policy development and regulatory functions to monitor and evaluate its implementation and provision of technical assistance to the counties. The functions transferred to county governments include direct service delivery and management of human resources. The appointed and elected county governments manage local government functions and jurisdictions.

1.4 Kenya Health Sector Strategic Plan (KHSSP) 2018-2023

The Kenya's Health Policy 2014-2030 and the Kenya Health Sector Strategic Plan 2018-2023 have been developed and anchored in line with the WHO health system building blocks, the Constitution of Kenya 2010 and Kenya Vision 2030, the country's economic blueprint, which seeks to improve Kenyans' livelihoods by providing an efficient and high-quality health care system with the best standard of care. Consistent with the SDG commitments, Kenya launched universal health coverage (UHC) in 2020, with an overall goal of ensuring access to preventive, promotive, and curative health services, with a deliberate shift in focus from curative to preventive health care. This is the context in which disease specific strategic orientations, such as ending the TB epidemic by 2030, are anchored.

1.5 Department of Laboratory Services (DLS) strategic plan 2022-2026

The Department of Laboratory Services is domiciled in the Directorate of Public Health in the Ministry of Health and comprises two Divisions namely; the National Public Health Laboratory (NPHL) and the Division of diagnostics and Clinical Support. The Department is responsible for the provision of Referral testing services across laboratory diagnostic network; Disease surveillance and monitoring; Support to regulatory bodies in validation of diagnostic commodities; Oversee and provide proficiency panels for quality assurance of diagnostic testing and calibration of diagnostic equipment; Technical assistance to facilities in lower tiers; Coordination and management of laboratory data for translation to public health policy and strategies towards effective disease control and emergency response.

The Department of Laboratory Services Strategic Plan defines the strategic directions the Department plans to take so as to achieve its mandate of delivering safe, reliable, quality laboratory services that meet national health priorities and international requirements and standards. This will in turn lead to protecting the health of Kenyans against new and emerging health threats. The following are the DLS strategic thematic areas aligned with TB laboratory network operational plan: Laboratory diagnostic services, laboratory based surveillance, diagnostic network optimization, laboratory quality management systems and laboratory accreditation, laboratory commodity security and quality, equipment management , biosafety and biosecurity.

This TB laboratory network operational plan is aligned with activities of the DLS in achieving its mandate in line with ending T.B.

1.6 The National Public Health Laboratory (NPHL)

National Public Health Laboratory comprises eight (8) reference laboratories (including National Tuberculosis Reference Laboratory) that provide referral services linking services across the laboratory network. In its current form, NPHL is mandated to perform specialized testing for priority infectious and non-communicable diseases, laboratory-based disease surveillance, food safety, provide quality assurance for the public health laboratory network and manage laboratory data at the national Data Centre. It further coordinates mobile laboratory outbreak response in disease hot spots; Supports regulatory bodies such as the Pharmacy and Poisons Board (PPB) and the Kenya Medical Laboratory Technologists and Technician Board (KMLTTB) by performing the assays required for validation, registration and approval of diagnostic kits, reagents and equipment; Capacity building and provision of technical assistance on specialized laboratory services to training institutions and public health facilities; Coordinates genomic surveillance of priority pathogens such as HIV, TB, Malaria, viral Haemorrhagic fevers, antimicrobial resistance, and other emerging and re-emerging infections; and Monitor food for conformity to food safety standards and communicate the results to the relevant law enforcement agencies.

1.7 The National Strategic Plan for TB, Leprosy, and Lung Health (2023/24-2027/28)

The National Strategic Plan (NSP) for Tuberculosis, Leprosy and Lung Diseases 2023/24 – 2027/28 describes key interventions and activities that will enable Kenya to move towards achieving the End TB Strategy's Milestones for 2030. The interventions are organized in six thematic areas which are formulated as strategic objectives in which the TB laboratory diagnostic network and operational plan will play a critical role in their achievements. These objectives include;

1. To increase TB preventive treatment coverage among eligible people from 32% in 2021 to 80% by 2028
2. To increase treatment coverage for DS-TB and DR-TB from 52% and 69% in 2021 to 70% and 80% respectively by 2028
3. To increase the treatment success rate for DS-TB and DR-TB from 86% and 81% in 2022 to 95% and 85% respectively by 2028
4. To strengthen provision of integrated TB/HIV and other comorbidity services at national and sub-national levels by 2028
5. To reduce the number of people diagnosed with Multibacillary Leprosy amongst new cases from 95% to <25% by 2028
6. To strengthen programme management, coordination, and accountability of TB services by 2028.

In the NTP-NSP, it's under specific objective 2.4 "Scale up access to quality TB diagnostic services, including the adoption of new technologies by 2028" that this TB laboratory operational plan will be elaborated

1.8 Purpose of the National Tuberculosis Reference Lab Operational plan

The NTRL Operational plan is aligned to the two strategic documents (NTP-NSP- 2023/24 – 2027/28 and DLS NSP-2022-2026) and is going to work as a framework to guide the TB Reference laboratory in strengthening the TB diagnostic services and by extension, the TB Lab Diagnostic Network to meet the needs of the country in ending TB disease. This operational plan will apply to all public, private, non-governmental laboratories and health facilities within Kenya whose mission is to address individual patient care and public health needs from the peripheral to the national level. The aim of the plan would be to guide operationalisation of the diagnostic components of the TB NSP and TB components of DLS-NSP through defining objectives, intervention, major actions and sub-activities. This operational plan will also provide for a Monitoring & Evaluation (M&E) framework with annual targets which the NTRL will carry out in order to work towards achieving the strategic objectives set out in the strategic plans of the NTLP and DLS. It is therefore the framework for the NTRL's day-to-day operations.

1.9 Analysis of Health Indicators: The burden of TB and HIV in Kenya

According to the WHO global list for high burden countries for TB, HIV associated TB and drug resistant TB (DR TB) 2021-2025 published in 2021, Kenya remains among the 30 high burden countries for TB and HIV associated TB as shown in table 1 below. These are countries that together contribute approximately 90% of the estimated global TB burden. Kenya was transitioned out of the list of 30 countries with the highest burden of DR TB, however it remains a public health threat and thus, is a priority area of focus for the country.

Table 1: WHO Global list of high burden countries for TB, HIV associated TB and Drug Resistant TB¹

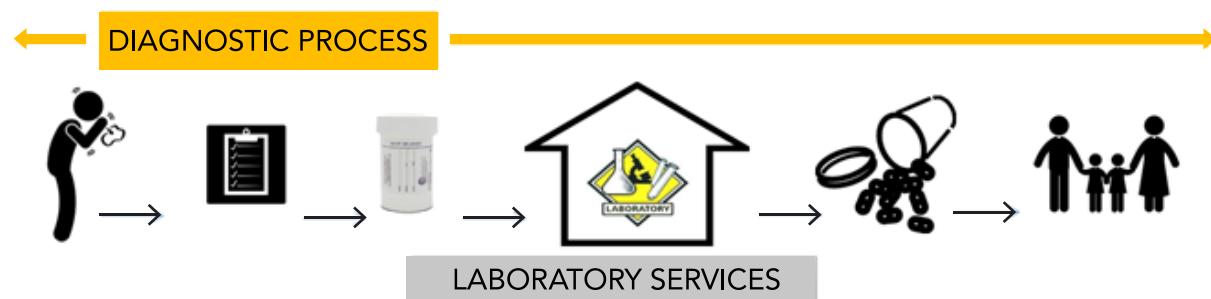
Brazil	China	Angola	
CAR	DR Congo	Bangladesh	
Congo	India	DPR Korea	
Ethiopia	Indonesia	Mongolia	
Kenya	Mozambique	Pakistan	
Lesotho	Myanmar	Papua New Guinea	
Liberia	Nigeria	Vietnam	
Namibia	Philippines		
Thailand	South Africa		
Uganda	Zambia		
UR Tanzania			
Botswana		Azerbaijan	
Cameroon		Belarus	
Eswatini		Kazakhstan	
Guinea		Kyrgyzstan	
Guinea-Bisau		Nepal	
Malawi	Sera Leone	Peru	
Russian Federation		Rep. Moldova	
Zimbabwe		Russian Federation	
		Somalia	
		Tajikistan	
		Ukraine	
		Uzbekistan	
		Zimbabwe	
TB/HIV		MDR/RR -TB	
TB			

¹ Global TB Report. WHO, 2021

1.10 Coverage of TB Diagnostic Services

Diagnosis is the weakest link in the care cascade. Laboratory testing is critical to close the diagnostic gap and find missing cases. Laboratory plays an important role in TB diagnostic services even as the country is working toward finding the missing TB cases.

Figure 3: Laboratory Services in Patient Diagnostic Process



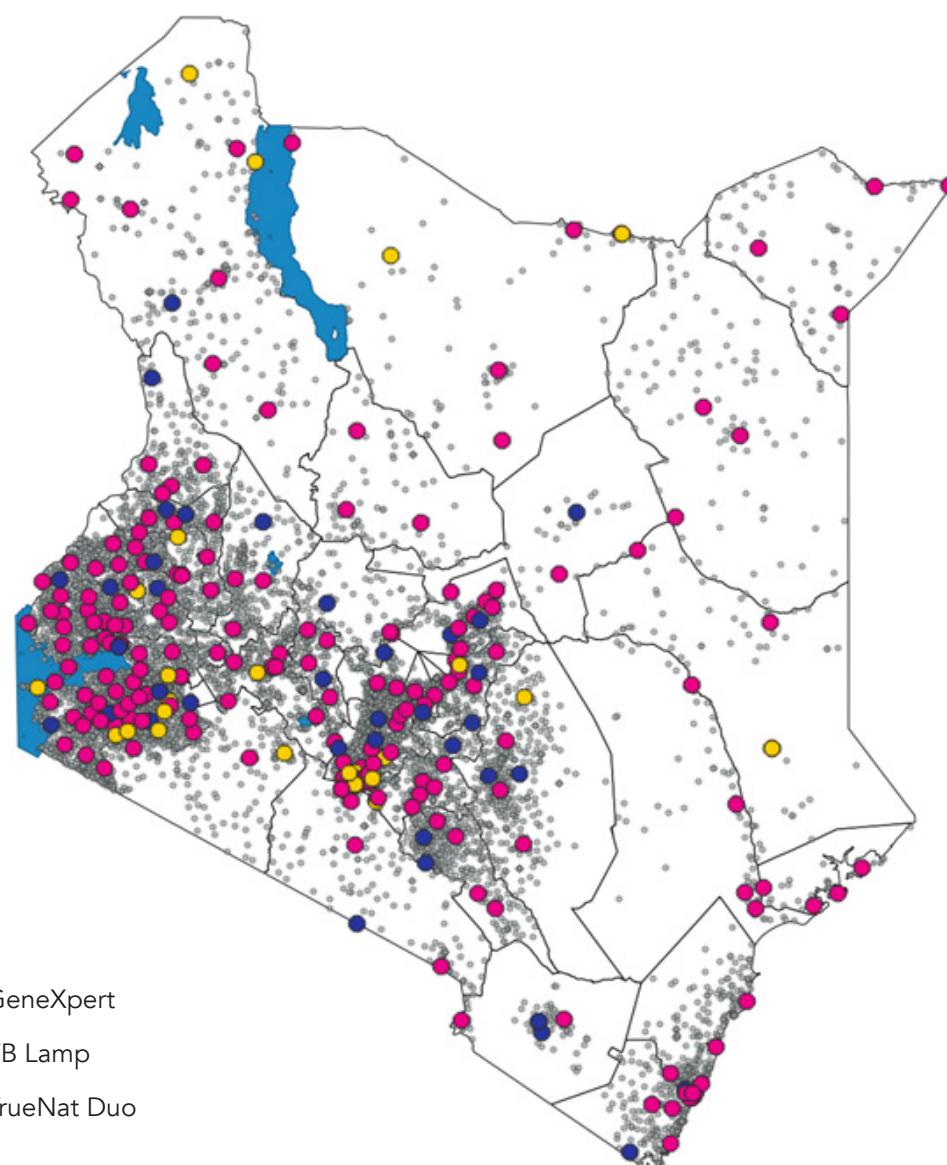
The diagnostic process as highlighted in the figure above starts when a person experiences symptoms and decides to seek care (i.e., passive case finding) or a health care worker (HCW) identifying a person to be evaluated for TB (i.e., active case finding). The process continues with the ordering of an appropriate test; timely and safe referral of the specimen under appropriate transit conditions to the laboratory for testing; accurate and quality-assured testing by the laboratory; return and receipt of the test results by the HCW; initiation of appropriate treatment; and monitoring of response to therapy. Attrition from or delays in any of the steps can reduce the clinical and public health impact of the laboratory test.

The diagnostic network is a shared responsibility between the TB program, TB diagnostic laboratories, and clinicians at each level of the health system. The network encompasses all points where community members seek care – both within the public and private sectors.

In 2021, the World Health Organization (WHO) introduced new rapid molecular diagnostics for Tuberculosis detection. Kenya has strived to realign herself and keep abreast with these new technological changes in order to reinvigorate her diagnostic and programmatic capacity in line with WHO End TB Strategy that calls for the early diagnosis of TB including universal drug-susceptibility testing (DST).

The national TB laboratory system and network includes three culture laboratories: the National TB Reference Laboratory (NTRL), KEMRI WRP-Kericho TB culture laboratory and KEMRI-Kisian TB Culture laboratory. There are also three regional, decentralized 1st and 2nd DST LPA laboratories (Malindi Sub-County hospital, Kitale County Referral Hospital, and Machakos County Hospital). The decentralized TB diagnostic network constitutes 226 Genexpert machines facilities (includes 37 placed in private facilities), 38 Truenat, 26 TB-LAMP and 3,159 smear microscopy facilities of which ~ 300 have LF LAM testing capability. This network serves approximately 10,000 public and private health facilities.

Figure 4: Kenya mWRD Network 2023



As depicted in the mWRD network above, there is considerable availability of state-of-the-art testing algorithms that rely on Xpert Ultra as the initial diagnostic test as per the WHO recommendations for universal DST. As depicted in the network coverage above onsite testing or referral services for WRD for all presumptive TB cases is not available for all health facilities in all sub-counties. In some sub-counties, access was at or near 100%, whereas gaps exist in other sub-counties.

There is also commendable adherence to the current diagnostic algorithm, even though AFB microscopy is still a diagnostic mainstay for some clinicians in the network. Even though testing for a full panel of second-line drugs is not yet available, the diagnostic algorithm includes access to DST for 1st line and 2nd line drugs by referral necessitating the need for additional training and sensitization of HCW on the algorithm.

A large, stylized green number '2' is centered within a white circle. The circle is outlined by a thick green line. The entire graphic is set against a yellow background.

Chapter Two

2.1 Vision

To be a centre of excellence in provision of quality TB Laboratory testing services.

2.2 Mission

To provide effective leadership for efficient, accessible, responsive and quality TB Laboratory network services that contribute towards achieving resilient and sustainable systems aimed at ending TB.

2.3 TB Laboratory Network Functions

2.3.1 National Public Health Laboratory (NPHL)

National Public Health Laboratory (NPHL) is a public health facility comprising several reference laboratory units that provide referral services linking national, international and county laboratories. The NPHL is mandated to perform specialized testing for priority infectious and non-communicable diseases, laboratory-based disease surveillance, and to provide quality assurance for the public health laboratory network.

Medical laboratories play a vital role in providing vital information that assist in prevention, diagnosis, treatment and management of diseases. This calls for a well-structured laboratory system that addresses issues of oversight and coordination to meet the public expectation.

While fulfilling its mandate of laboratory policy formulation and leadership, the NPHL ensures that its operation is within the management system requirements as prescribed by ISO 9000:2008.

The NPHL also promotes quality laboratory systems as it provides national referral services to both public and private health sector; two of the national laboratories are accredited to the ISO 15189:2012 standards with a third one having received approval for accreditation. Other NPHL reference laboratories are still being mentored towards accreditation; a proof that NPHL continues in its commitment towards total quality laboratory systems.

2.3.2 National Tuberculosis Reference Laboratory (NTRL).

The NTRL, is one of the 8 reference laboratories at NPHL and has various roles in the TB Laboratory network as per its delegated mandate by NPHLS. These roles anchor the lab's mandate towards managing and overseeing operational aspects of the lab network in TB diagnosis. This is a summary of the lab's mandate with regards to improving access to and quality of laboratory Tuberculosis diagnosis in the country;

1. Coordinate and provide oversight of TB Laboratory Diagnostic Networks in the country.
2. Carry out evidence-driven population-based surveillance to determine TB prevalence in the country.
3. Coordinate and provide routine laboratory-based TB testing and surveillance, using testing data to advise on appropriate patient level intervention. This includes, specialized testing for TB Phenotypic cultures and genotypic characterization for MDR, Pre-XDR and XDR TB through specimen referral networks across the country.

4. To provide Laboratory Quality assurance services through panel testing to support the accuracy and reliability of results generated by personnel engaged in TB Diagnostic procedures using smear microscopy, fluorescent microscopy, and all WHO-approved rapid diagnostic platforms
5. To provide specialized testing for TB Phenotypic cultures and genotypic characterization for MDR, Pre-XDR and XDR TB through specimen referral networks across the country
6. Provide technical leadership in the development and review of TB diagnostic policy guidelines. To provide for specimen repository/archival based on Kenya Biosafety Biosecurity guidelines on handling valuable biological materials (VBM) generated during testing and phenotypic TB cultures
7. Develop and review training materials for TB refresher training for laboratory personnel
8. Assist in the implementation of TB diagnostic policy guidance and algorithms in peripheral and regional laboratories.
9. Take the lead in carrying out technology verification or/ and validation of new TB testing technologies; as a gatekeeper technical institution appointed by the regulator of in-vitro diagnostics in Kenya for product listing, registration and licensing for marketing and use in Kenya

2.3.2 County and Sub County laboratories.

The TB lab diagnostic network in the figure below provides a highlight on the key functions for each lab in TB testing. These labs operate at the intermediate and peripheral levels of the network.

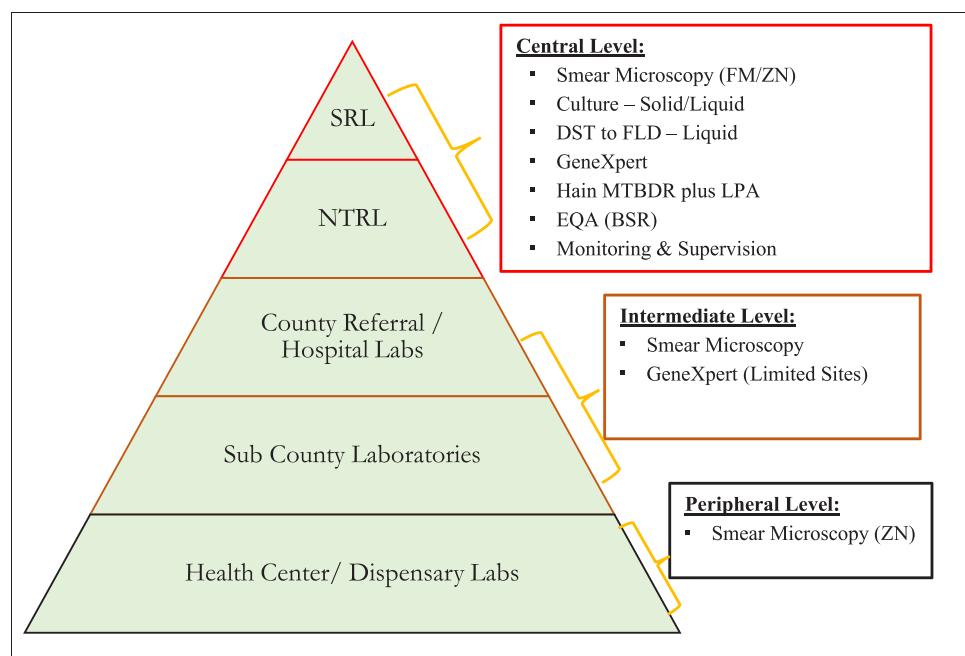


Figure 5: Levels of Kenya's TB Laboratory Network²

² DLS Strategic Plan 2022-2026

- **Peripheral/Level I – Dispensary and Health Centre Labs:** Laboratories at this level perform microscopy using ZN or FM, depending on the workload. They refer specimens for mWRD tests such as GeneXpert/TrueNat to the intermediate level laboratories within their SRS network. Upon clinicians' request, some of these sites refer specimens to the central level laboratories for culture and DST.
- **Intermediate/Level II – Sub County and County Labs:** The county and sub-county laboratories are involved in the diagnosis of new cases/treatment follow-up using either ZN or FM. Some of the facilities are equipped with a mWRD instrument. Specimens from all the retreatment cases are referred to the central level labs for further analysis. Some County labs here function as Regional Laboratories with additional capacity for 1st and 2nd line mWRD DST through LPA platforms, these include County Referral Hospital laboratories in Malindi, Kitale, Machakos.
- **Central/Level III – Reference and Supra-Reference Labs:** The NTRL performs solid culture (LJ), liquid culture (MGIT), drug susceptibility testing (DST) for 1st and 2nd line drugs on liquid medium, microscopy (ZN & FM), LPA (R/H), and mWRDs. It is also involved in providing External Quality Assurance (EQA) and technical assistance for microscopy and mWRD tests to county laboratories. Other facilities with capacity to perform culture and drug susceptibility testing (DST) include KEMRI Kisian in Kisumu, Walter Reed Kericho, IOM (Dadaab and Nairobi), Aga Khan, Nairobi hospitals, and CRDR-KEMRI Nairobi.

A large, bold green number '3' is centered within a white circle. The circle has a thin green outline and is set against a yellow background.

Chapter Three

3.1 Operational Situational Analysis of the TB Laboratory Diagnostic Network

This chapter provides a highlight of the situational analysis across key thematic areas as discussed and realised from the available data presented during the development of the operational plan, a detailed point-by-point analysis is provided in annex 1.

3.1.1 Legal & Policies framework:

The Constitution of Kenya 2010, establishes the right to the highest attainable standard of health for all citizens, which is operationalized through the Kenya Health Policy and the Kenya Health Strategic Plan. These documents outline goals, strategies, and priorities for improving healthcare access and outcomes in the country. Within the diagnostic network, all laboratories must be registered by the KMLTTB to ensure adherence to quality standards. Specifically for TB diagnostic laboratories, registered personnel are required, and TB diagnostic services are provided free of charge to enhance accessibility for all individuals.

To strengthen TB services, the NTLP has developed a strategic plan covering 2023/24-2027/28, focusing on prevention, diagnosis, and treatment. Additionally, the DLS has a strategic plan for 2022-2026, to guide high-quality laboratory services. These initiatives demonstrate Kenya's commitment to improving healthcare, ensuring free TB diagnostics, regulating laboratory personnel, and implementing comprehensive strategies to address TB challenges.

Overall, these policy and strategic documents, combined with constitutional provisions, highlight Kenya's dedication to enhancing healthcare services and promoting equitable access to quality care throughout the country.

Key Gaps;

1. Operationalization of the DLS Strategic Plan
2. The NTRL has never had a comprehensive work plan for the TB diagnostic Network, hence sub-optimal operationalization in the DLS and NTP strategic plans.

3.1.2 Structure and Organization of the TB Diagnostic Network:

The diagnostic network in Kenya is structured into four tiers, encompassing various facilities. At the top tier, there are the National reference laboratories. The next tier comprises County Referral Hospital laboratories, followed by sub-county referral hospital laboratories, and finally, Health center laboratories (Figure 4: Levels of Kenya's TB Laboratory Network). Due to the devolution of health services, the county government is responsible for handling health services at the counties.

Within this network, the technical and operational oversight of laboratory services falls under the jurisdiction of the National Public Health Laboratories, which operates under the Department of Laboratory Services. Management of TB Laboratory Diagnostic services are provided through both the National TB Program and the National Tuberculosis Reference Laboratory (NTRL).

To support tuberculosis diagnosis, the TB diagnostic network includes several dedicated facilities. It consists of one national TB reference laboratory, backed up by a culture laboratory. Additionally, there are three molecular (LPA) regional testing labs, 38 TRUENAT facilities, and 26 TB-LAMP facilities. In conjunction with these specialized labs, there are 2,550 AFB microscopy

sites. There are 285 private TB diagnostic laboratories operating alongside the public healthcare system. These collectively contribute to the overall laboratory diagnostic capabilities and services available throughout the country³.

Key Gaps:

1. Sub optimal engagement of the NTRL in the coordination of the TB diagnostic network
2. Sub optimal engagement of the Private sector labs in TB diagnostic network

3.1.3 TB Diagnostic coverage:

The tuberculosis (TB) diagnostic landscape in the country consists of two culture labs, one research lab, and one government-owned lab that conducts both 1st and 2nd line drug susceptibility testing (DST). Additionally, there are three decentralized Line Probe Assay (LPA) labs, 37 TrueNat facilities, 26 TB LAMP facilities, 2,550 smear microscopy facilities, and 283 LF LAM diagnostic facilities. Nationally, the coverage of mycobacterium growth indicator tube (MGIT) mWRD testing is at 47%, with all 47 county referral hospital labs equipped with mWRDs. However, only 66% of sub-county hospitals have access to mWRD tests. The proportion of people with presumptive TB who are actually tested for TB is 51%, and although LF LAM testing has been introduced, the corresponding comprehensive data is not currently available. According to the World Health Organization (WHO) report of 2022, There were 63% of newly confirmed TB cases that tested for rifampicin resistance, while only 7% of multidrug-resistant (MDR) cases (32 out of 465) are tested for fluoroquinolone resistance⁴.

Overall, the laboratory TB diagnostic landscape includes a variety of testing facilities and methods, with varying levels of coverage and testing rates for different diagnostic tests. Efforts are being made to expand access to mWRD testing and improve testing rates for presumptive TB cases. However, there is still room for improvement in the testing of rifampicin and fluoroquinolone resistance among TB patients, particularly those with MDR-TB.

Key Gaps:

1. Inadequacy of coverage by mWRD diagnostic platforms
2. Higher proportion of presumptive case diagnosed clinically at 41%

3.1.4 Specimen referral system:

At the county level, there is an integrated sample referral guidelines and system⁵. However, this system is not implemented at the national public health labs. Instead, a paper-based system is utilized for tracking samples collected for TB microscopy, MTB/RIF Ultra Xpert, and culture. It is worth noting that only 32% of facilities have some form of sample referral system in place⁵.

Currently, the sample referral process operates under a mixed funding where donors facilitate contracted riders and healthcare workers (HCWs) who are responsible for dropping off samples at designated courier offices. On average, each facility receives three rider visits per week. These riders collect the samples and transport them either to the county testing sites or to collection hubs.

³ Kenya TB Diagnostic Network Assessment, 2023.

⁴ Global Tuberculosis Report 2022. Geneva: World Health organization; 2022.

⁵ National Guideline for Integrated Laboratory Specimen Referral, 2019

For samples being sent to the culture testing labs, the services of G4S and EMS couriers are utilized. Once the samples reach the labs, the results are transmitted electronically back to the requesting facilities. This ensures a streamlined communication of results.

In terms of sample tracking, there is ongoing development in the implementation of remote logging of samples. This would enable better tracking and monitoring of samples throughout the referral process, further improving the efficiency of the system.

Key Gap;

1. Sub optimal Integration of the SRS across the counties and the three main disease programs of Malaria, HIV and TB

3.1.5 TB diagnostic algorithm:

There is a diagnostic algorithm developed by the National TB program and in use at all TB diagnostic and treatment facilities in the country at 80%. Algorithm has been reviewed to capture new tests and is awaiting approval, printing and dissemination. It provides for mWRDs as an initial test for all presumptive TB patients and thus responsive to the epidemic, patient-centred and aligned to the WHO End TB strategy. IT focuses on the whole diagnostic cascade, from screening to treatment completion.

Key Gap;

1. Sub optimal knowledge and practice on the diagnostic algorithm among healthcare workers across the network

3.1.6 Biosafety and Biosecurity:

The level 4 to 6 lab facilities in the network generally have safety officers, but the conduction of lab risk assessments is inadequate³. While some facilities have round the clock access to utilities like water and electricity, the sustainability of costs poses a threat. The country lacks sufficient waste management infrastructure such as incinerators for hazardous waste disposal, and there is a lack of resources to support the transportation of waste within the disposal network. There is a National Healthcare Waste Management Guidelines though not fully operationalized in all facilities. Healthcare worker (HCW) screening, such as for latent TB and hepatitis B, is conducted but limited to a few facilities. While post-exposure prophylaxis (TPT) is provided for free in public health facilities, some HCWs decline to take it. Coverage for hepatitis B vaccination is not comprehensive.

There is no TB specific Biosafety and Biosecurity guideline for use in the TB Lab diagnostic network. Refresher training for biosafety is conducted annually, but it does not reach all staff members and tiers. Infrastructure design and building requirements are defined in guidelines, but adherence is lacking in lower-level facilities. Personal protective equipment (PPE) support is available and used, but N95 fit testing is conducted only in a few accredited labs, and there is no fit testing program in place. BSC (biological safety cabinet) certification support is insufficient, as most BSCs in counties are not certified. Biomedical equipment (BME) support is provided by nine certified individuals in Kenya, with training of trainers (TOT) programs conducted in counties. Not all infection prevention and control (IPC) officers have laboratory training, and the availability of safety standard operating procedures (SOPs), manuals, and guidelines may vary across facilities.

Key Gaps;

1. Lack of TB specific biosafety biosecurity manual
2. Sub optimal operationalization of key guidelines such as the Healthcare Waste Management
3. Sub optimal support for key biosafety biosecurity and IPC activities

3.1.7 Human resources for the TB laboratory network:

The Kenya Human Resources For Health Strategic Plan (KHRHSP) 2019-2023 provides a framework for managing human resources in the healthcare sector. The plan aims to address challenges related to staffing, skills, and distribution of healthcare professionals. However, the laboratory policy guideline in operation is still based on the 2006 version and requires updating to reflect the current status of laboratory practices.

The National Tuberculosis Reference Laboratory (NTRL) has a total of 15 staff members, with 13 laboratory scientists and 2 support staff. Out of these, 13 are supported by donors, while 2 are supported by the Government of Kenya (GOK). However, the contracts for the 11 donor-supported officers are set to end in December 2023. To ensure optimal operations, the program requires an additional 18 staff members. In addition, the KEMRI TB lab has 10 staff members, all of whom are supported by donors.

In county health facilities, laboratory staff members are not classified based on disease specialty. While the majority of lab staff in public health facilities are registered and regulated by the Kenya Medical Laboratory Technicians and Technologists Board (KMLTTB), research labs have specialized staff who are not registered under the same regulatory body. These differences in classification and registration pose challenges in standardizing and regulating laboratory practices across different types of facilities

Key Gap;

1. Lack of human resource plan for TB labs at all levels

3.1.8 Diagnostic data management & connectivity3:

There are standardized data recording and reporting tools such as request forms, registers, job aids, and tools used to ensure consistency in data collection and reporting. These tools include results reporting tools with built-in results interpretation. The Labware system is employed to establish data connectivity between patients, culture tests, and sample referral, facilitating efficient information flow. However, there exist sub optimal utilization of the available data integration platforms, for example, the Microscopy Proficiency Testing (PT) is not yet connected to the External Quality Assurance (EQA) platform. At the National Public Health Laboratories (NPHL), Labware serves as the primary database for TB/HIV-related data. Guidelines for data storage, retrieval, and archiving are in place to ensure proper management of information even though usage is still below par. Additionally, there is an existing online reporting system for PT.

The TIBULIMS system links various components mWRD testing platforms, including patient data, GenXpert, Truenat, and culture. There is an established access levels to data are implemented within the laboratory aligned to the Kenya Data Protection practices⁶. Adequate measures for data backup, retrieval, and archival are also established, with defined time frames for storing patient data in reference labs.

Key Gaps:

1. Lack of an interoperable linkage across the labware data base, programmatic TiBU data base and GXLIMS
2. Lack of a diagnostic network performance dashboard

3.1.9 Quality management systems:

The National Tuberculosis Reference Laboratory (NTRL) has achieved ISO-15189 and ISO-17043 accreditation, indicating its adherence to international quality standards. The NTRL also has the capacity for proficiency testing (PT) production, creating PT panels and distributing them to participating laboratories according to a schedule. The NTRL monitors the performance of external quality assessment (EQA) and conducts support supervision for tuberculosis (TB) laboratories. Quality management systems (QMS) are implemented in the laboratory, as evidenced by the existence of a quality manual in accredited laboratories and those implementing quality programs. Standard operating procedures (SOPs) specific to TB diagnostics are available and developed by the NTRL, although not all facilities have copies of these SOPs.

Accredited laboratories perform routine analysis of quality indicators and track their performance. EQA programs are available, and rechecking is offered with donor support for all acid-fast bacilli (AFB) sites. However, enforcement is needed to ensure widespread participation in these activities. PT materials are available for tests such as GeneXpert, LPA, and Truenat, but some tests like TB LAM and TB LAMP have not yet been enrolled due to the unavailability of PT materials in the country or commercially. Support supervision is conducted annually for sites participating in PT, and blinded rechecking is also performed.

Overall, the NTRL demonstrates a commitment to quality assurance and quality control through accreditation, PT production, SOP development, and regular support supervision, although there are areas where further improvement and enforcement are needed to ensure consistent adherence to quality standards across all TB diagnostic facilities.

Key Gaps:

1. Lack of standardized SOPs across the TB lab diagnostic network
2. High reliance on donor support for EQA activities

3.10 TB/HIV:

The text highlights several key points related to the integration of TB/HIV services. The laboratory request form tracks both HIV and TB status, indicating an integrated approach. Policy guidelines are also integrated to ensure cohesive management of TB and HIV. Notably, TB/HIV laboratory services are provided free of charge. Compulsory TB screening is conducted for all HIV patients, and TB preventive therapy (TPT) is offered to all HIV-positive individuals. There is availability of

⁶ Data Protection Act 2022

LF-LAM (urine-based TB diagnostic test), along with the integration of sample referral systems, ensuring efficient and coordinated sample management between TB and HIV testing facilities. The mWRD platforms in use in some facilities have been optimized for both TB and HIV diagnosis.

Key Gaps:

1. Lack of a clear framework to guide both multi-disease and multi-platform diagnosticplexing.

3.1.11 Operational Research:

According to the National Tuberculosis Program (NTP) annual report for 2021, a sentinel surveillance was conducted, but the findings have not been shared yet. Additionally, there is an ongoing Nairobi prevalence survey conducted by the Center for Global Health Research (CGHR) in collaboration with the NTRL. Furthermore, there are plans for a drug resistance (DR) survey in the future. However, there is no evidence of an operational research (OR) conducted by the NTRL recently, and the capacity to carry out OR at the NTRL is limited.

In summary, while a sentinel surveillance was completed, the dissemination of its findings is pending. Ongoing efforts include a prevalence survey in Nairobi and plans for a DR survey. However, the NTRL has not conducted recent OR, and its capacity for OR is currently constrained.

Key Gaps:

1. Sub optimal utilization of TB Lab diagnostic data for operation research
2. Lack of a TB Lab specific generic protocol to guide OR and lab evaluations
3. Capacity limitations of NTRL technical staff to conduct/lead OR

3.1.12 Infrastructure of the laboratory network for TB diagnostics:

The National Policy Guidelines for Medical Laboratory Physical Infrastructure are in place, with the last review conducted in 2015. These guidelines provide a framework for the physical infrastructure requirements of medical laboratories in Kenya. Additionally, there is a specific TB guideline that addresses the laboratory setting for TB diagnostics, aligning with the Kenya WHO recommendations for the period 2022-2026. Currently, there are two laboratories that comply with Biosafety Level III (BSL III) standards, indicating their capability to handle high-risk pathogens associated with TB.

Technical Assistance reports from the Diagnostic Network Assessment, Green Light Committee, Diagnostic Network Optimization, and End-Term Review indicate that only a few health facility laboratories meet the infrastructure requirements outlined in the guidelines. Apart from the general medical laboratory infrastructure guidelines, there are also separate guidelines specifically focused on biosafety and biosecurity, which include elements related to infrastructure management to ensure the safe and secure handling of laboratory materials and operations.

Key Gaps:

1. Inadequate availability of key infrastructural requirements as per lab level
2. Sub optimal implementation of the lab infrastructure guidelines in the intermediate and peripheral level facilities

3.1.13 Equipment maintenance, calibration and validation of TB laboratory equipment:

The assessment of facilities for equipment is conducted by a national team, ensuring that the appropriate equipment is selected and suitable for the intended purposes. The verification of equipment and training is carried out during the installation process in collaboration with the Kenya Medical Laboratory Technicians and Technologists Board (KMLTTB). Follow-up activities and routine maintenance or calibration are performed as required based on the functions of the specific equipment. The availability of Service Level Agreements (SLAs) between equipment providers or stakeholders and the Ministry of Health (MOH) ensures clear expectations and responsibilities for equipment maintenance.

However, it is noted that there are challenges related to the high costs of service contracts and the absence of a unified maintenance and management program, as highlighted in the Diagnostic Laboratory Strengthening Strategic Plan (DLS-SP) for the years 2022-2026. To address equipment calibration needs, there is the existence of a National Equipment Calibration Centre mentioned in the same strategic plan. Additionally, an equipment list specifically for TB diagnostic work is available, aiding in the identification and management of the necessary equipment for TB diagnostics.

Key Gap;

1. Lack of a comprehensive and unified maintenance/management plan for TB Laboratory diagnostic equipment

3.1.14 Management of laboratory commodities and supplies within the TB laboratory network:

The procurement of commodities for the NTRL is primarily supported by donors through the Global Fund (GF) grant. The NTRL conducts annual forecasting and quantification exercises to determine the required commodities for the lab. Centralized procurement and warehousing are managed at the national level through the Kenya Medical Supplies Authority (KEMSA). To monitor commodity status, a functional TB commodity security committee operates at the national level. Commodity management at the NTRL is tracked using stock cards, and consumption reporting and requisition of TB commodities are facilitated through the DHIS2 and TB allocation tool. The procurement process for GeneXpert commodities is currently done via the Online GXLIMS and KHIS platforms. However, stockouts of essential culture and drug-susceptibility testing (DST) commodities are experienced frequently, and there is irregular availability of TB laboratory commodities like GeneXpert cartridges.

The country has a national guideline specifically focused on supply chain management of laboratory commodities, providing guidance for effective procurement and inventory control. Additionally, the NTRL has a standard operating procedure (SOP) in place for purchasing and managing the inventory of lab commodities. Despite these measures, the erratic stock availability of certain TB laboratory commodities, such as GeneXpert cartridges, remains a challenge, leading to potential disruptions in diagnostic services.

Key Gaps;

1. Lack of NTRL commodities focal person in key TB Lab commodity committees
2. Sub optimal utilization of the DHIS2 for commodity forecasting, quantification and ordering

3.1.15 Financing of TB laboratory diagnostic Services:

Funding for TB in the country is done by both domestic and international support in a proportion of 49% and 51% respectively. Operations at the NTRL laboratory is highly financed by the partners, - NSP ETR Report 2022.

Key Gap:

1. Insufficient funding for TB lab services

3.2. SWOT Analysis of the TB Laboratory Diagnostic Network

The existing TB laboratory network possesses key strengths, weaknesses, opportunities and threats which were identified through discussions with various stakeholders as highlighted below. These points summarize the key;

1. Strengths with aspects related to policies, infrastructure, coordination, training, laboratory services, and partnerships in the context of TB diagnostics and healthcare management.
2. Weaknesses that highlight challenges in planning, coordination, funding, human resources, data utilization, and referral systems within the TB diagnostic network.
3. Opportunities highlighting the potential for improved testing integration, partnerships, utilization of advanced technologies, and support from both public and private sectors, which can significantly enhance the capabilities and effectiveness of the TB laboratory diagnostic network.
4. Threats highlighting the risks associated with funding, workforce planning, external factors, and the overall stability of the healthcare system, which can impact the continuity and effectiveness of TB laboratory diagnostic services.

Table 2: Lab Diagnostic Network SWOT Analysis Summary

Strengths	Weaknesses
<ol style="list-style-type: none">1. Policies, legal, and regulatory framework for health practices and laboratory practices are in place.2. National strategic plans for healthcare are available and regularly updated.3. The laboratory network is well-defined and structured in tiers.4. The Ministry of Health (MOH) and National Public Health Laboratory (NPHL) have a laboratory directorate/department to coordinate services.5. The NPHL collaborates with the National Tuberculosis Program (NTP) to deliver TB laboratory services.6. The initial test for TB diagnosis, mWRD, has been adopted.7. Standard training materials for TB diagnostics are available, and periodic training and refresher courses are conducted.	<ol style="list-style-type: none">1. Limited involvement of the National Tuberculosis Reference Laboratory (NTRL) in planning and coordination of network activities.2. Insufficient utilization of operational research (OR) data to inform national policies and implementation of new diagnostic tools.3. Inadequate coordination between the National Tuberculosis Program (NTP) and NPHL, affecting the functionality of the national TB diagnostic network.4. Funding shortages for key TB laboratory network activities, including quality management, commodity security, human resources, infrastructure, and diagnostic coverage.5. Workforce shortages to support the needs of the TB network.6. Limited utilization of laboratory data for decision making and the absence of a TB lab diagnostic dashboard.7. Poor linkage and referral of presumptive TB patients to testing or referral facilities, along with inadequate coverage of mWRDS (initial TB test) and low utilization of laboratory services such as GeneXpert.

Opportunities	Threats
<ol style="list-style-type: none"> 1. Integration of testing services using multiplexing: By leveraging multiplexing technologies, multiple tests can be performed simultaneously on the same platform, streamlining testing processes and improving efficiency. 2. Collaboration with international and local partners: Collaborating with partners can enhance knowledge sharing, resource pooling, and technical support, leading to improved diagnostic services and network functionality. 3. Public-private partnership: Engaging the private sector can help expand access to TB diagnostics, leverage their expertise and resources, and improve the overall reach and effectiveness of the diagnostic network. 4. Social Corporate Responsibility (CSR) programs by companies: Companies can contribute to TB diagnostic efforts through CSR programs, including financial support, provision of resources or equipment, and community engagement initiatives. 5. Genomic sequencing support from the NPHL's genomic center: The presence of a genomic center at NPHL enables the utilization of advanced genomic sequencing technologies, allowing for enhanced understanding of TB strains, identification of drug resistance, and development of targeted treatment approaches. 	<ol style="list-style-type: none"> 1. Over reliance on donor support: Dependence on external funding for TB diagnostics poses a threat to sustainability and continuity of services if donor support decreases or ceases. 2. Human resource transition plan: Inadequate planning for workforce transition can disrupt laboratory services and lead to a loss of skilled personnel, impacting the functioning of the TB diagnostic network. 3. Pandemics and natural calamities: Outbreaks, pandemics, and natural disasters can disrupt healthcare systems, including TB diagnostics, causing interruptions in testing, supply chain disruptions, and loss of infrastructure. 4. Global commodity security: Ensuring a consistent supply of essential commodities for TB diagnosis is crucial. Global commodity security threats, such as shortages, trade disruptions, or price fluctuations, can hinder access to necessary diagnostic resources. 5. Sustainability of implementation plans following governance transition: Transitions in governance, such as political changes or shifts in healthcare policies, can pose challenges to sustaining and implementing effective TB diagnostic plans and strategies.



Chapter Four

4.1 Strategic Objectives and Interventions for the Operational Plan

Following analysis of the network's current situation and SWOT, key strategic interventions and major actions were identified as follows upon which specific actions were then generated in the form of sub activities for implementation in the course of this operational workplan.

The objectives of TB reference laboratory are aligned with the 3 objectives of the End-TB strategy listed as below:

1. Increase access to rapid TB diagnostics (mWRD) from 47 % in 2023 to 80% by 2028.
To increase access to the mWRD for lab diagnosis, the operational plan has one key strategic intervention for the duration of this plan.
2. Reach universal access to DST for Bacteriologically confirmed new and retreatment cases from 60% and 75%⁷ respectively to 100%.
To increase DST coverage for both DS-TB and DR-TB in line with the 2030 global EndTB goals, NTRL through this operational plan has focused on strengthening both phentoypic and genotypic testing (for First line and Secondline drugs) as a key strategic intervention.
3. Strengthen the quality of TB Diagnostic Laboratory services from 53%⁸ to 80%
With a 53% of quality index for TB lab diagnosis, this operational plan focuses on three key strategic interventions to guide the implementation towards this objective.
4. Strengthen management of the TB laboratory network to achieve operational efficiency from 56%⁸ in 2023 to 80% in 2028
To strengthen coordination and management of the TB laboratory network in the effort to achieve operational effectiveness and efficiency. To achieve this objective the operational plan has adopted three strategic interventions with corresponding sub activities.

⁷ DNTLDP Annual Report, 2022

⁸ National Guideline for Integrated Laboratory Specimen Referral, 2019

Table 3: Operational Plan Strategic Objectives, Interventions and Major Actions

Strategic Objective 1: Increase access to rapid TB diagnostics (mWRD) from 47 % in 2023 to 80% by 2028		
Strategic Interventions (SI)	Major Actions/Activities	Expected Outcome
SI1: Expand coverage for TB diagnostic services	<p>1.1. Comprehensive Assessment of the country's current TB laboratory diagnostic status.</p> <p>1.2. Redesigning and strengthening the strategy for equitable distribution of equipment for diagnostics.</p> <p>1.3. Enhance the utilization of the current testing platforms for Multi-disease and Multi-platform testing (Multiplexing).</p> <p>1.4. Procure and increase the number of mWRDs including the 10 color Xpert machines to be placed in the lower facilities to expand molecular TB testing (1st and 2nd line DST).</p> <p>1.5. Strengthen and expand the sample referral network in the country.</p> <p>1.6. Expand testing for TB among high-risk populations using non-sputum samples</p>	Increased access to mWRD as the 1 st test
Strategic Objective 2: Reach universal access to DST for Bacteriologically confirmed new and retreatment cases from 60% and 75% respectively to 100%.		
SI2: Strengthen culture and drug susceptibility testing for both phentoypic and genotypic molecular, (For First line, secondline and potential XDR diagnosis).	<p>2.1. Increase access to Culture, 1st and 2nd line DST for all previously treated including relapses and for RR patients.</p> <p>2.2. Scale up the use of low and moderate complexity mWRDs for diagnosis and detection of resistance to RIF, INH and FQ.</p> <p>2.3. To support remote logging in the facilities with TB diagnostic capacity of either Culture or molecular testing across the country.</p> <p>2.4. To improve surveillance and diagnostic capacity for drug resistance by establishing the country's capacity to carry out genome sequencing for M.tuberculosis complex and requisite technical capacity.</p>	Increase access to DST for all eligible TB patients

Strategic Objective 3: Strengthen the quality of TB Diagnostic Laboratory services from 53% to 80%		
SI3: Strengthen the Quality of Laboratory services	<p>3.1. Sustain the existing quality standards at the National level.</p> <p>3.2. Implementation of National quality management framework for TB laboratories.</p> <p>3.3. Increase the Proficiency testing (PT) coverage for AFB Microscopy, mWRDs and new technologies in health facilities.</p> <p>3.4. Increase implementation of Laboratory continuous quality improvement initiatives (LCQI) TB testing facilities</p> <p>3.5. Developing Laboratory Quality system in line with National standards and quality.</p> <p>3.6. National TB Laboratory diagnostics review of Quality performance indicators</p>	Improved quality of TB lab diagnostic services
SI4: Enhance management of laboratory supplies and equipment	<p>4.1. Develop a system to support Forecasting n Quantification (FnQ) for lab commodities</p> <p>4.2. Train laboratory staff on the utilization of the FnQ system.</p> <p>4.3. Strengthen laboratory logistics and supply management.</p> <p>4.4. Develop and implement a comprehensive equipment and commodities procurement plan</p> <p>4.5. Sustain and procure appropriate SLA for TB diagnostic equipment</p> <p>4.6. Ensure adequate equipment functionality</p> <p>4.7. Enhance timely provision of all culture and DST supplies, commodities</p>	Uninterrupted testing services
SI5: Strengthen biosafety and infection Prevention in TB laboratories	<p>5.1. Development of a TB Lab specific biosafety biosecurity manual</p> <p>5.2 Provision of PPEs at the laboratory, .i.e., for National level to support for reference laboratories, as counties get support from their respective local government.</p> <p>5.3. Advocate for Proper waste segregation and incineration in all sites.</p> <p>5.4. Support BSL III Quaterly service and Annual certification of the cooling system and the HVAC maintenance</p>	Improved workplace safety, minimized risk of laboratory-acquired infections, and assured integrity of TB laboratory diagnostic processes

Strategic Objective 4: Strengthen management of the TB laboratory network to achieve operational efficiency from 56% in 2023 to 80% in 2028.

SI6: Capacity building Laboratory staff with Technical skills and adequate knowledge	<p>6.1. Advocate for domestic resource mobilization/funding by The national and county governments to support recruitment of staff at NTRL and TB Testing laboratories, thus Increasing staffing at all health facility level laboratories.</p> <p>6.2. Knowledge exchange program local and international.</p> <p>6.2. Build the capacity of laboratory staff in TB testing. Refresher training on existing tests and training on new TB diagnostic technologies</p>	Adequate staff competency to provide TB lab diagnostic services
SI7: Integrate laboratory management system and patient management systems to improve testing and resulting of TB investigations and treatment outcomes	<p>7.1. Strengthen the disease specific system needs linkage to the overarching to the PMS.</p> <p>7.2. Timely monitoring of treatment response at defined time points for DS-TB and DR-TB. (Availability of all TB diagnostic platforms).</p> <p>7.3. Adopt use of next generation sequencing for all TB bacteriologically confirmed patients – integrate NTRL data with TiBU</p>	An integrated information warehouse with round the clock data availability for decision making
SI8: Strengthen management and coordination of the Laboratory diagnostic network	<p>8.1. Restructure the laboratory network to a patient-centered, coordinated diagnostic network with participation and representation from networks of people affected by TB.</p> <p>8.2. Support the National TB Reference Laboratory to attain a WHO approval as a Centre of Excellence for TB diagnostics and Surveillance.</p> <p>8.3. Build capacity and mechanisms for responsive technical assistance.</p>	Optimized operational efficiency

An extended list with sub activities is annexed in Annex 1:



Chapter Five

5.1 Monitoring and Evaluation (M&E) Framework

Overview

This Chapter provides the framework and frequency of monitoring and reporting. The lab shall undertake Monitoring, Evaluation and Reporting to ensure that the Operational Plan implementation is as planned, timely corrective action will be taken to mitigate underperformance.

Figure 6: Operational Plan Logic Model

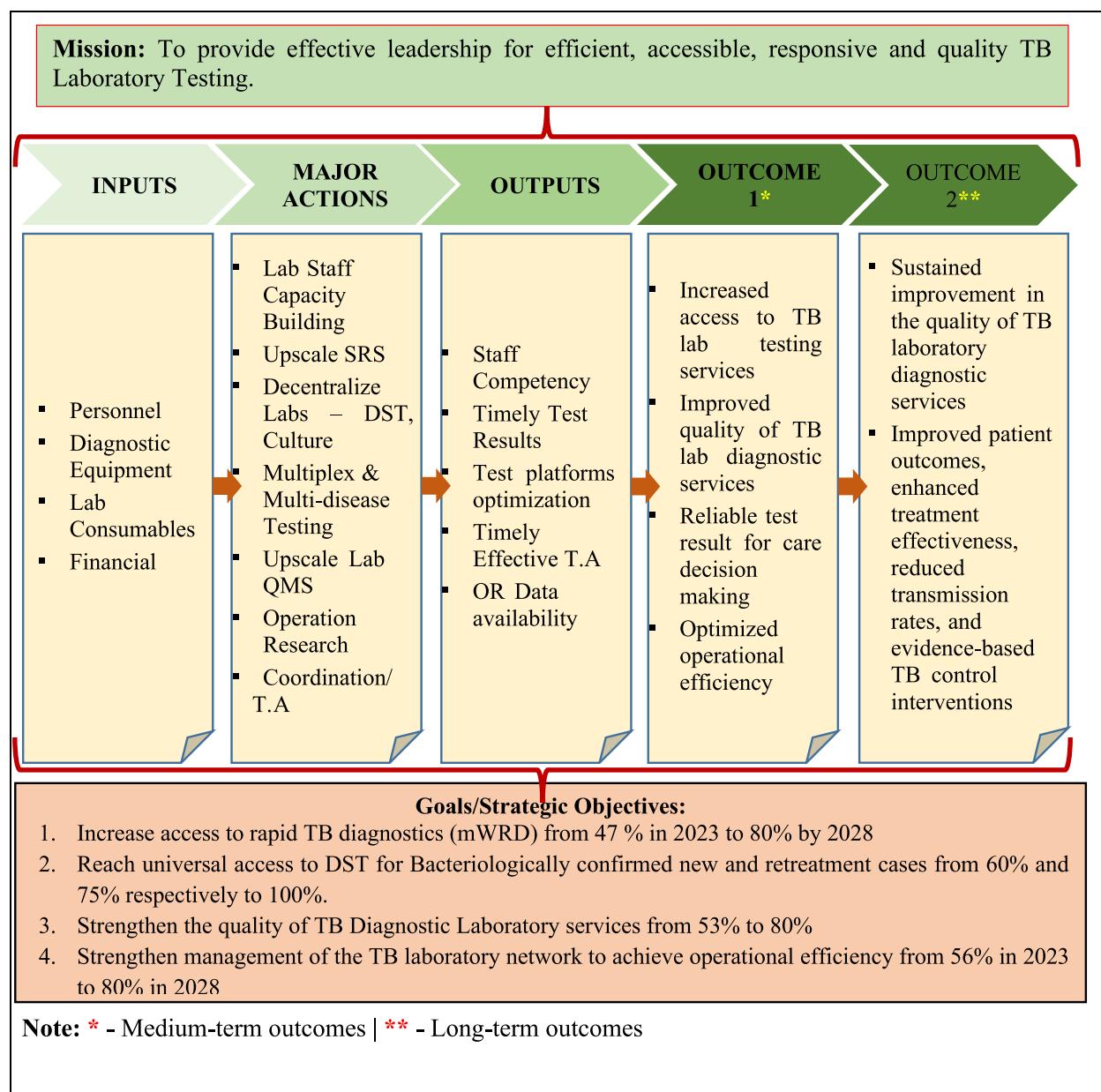


Table 4: Key Strategic Indicators M&E Framework

Indicator	Indicator Type	Numerator, denominator and calculation	Data Source	Periodicity	Responsible	Level of Collection	2023	2024	2025	2026	2027	2028
Proportion of individuals with access to rapid TB diagnostics (mWRD)	Outcome	Number of individuals with access to rapid TB diagnostics (mWRD) / Total Pt population x 100%	TIBU LIMS	Annual	NTP	National	47%	55%	60%	65%	75%	80%
DST Coverage Rate	Outcome	<p>Nume: Number of new and retreatment cases that have received DST</p> <p>Deno: Total number of new and retreatment cases.</p> <p>Result multiplied by 100%.</p>	TIBU LIMS	Annual	NTRL	National	60% : 75% ⁷	70% : 80%	80% : 85%	85% : 90%	95% : 95%	100%
Percentage of TB Diagnostic Laboratories meeting quality standards	Outcome	<p>Nume: Number of TB Labs meeting quality standards</p> <p>Deno: Total number of TB Labs in the diagnostic network assessed.</p> <p>Formula: (Number of TB Diagnostic Laboratories meeting quality standards / Total number of TB Diagnostic Laboratories) x 100%</p>	NTRL – QMS Reports	Quarterly	NTRL	National	53%	60%	65%	70%	75%	80%
Percentage Increase in Operational Efficiency of the TB Laboratory Network	Outcome	(Operational Efficiency in 2028 - Operational Efficiency in 2023) / Operational Efficiency in 2023 X 100%	County reports	Annual	NTRL	National	56%	60%	65%	70%	75%	80%

Note: For comprehensive major & sub activity indicators, see annex 4

5.2 Monitoring

This Monitoring and Evaluation Framework represents the overarching plan for undertaking monitoring and evaluation functions in the five year course of implementing the operational plan, it includes a set of high level indicators and a comprehensive list of intervention level indicators provided here as annex 4 to enable the lab and its stakeholders to develop appropriate monitoring and evaluation questions. The operational Plan will be evaluated during and after implementation together with the mid-term and end-term reviews of the NPHL and NTP SPs that its implementation is mirrored on. The aim here is to enable the lab gauge the extent of achievement of the intended results for the operational plan. The evaluation will be based on these key evaluation measures; relevance, efficiency, effectiveness, sustainability and impact measures. The Monitoring, Evaluation and Reporting process will be undertaken both at the Lab management and stakeholder levels.

The nature and scope of reporting will include:

1. Progress made in implementation against what was planned;
2. Causes of deviation from the Plan, if any;
3. Areas of difficulties and suggested solutions to challenges that may adversely affect implementation; and
4. Proposed corrective measures.

This will provide the lab with a clear link between the investments made, activities, outputs and outcomes/ impact of the interventions towards achievement of the strategic objectives. It will enable the lab to extract relevant information from the implementation of the accompanying Strategic Plans of the NTP and NPHLS which are key programmatic arms in the life of this operational plan. This will allow the lab to fine-tune its operations by embedding continuous improvement principles for future planning

The implementation plan will use an integrated monitoring and evaluation system that employs standardized M&E tools and procedures with reference to the NTP and NPHLS M&E systems/ operations. The lab shall improve its performance monitoring and review process and enhance knowledge management through improved documentation and utilization of its data. To this end, the lab intends to invest in building internal capacity to carry out key M&E functions.

5.3 Evaluation

This Operational Plan sets the course and direction for NTRL's 2023/24 – 2027/28 operational cycle. It prioritizes the lab's forward plans for its internal operations and by extension the TB lab diagnostic network to be implemented through successive annual work plans and other delivery mechanisms. To assess whether the laboratory will have realized its Vision, meaningful performance measures have been defined for each of the four Strategic Objectives. Progress will be monitored through annual targets highlighted in this plan, these will be set out within the annual work plans, and achievements against which will be published in the NTRL Operations Annual Reports. Achieving the strategic objectives will be the greatest pointer to the realization of the Operational Plan's intent.

Review of the Operational Plan

The implementation of this Operational Plan will be reviewed twice at the 3rd and 5th years for the midterm and end-term reviews respectively. The review will enable the lab and the stakeholders determine the relevance, efficiency, effectiveness, sustainability and impact of the four objectives.

5.3 Key Strategic Indicators Reference Sheets

Table 5: Strategic Indicator 1 Reference Sheet

Strategic Objective 1: Increase access to rapid TB diagnostics (mWRD) from 47% in 2023 to 80% by 2028	
Indicator 1.1: Proportion of individuals with access to rapid TB diagnostics (mWRD)	
Purpose	The indicator aims to increase from an estimated 47% in 2023 to 80% by 2028, indicating progress in improving access to timely TB diagnostic services. This measurement helps assess the effectiveness of efforts made to expand access to rapid TB diagnostics over time.
Type	Outcome Indicator
Definition	The outcome indicator measures the percentage of individuals who have access to rapid tuberculosis (TB) diagnostics using the molecular-based World Health Organization (WHO) recommended diagnostics (mWRD).
Baseline	47% in 2023 ⁹
Target	80% by 2028
Calculation (Numerator/ Denominator)	Number of individuals with access to rapid TB diagnostics (mWRD) / Total Patient Population x 100%
Monitoring	Annually
Data Source	TiBU
Disaggregated Activities	Annex 5
Remarks/ Assumptions	NTP projection of 10% annual increase for mWRDs, to cover 450 sites by the end of 2028 is achieved.

⁹ National Guideline for Integrated Laboratory Specimen Referral, 2019

Table 6: Strategic Indicator 2 Reference Sheet

Strategic Objective 2: Reach universal access to DST for Bacteriologically confirmed new and retreatment cases from 60% and 75% respectively to 100%.	
Indicator 1.1: DST Coverage Rate	
Purpose	The indicator aims to increase from an estimated 60% and 75% in 2023 to 100% by 2028, indicating progress in improving access to timely TB diagnostic services. This measurement helps assess the effectiveness of efforts made to expand access to rapid TB diagnostics over time.
Type	Outcome Indicator
Definition	DST coverage rate is the percentage of new and retreatment cases of the target population that have undergone Directly Observed Treatment, Short-Course (DST) within a specified time period. It indicates the level of universal access to DST among the target population.
Baseline	60% and 75% respectively ¹⁰
Target	100% by 2028
Calculation (Numerator/ Denominator)	To calculate the DST coverage rate; Num: number of new and retreatment cases that have received DST Den: Total number of new and retreatment cases. Result multiplied by 100%.
Monitoring	Annually
Data Source	TiBU
Disaggregated Activities	Annex 5
Remarks/Assumptions	The NTP/NTRL expansion plan of 50% of labs performing DST by 2028 is achieved.

Table 7: Strategic Indicator 3 Reference Sheet

Strategic Objective 3: Strengthen the quality of TB Diagnostic Laboratory services from 53% to 80%	
Indicator 1.1: Percentage of TB Diagnostic Laboratories meeting quality standards	
Purpose	The indicator will provide a percentage value that represents the level of TB diagnostic laboratories meeting quality standards. The objective is to increase this percentage from 53% to 80%.
Type	Outcome Indicator
Definition	This indicator measures the proportion of TB diagnostic laboratories that meet predefined quality standards for accurate and reliable tuberculosis (TB) diagnosis.
Baseline	53% in 2023 ¹¹
Target	100% by 2028

^{10, 11} National Guideline for Integrated Laboratory Specimen Referral, 2019

Calculation (Numerator/Denominator)	Divide the number of TB diagnostic laboratories meeting quality standards by the total number of TB diagnostic laboratories, and multiply the result by 100. Num: Number of TB Labs meeting quality standards Den: Total number of TB Labs in the diagnostic network assessed. Formula: (Number of TB Diagnostic Laboratories meeting quality standards / Total number of TB Diagnostic Laboratories) x 100
Monitoring	Annually
Data Source	NTRL Report
Disaggregated Activities	Annex 5
Remarks/Assumptions	All TB testing laboratories have some form of QMS

Table 8: Strategic Indicator 4 Reference Sheet

Strategic Objective 4: Strengthen management of the TB laboratory network to achieve operational efficiency from 56% in 2023 to 80% in 2028	
Indicator 1.1: Percentage Increase in Operational Efficiency of the TB Laboratory Network	
Purpose	The indicator shows a percentage increase of 42.86% in the operational efficiency of the TB laboratory network from 2023 to 2028. This indicates progress towards achieving the objective of strengthening the management of the network.
Type	Outcome Indicator
Definition	This indicator measures the improvement in operational efficiency of the TB laboratory network by comparing the percentage increase from the baseline year to the target year.
Baseline	56% in 2023 ¹²
Target	100% by 2028
Calculation (Numerator/Denominator)	(Operational Efficiency in 2028 - Operational Efficiency in 2023) / Operational Efficiency in 2023 * 100
Monitoring	Annually
Data Source	NTRL
Disaggregated Activities	Annex 5
Remarks/Assumptions	NTRL oversight role on the TB Lab diagnostic network is sustained.

Note: See annex 4 for a comprehensive listing for specific sub activities' indicators .

¹² National Guideline for Integrated Laboratory Specimen Referral, 2019



Chapter Six

6.1 Costing and financing the TB laboratory network operational plan

Financial Resource Requirements

The laboratory diagnostic network interventions and activities in this Operational Plan will be funded by both domestic sources through the exchequer and external sources through development partner sources.

The key result areas will be implemented through various strategies and activities as outlined in the Operational Plan Logic Model in Figure 3 to achieve the strategic objectives. The financial resources required for implementing the strategies and programs/activities are outlined in table xx below. The total amount required to implement the Operational Plan is KES/USD 1,096,158,227.00/7,741,069.00.

Table 9: Financial Resource Requirements for the Operational Plan

Strategic Intervention (SI)	2024	2025	2026	2027	2028	Totals (KES)
Financial Flow	15%	20%	25%	30%	10%	100%
SI1: Expand coverage for TB diagnostic services	48991659	65322212	81652765	97983318	32661106.00	326,611,060.00
SI2: Strengthen culture and drug susceptibility testing for both phentoypic and genotypic molecular, (For First line, secondline and potential XDR diagnosis).	5465085	7286780	9108475	10930170	3643390.00	36,433,900.00
SI3: Strengthen the Quality of Laboratory services	49342840.05	65790453.4	82238066.8	98685680.1	32895226.70	328,952,267.00
SI4: Enhance management of laboratory supplies and equipment	23151414	30868552	38585690	46302828	15434276.00	154,342,760.00
SI5: Strengthen biosafety ,Biosecurity and infection Prevention Control in TB diagnostic network	11943540	15924720	19905900	23887080	7962360.00	79,623,600.00
SI6: Capacity building Laboratory staff with Technical skills and adequate knowledge	15432891	20577188	25721485	30865782	10288594.00	102,885,940.00
SI7: Integrate laboratory management system and patient management systems to improve testing and resulting of TB investigations and treatment outcomes	4471350	5961800	7452250	8942700	2980900	29,809,000.00

SI8: Support the National TB Reference Laboratory to attain a WHO approval as a Centre of Excellence for TB diagnostics and Surveillance	5624955	9374925	9374925	11249910	3749970	37,499,700.00
Operational Plan Total	164423734.1	221106630.4	274039557	328847468	109615822.70	1,096,158,227.00

Budget assumptions for the implementation of the 2023/24-2027-28 Operational Plan. The assumptions made in developing the Operational Plan are that:

1. To enable utilization and 100% absorption of the funds;
 - a) Varying proportions of the funds will be allocated with a steady increase over the 5-year period, as indicated this will allow gradual utilization to enable a more practical and manageable implementation of the operational plan.

2. To enable Financing the implementation of the plan;
 - a) The Ministry of Health's support to the lab will be sustained.
 - b) The long-term co-operative agreements with development partners will be sustained.
 - c) Availability of implementing partners to bridge the implementation gaps where necessary



Annexes

Annex 1: Situation Analysis

Situation analysis topic	Current Situation	Current policies/Expectations/standards (national/ international)	Main weaknesses/ Gaps	Potential solutions
3.1.1: Legal & Policies <ul style="list-style-type: none"> Kenya health policy 2014-2030 Kenya health strategic plan 2018-2023. Article 43 (1) of the Constitution of Kenya, 2010. All laboratories in the diagnostic network are registered by the KMLTTB. There is a policy dictating that all lab personnel working in TB diagnostic laboratories must be registered by KMLTTB All TB diagnostic services are offered free of charge NTLDP strategic plan for TB services 2019-2023 	<ul style="list-style-type: none"> Enforcement of key areas related to TB control and diagnostic networks e.g roles and responsibilities of the NTP and health sector, TB notification, Drug-resistant TB, Private sector engagement, Biosafety and waste management, Disease surveillance, TB control in prisons, migrants, refugees, cross-border populations, and Occupational health Presence of national TB laboratory policy, guideline or strategic plan, fully aligned with other relevant policy documents including the national public health laboratory policy, national TB Strategic Plan and TB-HIV and PMDT policies and plans. Presence of licensing mechanism for TB laboratories in place. 	<ul style="list-style-type: none"> Current Kenya health strategic plan and NTLDP strategic plan policy expiring in June 2023 Continuous education and national standards of competency assessment and CPD points are not mandatory during license renewal by the regulatory body (KMLTTB) Not all diagnostic labs are registered by KMLTTB Current NSP does not address some operational needs of the TB diagnostic network. Policy or legislation mandating laboratories to report the detection of TB and DR-TB patients to the local and national. 	<ul style="list-style-type: none"> Disseminate and avail the NSP, Integrated Guideline for TB, Leprosy and Lung Disease to the county and subcounty Ensure that the objectives, targets and indicators of the NSP are understood, monitored and evaluated. Licensing of Laboratory workforce by the regulator (KMLTTB) should be based on continuous education Analyze TB laboratory-related targets and indicators of the NSP at all the tiers and competency-based assessment during license renewal by the regulatory body (KMLTTB) Counties do not have or are unaware of specific TB diagnostic budgets 	

	<ul style="list-style-type: none"> Draft NSP for July 2024-June 2028 at development stage. DLS strategic plan 2022-2026 awaiting approval. Continuous education and national standards of competency assessment and CPD points are offered but not mandatory during license renewal by the regulatory body (KMLTTB) Financing: 49% of funding for laboratory services is from the Government and 51% from donors. In addition, 100% of funding for rapid molecular tests and the specimen referral system is from donors Counties are unaware of specific TB diagnostic budgets NSP expiring June 2023. Current NSP does not address some operational needs of Tb diagnostic networks. 	<ul style="list-style-type: none"> Presence of a dedicated organizational unit in charge of laboratory coordination in Ministry of Health (MoH). Budgets with sufficient resources for the TB diagnostic network (including public and private sector service provision under NTP) Budget for TB laboratory and clinical diagnostic services covered by sustainable government funding and other local funding sources National policy which enables free diagnosis for all people being evaluated for TB, including all laboratory tests and X-ray Legislation in place, enforced and regularly reviewed to meet the standards. Health care workers within the TB diagnostic network are expected to comply with the regulations of the KMLTTB. 	<ul style="list-style-type: none"> Funding for TB laboratory services is mainly from donors – raising concerns of sustainability Keep all counties and other TB stakeholders abreast on specific TB diagnostic budgets. Increase domestic funding for TB services and strive for sustainability
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<p>3.1.2: Specimen referral system</p> <ul style="list-style-type: none"> • There is a paper based system for tracking samples • There is an integrated sample referral system at the county level but not the case with the national public health labs. • National guideline for integrated laboratory specimen referral networks-2019 • In the current mixed model, contracted riders and HCWs are facilitated by donors to drop samples at the courier offices. • Only 32% of facilities have some form of sample referral system • Each facility has an average of 3 rider visits per week. • Riders collect samples to the county testing sites or collection hubs • G4S and EMS couriers send samples to the culture testing labs. 	<ul style="list-style-type: none"> • The integrated sample referral system is designed to increase access, uptake and coverage of disease diagnostic, prevention and treatment monitoring; by ensuring scheduled, timely and reliable delivery of specimens to the testing (referral) sites and feedback of results to the referring facilities. • Training on TB specimen referral processes and procedures (e.g., specimen collection, storage and packaging; recording and reporting; transport; biosafety and spill procedures; etc.) • Use of triple packaging • Standard operating procedures (SOPs) for TB specimen transportation (including defined roles and responsibilities) • System in place for a sample and results tracking • Material Transfer Agreements (MTAs), Memoranda of Understanding (MoUs) and an international specimen referral system in place for TB specimens that require testing outside of the country 	<ul style="list-style-type: none"> • SOPs on sample collection, packaging and transportation not available in some facilities • Clinician handbook copies yet to be printed and disseminated to the counties. • Key performance indicators for sample referral have not been monitored. • Bulk of the referral system is mainly supported by donors. • 68% of facilities are not covered by SRS • Insufficient (50%) diagnostic facilities for TB diagnostic testing • Inadequate availability of onsite testing or referral services for WRD for all presumptive TB cases in all sub-counties • Integrated specimen referral system does not reach all facilities • Logistics of transporting specimens to NTRL for culture/DST is problematic especially hard-to-reach sites 	<ul style="list-style-type: none"> • Dissemination of the SOPs on sample packaging and transportation • Dissemination of clinician handbooks • NTRL should monitor KPIs for sample referral regularly • MOH to source for local funding to cater for SRS • Establish sufficient diagnostic facilities that ensures >80% of the population is at a maximum of 5 km from the lowest laboratory tier • Procure additional WRD instruments to ensure access to testing including at remote locations and at current WRD sites that are overloaded • NTP should collaborate with partners and counties to have joint planning and budgeting for coordinated and more efficient specimen transport with documented county plans, with pooled funding as needed for equity and sustainability • Develop curriculum and train all health care workers and Riders involved in TB specimen referral upon hiring on specimen referral processes and procedures, including competency testing and periodic on-the-job refreshers
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	<ul style="list-style-type: none"> NPHL has an integrated clinician handbook awaiting printing and dissemination to the counties. Diagnostic facilities that ensures >80% of the population is at a maximum of 5 km from the lowest laboratory tier Current WRD sites that are overloaded 	<ul style="list-style-type: none"> County plans on specimen referral not always available Not all personnel involved in TB specimen referral are trained Lack of standardized triple packaging materials Access to TB infection testing is not routinely available, reducing TPT uptake by TB contacts Continuity of operations plans were not available in most peripheral laboratories 	<ul style="list-style-type: none"> NTP to develop a budgeted plan for roll-out of MTB-antigen specific skin tests and/or near-POC IGRAs for TB infection testing of contacts to increase TPT uptake Ensure that the linkages and frequency of pickups match the needs of the TB program Develop and deploy an online tracking system for specimen referral and results return Monitor and evaluate the performance of the specimen referral system using an M&E framework with key indicators defined, data collection, reporting, responsibilities, etc. Provide logistical support to NTRL for culture/DST especially in hard-to-reach sites Establish county plans on specimen referral NTP/NTRL to develop written and annually updated national emergency/continuity of operations plans, to be adapted by counties
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<p>3.1.3: TB diagnostic algorithm and laboratory clinical interface</p> <ul style="list-style-type: none"> There is a diagnostic algorithm developed by the National TB program and in use at all TB diagnostic and treatment facilities in the country. Algorithm has been reviewed to capture new tests awaiting approval, printing and dissemination. Training and sensitization on TB diagnostic algorithms not done to all facilities and clinicians. 	<ul style="list-style-type: none"> National TB laboratory testing algorithm available that is responsive to the epidemic, patient-centered, address the laboratory goals of the WHO End TB strategy National TB diagnostic algorithm focus on the whole diagnostic cascade, from screening to treatment completion Comprehensive training on diagnostic algorithms, testing methods, specimen collection, test requisition forms and specimen referral provided to all laboratorians, clinicians and other providers. Diagnostic tests ordered according to standard diagnostic algorithms. Diagnostic testing (either onsite testing or by referral) available for all tests prescribed in the national TB laboratory testing algorithm. 	<ul style="list-style-type: none"> Not all TB diagnostic sites have the diagnostic algorithm Suboptimal training and dissemination Reviewed algorithm yet to be disseminated to facilities. HCWs in some facilities do not adhere to the TB diagnostic algorithm some clinicians still relied on AFB microscopy. The algorithm does not address the use sensitive screening methods or detection of TB infections Diagnostic and implement a scale-up plan for molecular and phenotypic DST for new repurposed drugs along with an efficient specimen referral system to ensure adequate capacity and prompt testing. Country transitioning from using the Xpert MTB/RIF test to the Xpert Ultra test.
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	<ul style="list-style-type: none"> DST for rifampicin and other key first-line anti-TB drugs (at least DST for isoniazid), key second-line drugs and new molecules for DR-TB treatment. All health care workers at the various levels of diagnostic and treatment sites are expected to adhere to the TB diagnostic algorithm while handling TB patients. The algorithm is reviewed and updated regularly to include new updates and testing platforms 	<ul style="list-style-type: none"> No reference document forTB biosafety biosecurity activities Safety is compromised Not all labs conduct risk assessment Disruption of TB lab diagnostic work Suboptimal waste management Sub optimal current mWRDs waste management 	<ul style="list-style-type: none"> Develop and disseminate a national biosafety biosecurity manual Train and Appoint safety officer in labs Plan and implement routine risk assessment for labs Establish mechanisms to enable access to functional support utilities Establish mechanism to enable access to incineration services for TB labs
3.1.4: Bio-safety and Biosecurity	<ul style="list-style-type: none"> Lack of a National TB specific biosafety biosecurity manual (2023 Diagnostic Network Assessment) DNA report Most level 4 to 6 have safety officers Scheduled risk assessment. Utilities such as water, electricity are available to some facilities, however issues to do with sustainability of cost are a threat. (2023 DNA Report) 	<ul style="list-style-type: none"> Presence of TB specific biosafety and biosecurity manual which covers - safe handling of TB samples (specimens, isolates, strains) based on bio-risk assessment Designated safety officers available in all facilities Lab risk assessment is inadequately conducted All TB labs should have access to these utilities round the clock 	

	<ul style="list-style-type: none"> Inadequate availability of incinerators in country compromise waste disposal Gene Xpert Testing Cartridges (GTC) wastes guidelines exists however not all facilities adhere BME exist in Kenya ,TOT have been trained in countries Not all IPC officers are Lab trained Availability of safety SOP and manuals and guidelines HCW screening - Prophylactic support Waste management -collection,segregation,disposal,GTC, Autoclaves,Incineration,pit open burning HCW screening is conducted but to few facilities e.g Latent TB and hep B TPT is free in public health facilities in case of exposure however some HCW declines . Vaccination experts-But not all 	<ul style="list-style-type: none"> Provision of accessible incinerator Availability of a comprehensive waste management manual - including the current mWRDs TB laboratory staff received health screening including assessing of signs and symptoms of TB in the past 1 year Standardized procedures for collecting, storing and disposal of waste Laboratories have access to e.g., autoclaves or incinerators for safely disposing of infectious waste Consistent application of TB laboratory-specific building requirements to all laboratory facilities Regular maintenance of TB laboratory facilities and uninterrupted availability of general utilities (water, energy, communication lines) HCW screening is conducted but to few facilities e.g Latent TB and hep B All lab needs to have designated safety staffs Biorisk assessment as need arises. Facilities to adhere to GTC waste guidelines Scale up the HCW screening 	<ul style="list-style-type: none"> Lack of resources to support waste management cycle Lack of sensitization on GTC waste Lack of sensitization/ and resources to screen all HCW. Should be mandatory to screen HCW All HCW should be provided for with TPT when exposed Fit testing not conducted for all HCW due to knowledge. Not all HCW are trained on Biosafety, due to knowledge. Retraining of BME in the counties underway Compilation annual safety reports Ensure lab IPC officer/ in all health facilities are included in IPC committee. Ensure lab officer are IPC trained.
			<ul style="list-style-type: none"> Counties to prioritise allocations for risks assessment and waste management . Counties to facilitate waste transportation to incinerators . Develop annual training Plan for all HCW Sensitization on GTC waste management. Formulate Mandatory screening policy ,TPT and vaccination for HCW. Establish fit testing program in Health facilities. Mapping for BSC in the country is planned and NPHL in collaboration with Amref are currently supporting servicing . Re-training of BME in the counties underway Compilation annual safety reports Ensure lab IPC officer/ in all health facilities are included in IPC committee. Ensure lab officer are IPC trained.

	<ul style="list-style-type: none"> • Refresher training for biosafety is conducted annually but not to the entire staffs and tire • Infrastructure design and building requirement • TB laboratories utilities -water, electricity • PPE support- availability,practice • N95 Fit testing -Fit testing is conducted in a few accredited labs and no fit testing program in place. • Biosafety refresher training is annually conducted but not to all staffs • The laboratory design and plans are defined in the guidelines however at lower level facilities this is not adhered to. • BSC certification support- most of BSC in counties are not certified • BME support-9 certified
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3.1.5: Human Resources/ Workforce	<ul style="list-style-type: none"> Kenya Human Resources For Health Strategic Plan (KHRHSP) 2019 - 2023 Laboratory policy Guideline 2006 in operation pending review to capture current status The NTRL is staffed with 13 laboratory scientists, 11 of whom are supported by GF, with the other two supported by Gok. NTRL have 13 staff ,2 are GOK and 11 are donor supported whose contracts end in Dec 2023.Program needs 18 more additional staffs for optimal operations. KEMRI TB lab has 10 who are all donor supported In counties Health facilities Lab staffs are not classified as per diseases speciality Majority of Lab staffs in public health facilities are registered and regulated by KMLTTB however research labs have specific specialities who are not registered 	<ul style="list-style-type: none"> Higher levels of skill and training are needed to perform advanced testing for DST and surveillance at central and intermediate level laboratories. Limitations on the number of tests performed by technicians in order to reduce errors and ensure quality Practical training on TB testing part of the pre-service curriculum including TB biosafety, biosecurity and QMS Training program for laboratory management Presence of continuous education training programs Licensing of laboratory workers based on education, continuous education and competency National staffing plan for the TB diagnostic network based on workload forecasting Numbers of different categories of TB laboratory workers sufficient to cover the workload needs at all levels 	<ul style="list-style-type: none"> The National Strategic Plan doesn't elaborate on salaries, retention, and career development Curriculums are not updated to include modern classical TB diagnostic technologies Inadequate management training programs for laboratory managers/supervisors across the tiers of the diagnostic network 11/13 (85%) of lab personnel at NTRL and 100% at Kisian are donor-supported. Inadequate human resource countrywide. The 13 laboratory scientists at NTRL are not adequate to meet the current demands of the program 	<ul style="list-style-type: none"> Advocate for absorption of donor supported staff. Need to conduct a HR needs assessment for the TB diagnostic network The NTRL reports that an additional 18 laboratory scientists would be required to meet the current demands of the program Update the current curriculums to include modern classical TB diagnostic technologies MOH to recruit. Strengthen the training program in laboratory management in the network (e.g., leadership and governance, QMS, supervisory skills, planning and budgeting, and communication skills) Establish performance improvement plans and a training management system to ensure that all staff receive all necessary initial and refresher training
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	<ul style="list-style-type: none"> Licensing of Laboratory workforce by the regulator (KMLTTB) is not based on continuous education and competency-based assessment. The national staffing plan/policy is not based on workload forecasting. Some specialties do not have Regulation body. 	<ul style="list-style-type: none"> Develop remote training packages and use them to expand access to training, update existing materials National staffing plan/policy should be based on workload forecasting. The plan should be implemented at all levels of the network Employ sufficient workforce for all categories of TB laboratory workers The NSP should prioritize and address the gaps within the workforce and implement the HR plan NTLD & NTRL should develop and disseminate a career development policy Establish standardized competency-based job descriptions for all positions across the network Enforce and create more regulatory bodies .
<ul style="list-style-type: none"> National TB laboratory strategic plan or national TB strategic plan address key issues of the laboratory workforce including staffing, salaries, retention, career development, etc. and is it implemented Competency-based job descriptions available for all positions in the laboratory Competency assessments routinely conducted and documented 		

3.1.6: Diagnostic data management & connectivity	<ul style="list-style-type: none"> Use of standard request forms /registers, job aids. Request with all test details Standard tools for collecting and reporting data Results reporting tools / and interpretation are available. Data connectivity databases – Labware system -connects patients, culture tests and sample referral Microscopy is not connected to LIMS Labware at NPHL is the main database used for TB/HIV Data storage,retrieval and archiving guidelines exist Data archival -patient data are stored and time frame defined in Reference labs. 	<ul style="list-style-type: none"> Standardized test request forms for all testing and being used at all levels Quality control of data entry performed Data collected and analyzed Standardized forms used for collecting and reporting data on the performance of the diagnostic network Are reporting forms for all TB tests standardized and include information on interpretation of results An electronic system supporting the reporting of diagnostic data to clinicians for patient management Data connectivity solutions been implemented in the TB diagnostic network EMRs do not exist at all facilities and separate system exist for TB and HIV EMRs do not exist at all facilities and separate system exist for TB and HIV Data systems should be in place to integrate TB services 	<ul style="list-style-type: none"> Use of obsolete documents at facilities Lack of Training on data tools and usage Limited Access rights for data systems by HCW Lack of TB labs specific annual report NTRL/ KEMRI NTRL lacks a designated data personnel. Inadequate Network and bundles support Role of NTRL on DR TB surveillance data not clear Lack of electronic systems to report lab KPIs, equipment maintenance, supply chain, quality assurance etc. Lack of online reporting system for Microscopy pt TIBU LIMS system is frequently offline, sometimes for the whole day
	<ul style="list-style-type: none"> Investigate issues and reduce downtime of TIBU LIMS Ensure data backup capabilities and processes are available at all facilities (TIBU LIMS backed up to cloud) Integrate TB and HIV systems into a single EMR Integrate TIBU, KHS, Kenya EMR and other relevant information systems into a single platform. Ensure all facilities have access and training to the EMR Implement TIBU-lite in facilities without access to the full platform Integrate electronic test results directly into EMR from capable platforms to reduce effort/ errors associated with data transcription Ensure all WRD devices have a means to transmit results – data bundles for user phone as a backup Increase digital capability to collect and report KPIs, equipment maintenance, supply chain, QA, etc. 	<ul style="list-style-type: none"> Use of obsolete documents at facilities Lack of Training on data tools and usage Limited Access rights for data systems by HCW Lack of TB labs specific annual report NTRL/ KEMRI NTRL lacks a designated data personnel. Inadequate Network and bundles support Role of NTRL on DR TB surveillance data not clear Lack of electronic systems to report lab KPIs, equipment maintenance, supply chain, quality assurance etc. Lack of online reporting system for Microscopy pt TIBU LIMS system is frequently offline, sometimes for the whole day 	<ul style="list-style-type: none"> Investigate issues and reduce downtime of TIBU LIMS Ensure data backup capabilities and processes are available at all facilities (TIBU LIMS backed up to cloud) Integrate TB and HIV systems into a single EMR Integrate TIBU, KHS, Kenya EMR and other relevant information systems into a single platform. Ensure all facilities have access and training to the EMR Implement TIBU-lite in facilities without access to the full platform Integrate electronic test results directly into EMR from capable platforms to reduce effort/ errors associated with data transcription Ensure all WRD devices have a means to transmit results – data bundles for user phone as a backup Increase digital capability to collect and report KPIs, equipment maintenance, supply chain, QA, etc.

<ul style="list-style-type: none"> PT online reporting system exists for Gene Xpert however the Microscopy lacks the online reporting system. TIBULLIMS -link Patient, Genxpert, truenat and culture Lack of OR platform at NTRL Access levels to data are implemented in labs Back up and retrieval data 	<ul style="list-style-type: none"> A fully functional laboratory data unit with adequate numbers of trained personnel, hardware and software statistical data reported, analyzed, used for decision making purposes and shared within MoH and other government agencies Up to date and implemented national plan for surveillance of TB and DR-TB Policies and procedures governing the security of laboratory data and confidentiality of patient data SOPs and policies in place to support the back up and retrieval of data All documents should be standardised and controlled, old versions should be retired and removed from circulation. Datta reporting to county/ National is primarily focus on test statistics 	<ul style="list-style-type: none"> Little evidence of SOPs for data use, management, storage & security at lower levels Lack of electronic systems to report lab KPIs, equipment maintenance, supply chain, quality assurance etc. TIBU LIMS system is frequently offline, sometimes for the whole day Little evidence of SOPs for data use, management, storage & security at lower levels Most users using unique usernames and passwords High risk of EMR data loss due to lack of backup capabilities and processes at lower level facilities Level of digital tools training at lower level facilities could be improved – many lab staff and clinicians not aware of how to extract data and run reports from the EMR systems if dashboards do not exist Data reported from connected diagnostics is basic and could be improved for county/ national level M&E 	<ul style="list-style-type: none"> Increase granularity of data collection from connected diagnostics to improve county/ national level device monitoring & evaluation (module utilisation, calibration status etc) Equip all facilities with site based communications to ensure data and communications auditability Increase level of digital training and data management Consider development/implementation of digital test ordering capability for capable facilities (those with computer and internet access) to ensure completeness of data entry and reduce transcription errors Revise test requisition forms and TIBU LIMS to include current portfolio of testing tools Consider migration/integration of all test reporting into a single format including DST tests Update LIMS and EMR to include current range of diagnostic tests (TruNAT sites could only record GX tests for example in their EMR) and plan for the introduction of new test platforms Implement exception reporting and other DQI tools to identify and fix errors 	

<p>3.1.7: Quality management systems</p> <ul style="list-style-type: none"> No evidence of documented structured approach for QMS implementation (2023 DNA) NTRL is ISO 15189 and ISO 17043 accredited NTRL produces PT panels and periodically distributes participating laboratories. Monitors EQA performance Existence of QMS programmes such as SLIPTA 	<ul style="list-style-type: none"> There should be a documented structured approach for QMS Documents and procedures required to ensure the quality of the TB diagnostic network and testing exist and are they accessible at all testing sites National standard operating procedures (SOPs) exist for all TB diagnostic technologies Quality indicators and performance measures monitored and evaluated for all TB tests Laboratory internal quality controls in place for all TB tests National EQA programs in place for all TB diagnostic tests at the different tiers Quality indicators - Accredited lab performs routine quality indicators analysis and tracking. IQC conducted for most tests however 	<ul style="list-style-type: none"> Uncoordinated QMS implementation SOP adherence is a challenge and lacks IQC materials . Laboratories to track quality indicator periodically Labs to have IQC and EQA programs in place for all test . Support supervision should be scheduled and conducted for all labs 	<ul style="list-style-type: none"> Develop and provide QMS framework to enable a structured approach to implementation Insufficiency resource to sustain accreditation in the country NTRL to scale up PT in all labs All NTRL Test must be enrolled in an EQA and with acceptable performance Do reference laboratories participate in international EQA (internationally certified/ or accredited EQA-ISO 17043) programs
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<ul style="list-style-type: none"> • Accredited 17043 • Some labs are accredited however costs of accreditation is a challenge -KENAS fee is high and its partner driven. • Lab QA - Implantation of quality programs • International EQA and performance 	<ul style="list-style-type: none"> • Formal system of supportive supervision within the TB diagnostic network • Quality assurance officer available in each laboratory • Implementation of quality management activities in all laboratories providing TB testing • National certification standards for laboratories • Support supervision. - conducted annually for sites that are participating in PT and Blinded rechecking only, • NTRL has Capacity for PT production • PT-available for xpert LPA, Truenat and few AFB sites -however some test such as TB LAM, and TB LAMP are yet to be enrolled as PT material not vailable in country and commercial. 	

	<ul style="list-style-type: none"> • Rechecking -available and donor supported for all AFB sites however Need for enforcement . • SOP adherence is a challenge and lacks IQC materials . • EOAs available – • Availability of quality manual – • Exists in accredited laboratories and other labs that implement quality programs . • SOPs specific for TB diagnostics are available and developed by NTRL however not all facilities have SOPS copies.

3.1.8: TB/HIV	<ul style="list-style-type: none"> Request form track both HIV/TB status Algorithm is integrated Policy guideline integrated TB/HIV Lab services are free Screening for TB are compulsory for all HIV patients TPT is provided for all HIV positive patients Integration of sample referral systems Training content is currently based on the TB Leprosy Integrated guidelines. Not all health facilities are networked to the specimen referral system services. Above site (facility to national) specimen referral services are program specific Access to the LF-LAM for priority HIV+ patients 	<ul style="list-style-type: none"> Free TB testing for HIV+ persons with signs and symptoms of TB Free HIV testing for persons with signs and symptoms of TB and for TB patients Coordination between the TB diagnostic network and the HIV/AIDS diagnostic network TB diagnostic network collaborate with the HIV diagnostic network regarding laboratory and diagnostic services Specimen referral services for TB testing and HIV testing shared or coordinated National TB diagnostic algorithm include HIV testing 	<ul style="list-style-type: none"> Lack of review of the tools,incomplete completion Lack of distribution of algorithms Paid TB services in private health facilities Low uptake of TPT among eligible patients Poor road networks and poor coordination of ISRN Standardized sensitization content is partial/not available (83/214;38%) in all health facilities plus the private sector Not all personnel who provide TB/HIV services have received formal training (74/171; 43%). 	<ul style="list-style-type: none"> Scale up the dissemination of the integrated guidelines through a structured and standardized format Strengthen the collaboration between HIV and TB programs by operationalizing and scheduling regular COEs at all levels Adoption and Implementation of Multi-sectoral Accountability Framework(MAF) Allocate additional funding including county funds to strengthen specimen referral at all tiers Finalize and implement the national integrated sample referral guidelines Consider procurement and prioritized placement of mWRDs to health facilities in hard to reach areas Allocate additional funding including county funds to strengthen specimen referral at all tiers

	<ul style="list-style-type: none"> • Is diagnostic testing for HIV (either onsite testing or by referral) available as prescribed in the national TB • Access to LF-LAM for priority HIV+ patients • Standard TB test requisition form include fields for HIV status • Standard data collection forms adequately capture the relevant TB and HIV test statistics and performance indicators • 100 % uptake for TPT for all HIV patient • TB samples to be part of the ISRN 	<ul style="list-style-type: none"> • There is a central coordinating system at the National level and county/sub county levels. However, the meetings are not fully integrated (29/161) and partner driven. The private sector is not fully involved • Not all health facilities are networked to the specimen referral system services. Above site (facility to national) specimen referral services are program specific • Access to the LF-LAM for priority HIV+ patients LF LAM availability is limited (piloted in 256 health facilities and recently scaled up to 1300 HFs) • LF LAM recently delivered to some facilities and trainings are yet to be conducted. Thus while available, some are yet to start being utilized • TB LF LAM implementation guideline is currently being developed.
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3.1.9: Operation Research	<ul style="list-style-type: none"> A sentinel surveillance conducted, the findings yet to be shared - NTP annual 2021 report Nbi prev survey done - CGHR-NTRL - ongoing Planned DR Survey There is no evidence of a NTRL led OR in the recent past 	<ul style="list-style-type: none"> Conduct epidemiological and operational research - NTRL Mandate by NPHLS 	<ul style="list-style-type: none"> Programmatically relevant operational research and research on new TB diagnostics or algorithms is not conducted in the country No clear guide on the OR in the national policy 	<ul style="list-style-type: none"> Mentorship/training done to NTRL so that they can take lead in mentoring the countries Conduct high-quality programmatically relevant research in the country 	<ul style="list-style-type: none"> Policy guidance and resources allocation. strength a well-coordinated referral system that offers timely clinical decision making. 	<ul style="list-style-type: none"> Knowledge gap among NTRL staff on OR No finance allocation for OR activities 	<ul style="list-style-type: none"> Data from OR research should be used to inform national policy on the diagnostic network OR should lead to adopting new diagnostics tools or algorithms, policy revision and implementation

<ul style="list-style-type: none"> • 2023-NTRL CAPA T.A mission reports show a few health facility labs that meet infrastructure requirements • Additional guidelines exist separately: Biosafety-Biosecurity guidelines with elements of infrastructure management, 	<p>3.1.11: Equipment maintenance, calibration and validation of TB laboratory equipment</p> <ul style="list-style-type: none"> • There is no reports for post market surveillance for TB laboratory/ diagnostic kits • Assessment of facilities for equipment is done by the national team. 	<ul style="list-style-type: none"> • Availability of postmarket surveillance reports • Use of standardized quality-assured reagents at all levels of the TB diagnostic network • Regulatory procedures for the control of in vitro diagnostics (IVD) • Verification of the equipment and training done at installation time led in conjunction KMLTTB. • Follow-up and routine maintenance/Calibration done as per the equipment functions. 	<ul style="list-style-type: none"> • Availability of poor quality diagnostic kits • Lack of equipment maintenance program. • Biomedical engineers require refresher training to keep abreast with the ever-changing technology. • Delay of SLA renewal of other services and equipments • Standardized list of laboratory equipment • Procedure for validation of equipment • Availability of SLA between the provider/stakeholder and the MOH

<ul style="list-style-type: none"> • High costs of service contracts with no unified maintenance and management program (DLS-SP 2022-2026) • Existence of a National Equipment calibration centre (DLS-SP 2022-2026) • Lack of coordination mechanism for multi-disease testing 	<ul style="list-style-type: none"> • A maintenance plan (covers spare parts, storage and disposal) for all laboratory equipment at all levels • Review of SLA on annual basis done after review of the maintenance report and data by MoH through DNTLD-P/NTRL and other stakeholders to ensure value for money during the SLA • Use of diagnostic platforms for TB and other diseases (e.g., Xpert testing for TB and for HIV), including planning, procurement, use and maintenance 	<ul style="list-style-type: none"> • Use of diagnostic platforms for TB and other diseases (e.g., Xpert testing for TB and for HIV), including planning, procurement, use and maintenance • Procurement and distribution system allowing for the continuous supply of testing reagents in the country for public-sector laboratories and private or academic laboratories • A system to monitor and forecast supply consumption in the country 	
<p>3.1.12: Management of laboratory commodities and supplies within the laboratory network</p>	<ul style="list-style-type: none"> • Procurement of NTRL commodities is by donor support mainly through GF grant • NTRL conducts annual forecasting and quantification to determine the labs annual commodity requirements • procurement and warehousing is done centrally at the national level through KEMSA 	<ul style="list-style-type: none"> • No well established funding programme from the MoH-Kenya • Inconsistent supply of key NTRL commodities due to challenges in procurement lead times at kemsas. 	<ul style="list-style-type: none"> • Sensitization of all TB stakeholders on DHIS 2 platform • Proper forecasting and quantification, followed by timely budgeting procurement and distribution of lab supplies

	<ul style="list-style-type: none"> • Ensure well coordinated reporting and requisition of lab commodities • A adequate supply of all commodities 	Slow uptake on use of DHIS2 as the sole commodity consumption reporting tool.
A functional TB commodity security committee is in place at the national level that monitors NTRL commodity status	<ul style="list-style-type: none"> • commodity management at NTRL done using stock cards • DHIS2 and TB allocation tool in place for consumption reporting and requisition of TB commodities. Gene xpert commodities are currently requested through Online GXlims and KHIS. • stock out of essential laboratory commodities, such as gene-xpert cartridges, microscopy reagents, triple packaging materials, culture and DST commodities. • DST commodities for decentralized labs are supplied through NTRL • The country has a national guideline on supply chain management of all laboratory commodities • NTRL has an SOP on purchasing and inventory of lab commodities 	<p>Lack of common established electronic lab commodity management tool that can monitor minimum/maximum levels stock status</p> <p>Inaccurate forecasted quantities during forecasting and quantification</p> <p>Delayed tender evaluation and award</p> <p>Delayed custom clearance of key culture and DST commodities</p>

<p>3.1.13: Financing of TB diagnostic Services</p> <ul style="list-style-type: none"> Funding for tb in the country is done by both domestic and international support in a proportions of 49% and 51% respectively. Operations at the NTRL laboratory is highly financed by the partners, - NSP ETR Report 2022 	<ul style="list-style-type: none"> Global funding report 2022 Domestic funding does not trickle down to NTRL to take care of procurement of culture and DST commodities as well as preventive maintenance of diagnostic equipment. Absorption of donor supported staff to the ministry. 85% of human resource support at NTRL is through Partner support. (11 out of total 13 technical staff) 	
<p>3.1.14: Stakeholder analysis</p> <ul style="list-style-type: none"> Existence of IP; Centre for disease control and prevention,AMREF,CHS, NASCOP/NLTP,CHAI, Availability of specialized equipment service providers :Cepheid, BD, MOLBIO. Government Agencies;Kemsa and Meds, Regulatory bodies Documentation on referral labs for TB work exist 	<ul style="list-style-type: none"> Most activities are supported by implementing partners through donor support Some projects support by stakeholders take long to be approved using current laid down protocols Inadequate grants application 	<ul style="list-style-type: none"> Sustainability plan by main core government funding Increase grants application for funding

Annex 2: SWOT Analysis

Thematic Area	Strengths	Weaknesses
Diagnostic Network Coordination & Governance	<ul style="list-style-type: none"> o Policies, legal and regulatory framework for health practices and laboratory practices exist o National strategic plans are available and up to date o Well define structure of the laboratory network in tiers o Presences of the laboratory directorate/department at the MOH and NPHL to coordinate laboratory services o Established operational collaboration between NPHL and NTP for delivery of TB laboratory services o mWRD have been adopted the initial test for diagnosis for TB o Standard training materials for TB diagnostics are available for all TB tests o Training/refresher training are periodically conducted. o LIMS infrastructure exist at National level o Data connectivity solution are installed in some mWRDs facilities o Trained and competent laboratory professionals are available to conduct TB diagnostics across the network o Capacity at the NTRL to produce and manage PT materials for most TB diagnostics with regular support supervision and CAPA conducted for participating laboratories o Linkage of the NTRL with SRL-Uganda to technical assistance o Accreditation of NTRL by KENAS o Existence of an integrated sample referral system for multiple programs o Existence of the national calibration center of excellence 	<ul style="list-style-type: none"> o NTRL is not fully involved in planning for network activities: policy formulation, training, support supervisions, verification, and dissemination of new technologies in the network o Data from OR research should be used to inform national policy on the diagnostic network o OR should lead to adopting new diagnostics tools or algorithms, policy revision and implementation o Suboptimal coordination between NTP and NPHL, for ongoing engagement to optimize the functionality of the national TB diagnostic network. o Inadequate funding allocation for some key TB laboratory network activities e.g QMS, commodity security, HRH, biosafety biosecurity, infrastructure, diagnostic coverage and Operational Research o Shortages of workforce to support the TB network needs o Limited utilization of laboratory data for decision making o Lack of the TB lab diagnostic dashboard o Poor linkage of presumptive TB patients to TB testing or referral facilities. o Inadequate coverage of mWRDS in the country o Inadequate coordination of partner support at national and counties leading to duplications of activities o Low coverage of remote logging of TB culture samples o Limited capacity to conduct operational research o Delay on approvals both on partner and government o Suboptimal utilization of laboratory services e.g very low GeneXpert utilization (40%-TIBU) o Frequent stock outs of essential commodities for TB diagnosis

	<ul style="list-style-type: none"> o SLA available for all mWRD and major equipment o TB commodities are centrally managed through KEMSA o There exist a National commodity security committee o Existence of BSII labs to support DST o Existence of multiplexing and multi-disease capability e.g. using GeneXpert o Existence of robust collaboration with international and local partners support for TB diagnostic laboratory services o Availability of National Public Private Partnership/engagement frameworks o Social corporate responsibility for companies. o Availability of a commodity reporting and request platform through the DHIS2/KHIS 	<ul style="list-style-type: none"> o Limited dissemination of TB laboratory guidelines, clinician handbooks o Lack of standardized SOPs and job aids to peripheral facilities o Inadequate coverage of integrated sample referral system and gaps in sample tracking and monitoring of KPIs o Lack of a TB specific Biosafety biosecurity manual o Inadequate trainings and sensitization on; diagnostic platforms, biosafety and biosecurity practices o Sub-optimal engagement and coverage of the private and research laboratories in diagnostic network activities such as sample referral system, capacity building, technical support, monitoring and evaluation and EQA program o Suboptimal LIMS infrastructure at the county level o Lack of interfacing and interoperability of the TB laboratory HMIS infrastructure. Uncoordinated link of TB laboratory services between National and counties especially on matters of HRH o Low uptake of TB screening and TPT for healthcare workers. o Low PT coverage within the TB diagnostic network. o Inadequate resources for service contract plans to manage TB diagnostic equipment. o Staff shortage at NTRL and most counties which is exacerbated by a high staff turnover and lack of a mechanism to assess HRH needs o Lack of standardized equipment specifications guide o Low coverage of latent TB testing o Low uptake of non-sputum test for TB e.g stool, Gastric Aspirate o Low uptake on DHIS2 and TB allocation tool o Lack of an integrated commodity management and reporting tool for TB o High cost of accreditation services
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Opportunities	Threats
<ul style="list-style-type: none"> ○ Integration of testing services using the same platform e.g. using multiplexing. ○ Collaboration with international and local partners. ○ Public private partnership. ○ Social Corporate Responsibility Programs by companies. ○ Presence of a genomic Centre at NPHL that can support genomic Sequencing ○ Utilization of the new diagnostic technologies e.g IGRA ○ Utilization of the National Calibration Centre 	<ul style="list-style-type: none"> ○ Over Reliance on donor support. ○ Human resource transition plan ○ Pandemics and natural calamities. ○ Global commodity security. ○ Sustainability of implementation plans following governance transition ○ Cross-border political and social instability. ○ High staff turnover. ○ Access to potentially infectious materials ○ microorganisms for bioterrorism. ○ Terrain, hard to reach areas.

Annex 3: Intervention Activity Matrix

Strategic Objective 1		Increase access to rapid TB diagnostics (mWRD) from 47 % in 2023 to 80% by 2028	
Strategic Interventions	Major Actions	Sub-activities	Outcome targets
1. Expand coverage for TB diagnostic services	<p>1.1. Assessment of the country's current diagnostic status</p>	1.1.1 Develop assessment tools 1.1.2. Conduct field visits to specific counties 1.1.3. Report writing and dissemination of findings 1.1.4. Develop implementation plans for diagnostic platforms. 1.1.5 Dissemination of the DNA assessment findings to key stakeholders and implementing partners	1.1.1 Develop assessment tools 1.1.2. Conduct field visits to specific counties 1.1.3. Report writing and dissemination of findings 1.1.4. Develop implementation plans for diagnostic platforms. 1.1.5 Dissemination of the DNA assessment findings to key stakeholders and implementing partners

		1.4.1. Develop/review National Multiplexing guidelines (M&E,Fractional cost sharing)
		1.4.2. Dissemination of the Multiplexing guidelines for implementation.
	1.4. Multiplexing	1.4.4. Review the mWRD implementation strategy appropriately
		1.5. Procure and increase the number of mWRDs including the 10 color Xpert machines to be placed in the lower facilities to expand molecular TB testing (1st and 2nd line DST)
		1.5.1. Health facility capacity assessment, Trainings, Distribution and installation
		1.5.2 Procurement of mWRDS
		1.5.3 Procurement of 10 color Xpert machines
		1.5.4 National Technical assistance mission to mWRDS sites
		1.5.5. Procurement of commodities (2 modular mWRDs)
		1.5.6. Procurement of commodities 4 modular mWRDS
		1.5.7. Procure SLA for all mWRDs technologies to ensure the efficiency of implementation
		1.5.7. Support new mWRDs with power surges, inverters/batteries backup systems
		1.6. Strengthen and expand the sample referral network in the country
		1.6.1. National to guide on the establishment of county TB TWG TORs and re-mapping the SRS sites to TB molecular diagnostic sites due to the new tools
		1.6.2. Sensitization of courier service providers and front-line (TB Nurse, clinician, lab) healthcare workers on changes in the scope of sample networking
		1.6.3. National and counties to procure courier services for specimen referrals and results transmissions

	1.6.4. Training of courier providers
	1.6... National and Counties to procure triple packaging materials
	1.6.5. Digitize the integrated SRS tracking system across the country
	1.6.6. Set up a multistakeholder team to streamline integrated SRS
	1.6.7. Workshops to develop/revise integrated SRS guideline
	1.6.8. Dissemination of the SRS guideline to counties and support development of county-specific operational plans
	1.6.9. Establish county-specific SRS rollout plan (train, situational analysis, ToRs, SRS focal person)
	1.6.10 Technical Assistance to counties on SRS
1.7.	Expand testing for TB among high-risk populations using non-sputum samples
	1.7.1. Revise the guidelines to include the new WHO approved molecular tests and review the TORs to accommodate the non-sputum sample testing for TB
	1.7.2. Training of TOT for the National/County on non-sputum sample testing for TB
	1.7.3. Sensitization/ training of HCW on the non-sputum samples POC testing (sample collection, transportation, results interpretation)
	1.7.4. Support mentorship and technical assistance to counties to monitor implementation
	1.7.5. Procurement of LF LAM kits and consumables
	1.7.6. Procurement of TST/IGRA reagents and consumables
	1.7.7. Procurement of newer TB infection tests

		2.1. Increase access to Culture, 1 st and 2 nd line DST for all previously treated including relapses and for RR patients (For First line, second-line and potential XDR diagnosis).	2.1.1. Establish a sub-committee within the TB Diagnostic committee of experts to oversee Culture/DST expansion and implementation (10 color XDR machines)
2.	Strengthen culture and drug susceptibility testing for both phenotypic and genotypic molecular, (For First line, second-line and potential XDR diagnosis).	2.2. Scale up the use of low and moderate complexity mWRDs for diagnosis and detection of resistance to RIF, INH and FQ	<p>2.2.1. Develop an implementation plan for TB Culture/DST (plan, tools, MOU, Mentorship schedule)</p> <p>2.2.2. Carryout quarterly mentorship program to decentralised laboratories and facilitate intra laboratory exchange programs</p> <p>2.2.3. To increase laboratories with capacity for both Phenotypic and Genotypic Culture and DST by targeting laboratories with infrastructure</p> <p>2.2.4. Annual Exchange program for decentralised sites to NTRL</p>
		2.3. Enhance timely provision of all culture and DST supplies, commodities	<p>2.3.1. Carrying out of F & Q, resulting into prompt and adequate requisition reports to relevant authorities both at the national and local levels.</p> <p>2.3.2. Develop LPA decentralization plan/framework, training, monitoring implementation</p> <p>2.3.3. Quarterly LPA mentorship to decentralised Laboratories</p> <p>2.3.3. Quarterly LPA mentorship to decentralised Laboratories</p> <p>2.3.4. Online sensitization of CTLC/CMLC/SCTLC/SCMLC on MDR TB management, culture and DST testing services, surveillance to enhance referrals</p>

	<p>2.3.5. Sub County HCW sensitization on the importance of culture and DST services testing, surveillance and management for MDR TB to enhance referrals</p>
	<p>2.3.6. To decentralize culture services to Malindi, Kitale and Machakos in order of priority, equity and coverage of the country's network (based on a set criteria).</p>
	<p>2.3.7. To operationalize and support routine and ongoing, or a planned TB related sentinel surveillance activities</p>
2.4. To support remote logging in the facilities with TB diagnostic capacity of either Culture or molecular testing across the country	<p>2.4.1. To support remote logging activities</p> <p>2.4.2. Procurement of computers and installation for remote logging software</p> <p>2.4.3.. Building the counties technical capacity on remote logging activities</p> <p>2.4.4. Implementation of a phased roll out of new molecular technologies based on disease burden, workload etc.,</p> <p>2.4.5. To adopt other molecular platforms with capacity to test for TB/resistance to RIF, INH&FQ (Procurement, distribution, installation, and commissioning)</p> <p>2.4.5 Procurement ROCHE reagents</p> <p>2.4.6. To introduce C-Reactive protein as a TB screening test among PLHIV</p> <p>2.4.7. To introduce stool testing (Simple One Step stool processing method) to improve TB bacteriological confirmation and DR-TB detection among children</p>

	2.5. To improve surveillance and diagnostic capacity for drug resistance by establishing the country's capacity to carry out whole genome sequencing for M.tuberculosis complex and requisite technical capacity	2.5.1. Purchase of WGS instruments with all its accessories and its installation 2.5.2. Procurement of WGS reagents and consumables 2.5.3. Procurement of WGS instruments SLA 2.5.4. To carryout training on implementation and roll out of WGS across the country 2.5.5. Printing of genome sequencing plan, tools and SOP: 4000 A4 copies 2.5.6. Sensitization of National team on Genome sequencing testing and implementation in Kenya 2.5.7. Forecasting, quantifying and procurement of genome sequencing platforms and reagents 2.5.8. Develop a framework to monitor and evaluate the system (mapping of country resistance pattern, treatment success etc) DST quarterly	2.5.10. Conduct Refresher and upgrades on WGS as needed 2.5.11. Bi annual mmetings for data monitoring.	2.6. BSL III Quaterly service and Annual certification of the cooling system and the HVAC	3.1. Maintain the existing quality standards at the National level	3.1.1 Operational cost for NTRL accreditation status: (Management review meeting, internal audits,light lifting budget)
3 Strengthen the Quality of Laboratory services						

	3.1.2 Annual certification to maintain the NTRL accreditation status of ISO 15189:2022 and ISO 17043:2010
	3.1.3 Capacity build the staff on the standards (ISO: 15189:2022:17043; Internal audit: Biosafety/Biosecurity)
	3.1.4 Expansion of the Accreditation scope: ISO 15189 and 17043
3.2. Implementation of National quality management framework for TB laboratories	<p>3.2.1 printing of the manual</p> <p>3.2.2. Dissemination of the guidelines.</p>
3.3. Increase the Proficiency testing (PT) coverage for AFB Microscopy, mWRDs and new technologies in health facilities	3.2.3. CQI initiatives, mentorship through technical assistance into National PT
3.4. Increase implementation of Laboratory continuous quality improvement initiatives (LCQI) TB testing facilities	<p>3.3.1 Mapping, identification and enrolling additional facilities</p> <p>3.4.1. Develop a checklist for National quality management framework</p> <p>3.4.2. Capacity build all county and subcounty 1st and 2nd controllers on EQA Microscopy procedures to maintain their proficiency</p> <p>Sensitize and train facilities staffs on PT and importance</p> <p>Conduct Annual integrated PT performance review with stakeholders</p> <p>Develop and distributes PT data tools and SOPs</p> <p>3.4.3. Conduct TOT training to National program officers to carry out third level quality checks to EQA microscopy controllers</p>

	3.4.4. Capacity build the CMLC and SCMLC on the EQA systems monitoring	
	3.4.5. Capacity building of SCMLCs on EQA electronic reporting	
	3.4.6. Ensure and monitor both public and private facilities in are enrolled Quality Assurance programs (local, regional, external), and national Proficiency Testing (PT) program.	
	3.4.7. Strengthen the Public Private collaboration through provision of equipment, equipment servicing, reagents, EQA, training, and Technical assistance	
	3.4.8. Support the NTRL through PT production, IQCs production, distribution, results evaluations and including sites results feedback Mechanism	
	3.4.9. Conduct PT trainings, establish results feedback mechanisms and problems resolutions	
	3.4.10. Capacity build facilities participating in PT on CQI plan/ root cause analysis (RCA) to address non-conformities towards quality testing	
3.5. Capacity building Laboratory staff with Technical skills and adequate knowledge	3.5.1. Capacity build/ refresher training to the national lab team (NTRL/NTP) as TOT in all existing and new tools of TB diagnostic platform	
	3.5.2. Conduct targeted Laboratory officers training on existing and new tools (mWRDs) and other technologies.	
	3.5.3. Site technical supervisory visits to enhance staff outputsTech	
3.6. National Laboratory review meetings	3.6.1. National level; performance review meeting to enhance service towards TB diagnosis, covering data reviews, targets achievements, Feedback mechanisms, PT schemes performances, and QMS)	
3.7. National CAPA technical site Visit	3.7.1 Perform quarterly CAPA site visit to pt enrolled sites for TA on Pt performance	

		3.6.2. National consultative meetings for counties performances; CDH's, CMLCs, CTLC's to enhance TB diagnostic services towards TB diagnosis, covering data reviews, SRS, targets achievements, Feedback mechanisms, PT schemes performances, and QMS)
4. Enhance management of laboratory supplies and equipment	4.1. Sustain and procure appropriate SLA for TB diagnostic equipment	4.1.1. To consider reagent surcharge to factor in cost for equipment maintenance
	4.2. Procurement of all commodities through KEMSA	4.1.2. Develop a list and identify items to be procured with specifications and costing.
	4.3. Develop equipment procurement plan	4.1.3. Identify specific equipment
	4.2. Ensure adequate equipment functionality	4.2.1. Procure Annual service contract for assorted equipment at the national TB reference laboratory
		4.2.1.1. Quarterly reviews with county on equipment operations and performance
		4.2.3. Quarterly site mentorship on routine equipment monitoring
		4.2.4. Sustain availability of connectivity for remote monitoring
		4.2.5. Provide adequate training to Biomedical including refresher on laboratory equipment
		4.2.6 Purchase Laboratory equipment spare parts as requested by engineers for replacements of worn out parts
		4.2.7. Procure essential lab equipment for essential services (media dispensing machine, water distiller, slide warmers, NTRL Lap Tops

		4.2.8. Procurement of Laboratory accessories and computers for Microscopy sites
		4.2.9. Equipment service and maintenance for all TB related equipment at the reference level laboratories
4.7. Strengthen laboratory logistics and supply management.	4.7.1. Procure SLA for all mWRDS supplied through the National TB program	4.7.2. Conduct bi-annual equipment management review meetings, with both national and county TB program teams.
		4.7.2. Conduct regular meetings with various equipment vendors, to review performance, challenges, and best ways of enhancing efficiencies.
		4.7.3. Procure spares for NTRL equipment, Peripheral microscopes, and mWRDS UPS for unsupported Counties.
		4.7.4. Rollout the National TB laboratory allocation tool through capacity building of 43 counties
		4.7.5. TA for National TB laboratory allocation tool implementation
		4.7.6. Procure laboratory commodities and reagents, genome sequencing, mWRDs and Microscopy
		4.7.7. Perform monthly, quarterly, and annual Laboratory commodities management reviews(CMR)
		4.7.8. Conduct appropriate laboratory forecasting and quantification in conjunction for both national and county needs.
4.8. TB Mobile Labs- Cross boarder services	4.8.1. Servicing for TB Mobile labs	

		5.1. Procure adequate PPEs for NTRL and decentralized LPA labs
5. Strengthen biosafety and infection Prevention in TB laboratories	5.1. Provision of PPEs at the laboratory, i.e. for National level to support for reference laboratories, as counties get support from their respective local government.	5.2.1. Develop a module on TB Laboratory biosafety and biosecurity which will be incorporated into the national biosafety and biosecurity training curriculum.
	5.2. Support for Proper waste segregation and incineration in all sites.	5.2.2. Conduct biosafety and biosecurity risk assessment for the TB lab network.
		5.2.3. Training of officers on biosafety/ biosecurity, sample packaging and transportation for ease of obtaining the samples from the household.
6. Capacity building	6.1. The national and county governments to secure domestic funding to support recruitment of staff at NTRL and TB Testing laboratories, thus Increasing staffing at all health facility level laboratories	6.1.1. Conduct HR needs assessment for TB diagnostic services delivery, i.e., Laboratory officers
	6.2.Knowledge exchange program	6.2.1.participate of NTRL in knowledge sharing program at both National and international conferences
	6.2. Build the capacity of laboratory staff in TB testing. Refresher training on existing tests and training on new TB diagnostic technologies	6.1.2. Work with National, County and TB stakeholders (IPS) to consider staff hires as appropriate while ensuring adequate staff distribution.
		6.2.1. Conduct targeted Laboratory officers training on existing and new tools and technologies.
		6.2.2. Conduct continuous staff mentorship, refresher training to maintain proficiency
		6.2.3 Conduct Mentorship to LPA Decentralized sites

		9.2.3 Site supervisory visits to enhance staff outputs
7.0 Integrate laboratory management system and patient management systems to improve testing and resulting of TB investigations and treatment outcomes	8.1. Strengthen the disease specific system needs linkage to the PMS.	6.1.1. Develop an M & E that should spearhead all existing HIS (DHIS) into one interoperability backbone architecture.
		6.1.2. Strengthen linkage to care for people diagnosed with TB using mHealth technologies e.g. Use of LIMs at facilities.
		6.1.3. Integrate the lab LIMS of decentralized laboratories with NTRL labware
		6.1.4. Integrate NTRL labware with TIBU LIMS
		6.1.5. Integrate NTP-TIBU with the NTRL labware
		6.1.6. Development of microscopy USSD reporting system and linking it to TIBU.
		6.1.7. Linkage of TIBU-LABWARE and KHS
		6.1.8. Regular follow-up by the IT and lab teams to resolve difficulties
		6.2. Timely monitoring of treatment response at defined time points for DS-TB and DR-TB. (Availability of microscopy and culture)
		6.2.1. Ensure a phased rollout of remote logging to all TB diagnostic facilities
		6.3. Adopt use of next generation sequencing for all TB bacteriologically confirmed patients
		6.3.1. Integrate sequencing data with NTRL and TIBU

		6.3.2 Support trainings for 2 NTRL staff every year on genome sequencing
		8.0 .Enhancement of NTRL personnel on data management and utilization process to inform policy and intervention.
8. Support the National TB Reference Laboratory to attain a WHO approval as a Centre of Excellence for TB diagnostics and Surveillance	7.1. Restructure the laboratory network to a patient-centered, coordinated diagnostic network with participation and representation from networks of people affected by TB	7.1.1. Review TOR for diagnostic COE and constitution of its membership, roles, frequency of meetings etc.,
	7.2. Build capacity and mechanisms for responsive technical assistance.	7.2.1. Hold quarterly meetings for all stakeholders;
		7.2.2. Conduct sensitization workshops/ meetings on TA outcomes/feedback mechanisms.
		7.2.3. Conduct Laboratory exchange programs activities, locally and external (international) to enhance TA support.
		7.2.4 Workshops to develop and review training material
		7.3. Application to WHO for centre of excellence
		7.3.5 Recruit a key laboratory personnel to support TB laboratory commodities to support commodity management systems at DNTLD-P
		7.3.6 Establish a national laboratory procurement/logistics sub-committee to oversee Laboratory needs.
		7.4.2 Develop training curriculum for Laboratory TB commodities
		7.4.3 Capacity build NTRL, decentralized labs, County staff on laboratory supply chain and commodity management

Annex 4: Budget

Item	Currency	Cost (KSHS)	Assumption Notes
Printing			
Design and Printing Certificates	KES	150	per certificate
Per booklet less than 30 pages	KES	200	per booklet
Per booklet between 30 and 50 pages	KES	240	per booklet
Per Book over 50 pages	KES	320	per book
Per Book over 100 pages	KES	500	per book
Per Book over 200 pages	KES	700	per book
Design of booklets	KES	80,000.00	TA for design
printing of Registers	KES	2,000.00	Per register
Clinical Follow up card	KES	200	Per card
Clinical Encounter form	KES	100	Per form
Reporting forms	KES	200	Per form
Appointment Card	KES	100	Per card
Printing of Guidelines	KES	500	Per Guideline
Patient cards	KES	50	card
Facility Supervision booklet	KES	2,000.00	Per booklet
Activity Cost			
Tent hire	KES	10,000.00	Above 100 seater
Tent Hire	KES	5,000.00	100 seater
Hire of Chairs- Office Chairs	KES	100	per chair
Hire of Chairs -Plastic Chairs	KES	15	per chair
Lantern Lamps	KES	3,000.00	
Room Hire Outreach Activity-Towns	KES	1,000.00	
Room Hire Outreach Activity-Sub county	KES	500	
Lunch and refreshments (Field activity)	KES	2,000.00	Field activities outside catering
Performing groups facilitation	KES	20,000.00	Entertainment
Roadshow hire	KES	200,000.00	For social mobilization at venue per day
Event organizing agent	KES	200,000.00	For advocacy events
Event venue cost	KES	100,000.00	Per day
Activity Allowance			
Mobilization Allowance	KES	2,000.00	Per Activity
Lunch Allowance	KES	1,000.00	Per Activity
Lunch Allowance for peer facilitators	KES	1,000.00	Per Activity

SCASCO Mentorship Allowance	KES	2,000.00	Per Activity
Lunch Allowance-Driver	KES	750	Per Activity
Lunch Allowance CHVs-Communication Cities	KES	500	Per Activity
Lunch Allowance-Driver	KES	1,400.00	Per Activity
Lunch reimbursement within Sub County	KES	2,000.00	Per Activity
Dinner Allowance for peer Mobilizers	KES	1,000.00	Per Activity
CHV Lunch Allowance per activity	KES	500	Per Activity
Production of IEC			
T shirts Round neck	KES	350	per T-shirt
T-Shirt Polo	KES	1,000.00	per T-shirt
Caps	KES	300	per cap
Poster A2	KES	200	per poster
Poster A3	KES	100	per poster
Bronchures A4	KES	15	Per Bronchure
Leaflets	KES	15	Per Leaflet
Banners- Large	KES	35,000.00	per banner- Large
Printing of banners- Small	KES	10,000.00	Per banner- small
IEC materials design & developement	KES	200,000.00	Per package
Flip Chart	KES	1,000.00	Per Flip Chart
A3 posters	KES	100	Per poster
Courier services/1kg	KES	1,000.00	Per Kg
Consultancy for media plan	KES	300,000.00	Per Consultacy
Procurement of AD agency	KES	200,000.00	Per Advertising Agency
Media Planning agency	KES	300,000.00	Per Media Plan
Computers and other stationery			
Procurement of Laptops	KES	60,000.00	HP laptop
Procurement of Printers	KES	75,000.00	HP Desk Jet
Procurement of Anti-viruses	KES	2,500.00	Kaspersky
Procurement of tablets (for supervisor/field-work etc)	KES	20,000.00	Per tablet
Procurement LCDs (cheaper than always hiring)	KES	59,000.00	Epson/Sony
Desktop Computer	KES	60,000.00	HP
Power back up	KES	15,000.00	APC
Laptop computer	KES	80,000.00	HP/Dell/Lenovo
External Hard Disk (1 TB)	KES	7,500.00	Per Pc

Communication			
Staff monthly communication airtime	KES	5,000.00	per person
Internet for office	KES	3,000.00	per month
Airtime Per Activity	KES	2,000.00	Per Activity
Airtime Allowance -Staff	KES	1,000.00	Per month
Airtime facilitation for CHEWs	KES	1,000.00	Per month
Airtime-Planning and coordination	KES	2,000.00	Per Activity
Communication (fieldwork)	KES	1,000.00	Per person per day (max 5 days)
Communication for coordination - Airtime, Internet data	KES	1,000.00	For everything for planning and coordination per meeting
Consultant			
Consultant to conduct county investment.	KES	35,482.00	Per Day
Engage a consultant -(Local)	KES	40,000.00	Per Day
Engage a consultant -(Regional)	KES	55,000.00	Per Day
Engage a consultant -(International)	KES	70,000.00	Per Day
Short-courses (Local)	KES	120,000.00	Per Person
Short-courses (International)	KES	1,314,000.00	Per Person
Short-courses (Local) PR	KES	120,000.00	Per Person
Short-courses (International) PR	KES	1,314,000.00	Per Person
Remuneration for CHVs	KES	3,000.00	Per Month
Meeting Assumptions			
Transport			
Fuel	KES	40	Per Kms Ref AA rates inclusive of minor repairs
Transport reimbursement			
Within counties	KES	2,000.00	round trip
Within Sub counties	KES	2,000.00	round trip
Across Counties	KES	2,000.00	round trip
CHVs transport	KES	1,000.00	round trip
Transport Reimbursement-CHVs	KES	500	Per Activity
Transport reimburse- To Cities	KES	2,500.00	One way reimbursement

Other Transport			
Bus Hire per day	KES	30,000.00	Per day
Special counties (hard to reach areas)			
Within counties	KES	3,000.00	round trip
Across Counties	KES	10,000.00	round trip
Flights - Domestic	KES	30,000.00	return
Flights - International	KES	200,000.00	return
Air port transfer	KES	7,000.00	return
Full board			
Cities	KES	15,000.00	per person per day (KCB rate)
Towns	KES	10,000.00	per person per day (NCE Machakos)
Others	KES	8,000.00	per person per day
Sub counties	KES	5,000.00	per person per day
Conference Package			
Cities	KES	3,500.00	per person per day
Towns	KES	2,500.00	per person per day
Others	KES	2,500.00	per person per day
Stationary	KES	250	per head
Stationary (Inclusive of certificates)	KES	500	per person
Refreshments office meetings	KES	500	per person
Lunch Office meetings	KES	1,500.00	per person
Hall Hires, PAS and LCD			
Hall hire Cities	KES	10,000.00	per day
Hall hire Towns	KES	5,000.00	per day
Hall hire others	KES	3,000.00	per day
LCD Hire	KES	5,000.00	per day
PAS	KES	5,000.00	per day
Perdiem for meetings			
Cities	KES	10,500.00	Job group "P"
Towns	KES	8,400.00	Job Group "P"
Others	KES	7,000.00	Job Group "P"

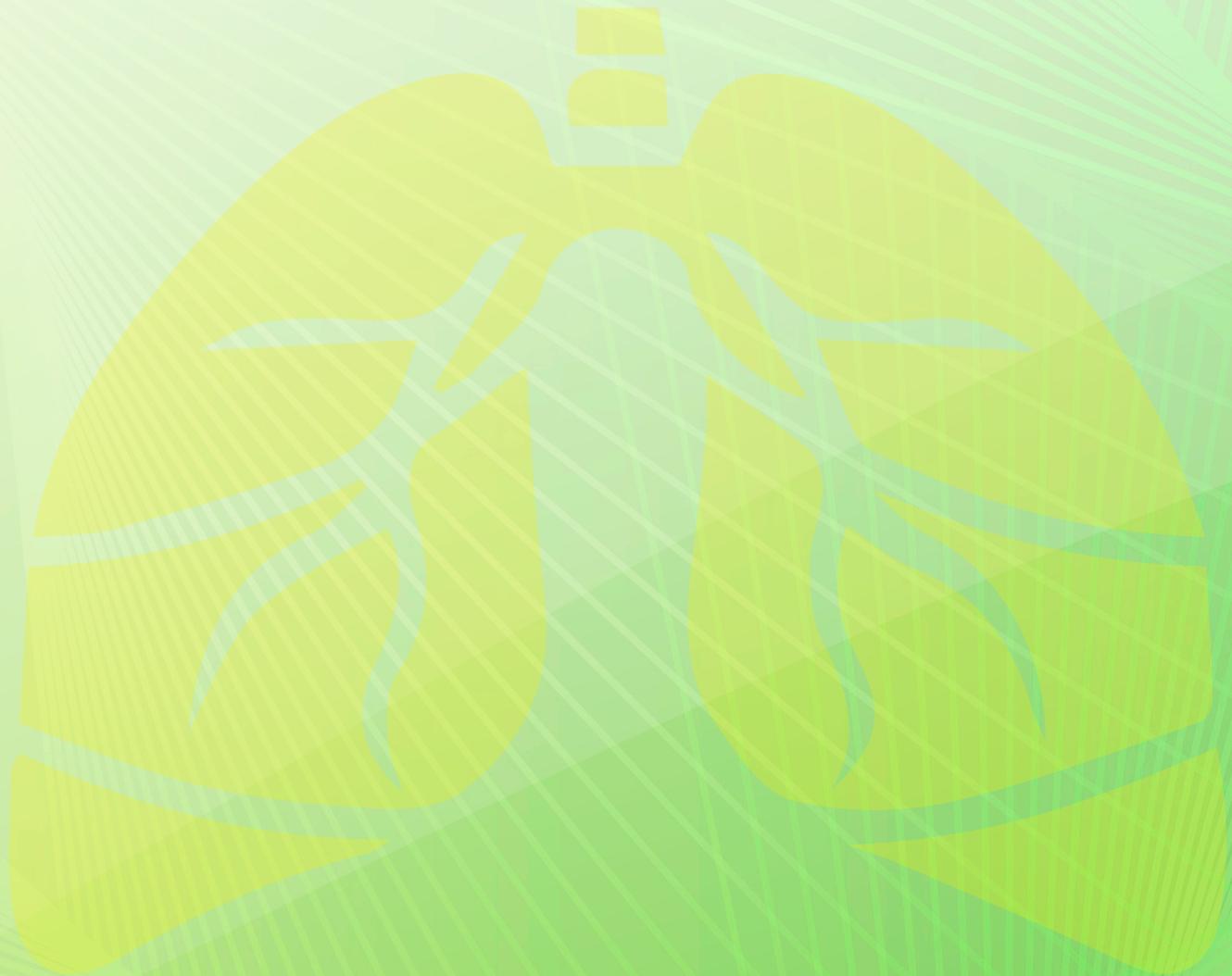
Perdiem for surveys/ implementation at sub-counties			
Cities	KES	11,200.00	Job group "N"
towns	KES	8,400.00	Job Group "N"
Others	KES	7,000.00	Job Group "N"
CHVs stipend	KES	2,000.00	per month
Driver per diem (City)	KES	4,200.00	H
Driver per diem (Town)	KES	4,500.00	H
Driver per diem (Others)	KES	4,200.00	H
Data collectors allowance per day	KES	4,200.00	
Meal Allowance			
Breakfast	KES	2,100.00	Job Group "P"
Lunch	KES	2,800.00	each Job Group "P"
Dinner	KES	2,800.00	each Job Group "P"
Driver Lunch (City)	KES	1,260.00	Job Group H
Driver Dinner (City)	KES	1,260.00	Job Group H
Driver Breakfast (City)	KES	945	Job Group H
Lunch CHVs	KES	500	per person per day
Facilitation			
Facilitation fee- cities	KES	7,000.00	Per day
Facilitators fee sub county	KES	5,000.00	Per day
Facilitation fee	KES	25,831.50	Per Activity
Facilitation fee at Sub county level	KES	2,000.00	Per day
Consultancy			
National (in-country)	KES	35,482.00	per day (WHO/PMI rates)
Regional Blocs	KES	50,688.00	per day (WHO/PMI rates)
International	KES	70,963.00	per day (WHO/PMI rates)
TV commercials production	KES	5,000,000.00	per set (one off)
Radio spot production	KES	350,000.00	per production
Airing of TVC (30 Seconds)	KES	150,000.00	per spot
Airing Radio spots (30 seconds)	KES	40,000.00	per spot
TVCs and Radio spot monitoring	KES	250,000.00	Per month

Print message development	KES	150,000.00	consultant
CD-Rom production	KES	200	per CD
Airing radio spot -local FM stations		15,000.00	per spot
Development of radio spot		40,000.00	per spot
Commodities			
Purchase of PCR log	KES	2,000.00	Per Kit
Acetic Acid	KES	250	500mls
Purchase of Cotton wool roll- 400g	KES	250	Per Kit
Purchase of Gauze Roll	KES	250	Per Kit
Applicator Stick	KES	1,100.00	Per Kit
Surgical Gloves	KES	1,700.00	Per Box of 5os
Clean Gloves	KES	750	Per Box of 5os
Sodium Hypochloride	KES	250	1 lrt
Purchase of hand Sanitizers 5 Ltrs	KES	2,700.00	5 Ltrs
Purchase of Autoclaving tapes	KES	200	Per Pack
Purchase of Glucsticks(1x50)	KES	2,000.00	Per Kit
RFT Reagents	KES	13,200.00	Per Kit
Liquid Hand wash	KES	500	500mls
Purchase of Sanitary pads	KES	100	Per Kit
Salaries			
Salary -Clinical officer	KES	89,000.00	Per Month
Salary -Nurse	KES	89,000.00	Per Month
Salary -HRIO	KES	89,000.00	Per Month
Salary- Medical Lab Officer	KES	89,000.00	Per Month
Salary- Psychologist/Counsellor	KES	89,000.00	Per Month
Mentor mothers monthly pay	KES	10,000.00	Per Month
Salary-HTS	KES	27,000.00	Per Month
Salary-HTS	KES	30,000.00	Per Month
Monthly Stipend-Mentor Mothers		10,000.00	Per Month
CHV Stipend		3,000.00	Per Month
Equipment			
Office Equipment			

Purchase of Office chair	KES	10,000.00	Per Pc
Purchase of ordinary chairs	KES	5,000.00	Per Pc
Purchase of Plastic Chairs	KES	500	Per Pc
Medical Equipment (Lab Equipment)			
Procure BP Machines	KES	9,000.00	Per Pc
Condom Dispenser Installation	KES	1,000.00	Per Pc
Purchase of HBV rapid Test Kits	KES	500	Per Pc
Examination Couch	KES	20,000.00	Per Pc
Purchase of Gully Pot	KES	500	Per Pc
Kidney Dishes	KES	500	Per Pc
AutoClave	KES	50,000.00	Per Pc
BP Machine	KES	2,000.00	Per Pc
Weighing Scale with Height Measure	KES	20,000.00	Per Pc
Purchase of Thermoguns	KES	6,000.00	Per Pc
Purchase of Glucometer	KES	2,500.00	Per Pc
Purchase of PCR Machine	KES	8,000,000.00	Per Pc
Procure Random blood sugar machines	KES	5,000.00	Per Pc
Condom dispensers	KES	3,500.00	Per Pc
Other equipment			
Back up generators	KES	499,000.00	Per Pc
Purchase of Motor Bike	KES	200,000.00	Per Pc
Other costs			
Cash transfer per PLHIV Households	KES	3,000.00	Per month
NHIF Monthly Premium	KES	500	Per month
Web site Subscription per year	KES	20,000.00	Per year
Insurance of Motor Vehicles	KES	100,000.00	Per Year

Annex 5:- Writing team/List of Contributors

No.	Name	Institution
1	Dr Immaculate Kathure	Head NTLD-P
2	Nellie Mukiri	MOH NTRL
3	Beatrice Kinaiya	MOH NTRL
4	Beatrice Khamala	MOH NTRL
5	Solomon Bundi	MOH NTRL
6	Samson Ireri	MOH NTRL
7	Haron Opwaka	MOH NTRL
8	Esther Wangari	MOH NTRL
9	Peter Mwangi	MOH NTRL
10	Jacinta Emacar	MOH NPHL
11	Wilson Kung'u	MOH NPHL
12	Charity Maina	MOH NPHL
13	Jeremiah Okari	DNTLD-P
14	Catherine Githinji	DNTLD-P
15	Dr Stephen.K. Macharia	DNTLD-P
16	Dr Ibrahim Daud	Walter REED, Kericho
17	Zipporah Mwongera	KEMRI, Nairobi
18	Ruth Sitati	KEMRI, Kisumu
19	Dr. Muthoni Junghae	CDC
20	Franklin Mboya	CDC
21	Margaret Mburu	CDC
22	Dr. Dennis Wanyama	Amref Health Africa
23	Ronald Odero	Amref Health Africa
24	Erick Opiyo	Amref Health Africa
25	Kennedy Muimi	CHS
26	Irungu Karuga	CHS
27	Abdunoor Nyombi	SRL Uganda
28	Patrick Ademun	SRL Uganda
29	Oduor Otieno F.	SYSTEMS Evaluation Ltd
30	Dr Peter Lokamar	Head NPHL
31	Dr. Eunice Omesa	WHO
32	Felix Mbetera	DNTLD-P



**NATIONAL TUBERCULOSIS, LEPROSY
AND LUNG DISEASE PROGRAM**

National Tuberculosis, Leprosy and Lung Disease Program,

Afya House Annex 1st Floor | Kenyatta National Hospital Grounds

P.O. Box 20781-00202 Nairobi, Kenya

Website: www.nltp.co.ke | **Facebook:** NTLDKenya | **Twitter:** @NTLDKenya