THE UNITED REPUBLIC OF TANZANIA

MINISTRY OF HEALTH

NATIONAL TB AND LEPROSY PROGRAM

TB Laboratory Operational Plan 2022/23

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List of Abbreviations

ADDO	Accredited Drug Dispensing Outlets
AFB	Acid Fast Bacilli
BMC	Bugando Medical Centre
BSC	Biosafety Cabinets
CTRL	Central TB Reference Laboratory
DLT	District Laboratory Technologist
DST	Drugs Susceptibility Testing
EMS	Expected Mail Service
EPTB	Extra-pulmonary TB
ESRS	Electronic sample referral system.
ETL	Electronic TB and Leprosy Register
FM	Fluorescent Microscopy
HCW	Health Care Worker
HMIS	Hospital Management Information System
HR	Human Resource
IDDS	Infectious Disease Detection and Surveillance
KIDH	Kibong'oto Infectious Disease Hospital
LDR	Local Data Repository
LED	Light-Emitting Diode
LJ	Lowenstein Jensen Media
LPA	Line Probe Assay
MDR	Multi Drug Resistant
MGIT	Mycobacteria Growth Indicator Tube
MoH	Ministry of Health
MSD	Medical Stores Department
MZRH	Mbeya Zonal Referral Hospital
NSGRP	National Strategy for Growth and Reduction of Poverty
NSP-VI	National Strategic Plan VI
NTLP	National Tuberculosis and Leprosy Program
NTM	Nontuberculous Mycobacteria

PPM	Planned Preventive Maintenance
PT	Proficient Testing
QA	Quality Assurance
QC	Quality Control
QI	Quality Improvement
RLT	Regional Laboratory Technologist
RTLC	Regional TB and Leprosy Coordinator
SDGs	Sustainable Development Goals
SRL	Supra-national Reference Laboratory
TB	Tuberculosis
TBLOP	TB Laboratory Operational Plan
TMDA	Tanzania Medicines and Medical Devices Authority
TST	Tuberculin Skin Testing
UN	United Nations
UNHLM	UN High-Level Meeting
USAID	United States Agency for International Development
WHO	World Health Organization
XDR	Extensively Drug-resistant
ZN	Ziehl Neelsen Stain
ZTRL	Zonal Tuberculosis Reference Laboratories

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Dr. Riziki Kisonga

PROGRAM MANAGER

National Tuberculosis and Leprosy Program (NTLP)

Executive Summary

The current TBLOP 2022/23 was prepared in a participatory manner to ensure that TB laboratory interventions align with the NTLP Strategic Plan- VI (NSP-VI) and addresses the TB laboratory challenges identified from various assessments. The plan builds on the significant achievements to date from the implementation of NSP V, addresses gaps identified during the past five years, and seeks to scale up best practices to achieve universal access to high-quality TB diagnosis services. This TBLOP 2022/2023 was developed with the involvement of the TB zonal laboratories to incorporate challenges specific to zonal-level TB laboratories, enhance decentralization, and improve capacity and quality of TB testing at the zonal level.

It places strong emphasis on four major laboratory strategic interventions of Objective 2 in the (NSP-VI 2021–2025) namely; enhancing universal access to TB diagnosis services, strengthening quality assurance (QA) in TB diagnosis across the network, strengthen supply chain management for TB laboratory commodities at all levels and expand the coverage and utilization of phenotypic and genotypic DST. It contributes to the overall targets of the NSP VI, which are patient-centered and attempts to fulfill the UN High-Level Meeting (UNHLM) commitments and reach the End TB Strategy milestones. The outlined activities in the TBLOP aim to strengthen and scale up innovative approaches in the areas of TB laboratory quality improvement (QI), commodities management systems strengthening, and expanded utilization of new WHO-recommended rapid diagnostic technologies.

The plan contains a section detailing the structure of the TB laboratory network and its infrastructure at all levels. Explanations of the linkages with the general health system, supra-national reference laboratories, private sector laboratories, as well as regulatory, legal, political and economic considerations have also been included. It also includes information on the available TB specific tests and their coverage, TB laboratory network human resources, maintenance and validation of the TB laboratory equipment, laboratory quality management systems, and laboratory commodities.

Finally, this plan unveils four key priority intervention areas for the government financial year 2022/2023. The table below summarizes the total budget for the four key intervention areas.

Key intervention area	Total (TZS)	Total (USD)
Enhance universal access to TB diagnosis services	415,395,000	180,607
Strengthen supply chain management for TB laboratory commodities at all levels	3,670,784,108	1,595,993
Strengthen quality assurance (QA) in TB diagnosis across the network	6,288,473,824	2,734,119
Expand the coverage and utilization of phenotypic and genotypic DST	1,421,867,371	618,203
TOTAL	11,796,520,303	5,128,922

1.0 Vision and mission statements

1.1 Vision

Well-coordinated, high-quality, sustainable, nationwide TB laboratory services accessible and affordable to all.

1.2 Mission

Ensure universal access to high-quality, efficient TB laboratory services at all levels of public and private laboratories to reduce the burden of the disease in Tanzania.

2.0 Introduction

The National Tuberculosis and Leprosy Program (NTLP) was launched by the government of Tanzania in 1977 as a combined program addressing both TB and Leprosy diseases. The mission of the program is to provide high-quality TB and leprosy interventions with a focus on universal access, equity, gender, and those most at risk through effective and sustainable collaboration with partners and stakeholders at all levels (NTLP, 2020). The NTLP, through its intensified efforts, contribute positively to the country's efforts to meet the 2025 vision goals, the National Strategy for Growth and Reduction of Poverty (NSGRP) targets, and the Sustainable Development Goals (SDGs). Thus, investment in care and control can significantly contribute to poverty reduction in Tanzania (WHO, 2015).

To end TB, rapid and accurate diagnosis of both active TB disease and latent TB infection is critical for timely initiation of treatment and ultimate control of the disease (TB Diagnostic Landscape, 2017). Tuberculosis disease is classified into two types: pulmonary TB, which affects the lungs, and extra-pulmonary TB (EPTB), which typically attacks other parts of the body besides the lungs. These two types have different diagnostic procedures. Pulmonary TB is usually diagnosed by examining sputum by microscopy and/or any other recommended TB rapid molecular diagnostic tests. Extra-pulmonary TB is diagnosed in different ways, including aspirates/histopathology from the sites involved, radiography, and clinical diagnosis.

In Tanzania, the initial recommended TB diagnostic method is rapid molecular tests such as Xpert MTB/RIF/Ultra. Other TB diagnostic methods currently used in Tanzania include smear microscopy and radiography in patients with clinical signs suggestive of TB.

2.1 Organization and Structure of TB Laboratory Network in Tanzania

The TB laboratory network in Tanzania is integrated within the health laboratory services and coordinated by MoH through the NTLP. The NTLP supports the network of laboratories that provide services for TB diagnosis and treatment monitoring for patient care.

In the United Republic of Tanzania, the network comprises four levels: the Central Tuberculosis Reference Laboratory (CTRL) at the national level, zonal TB laboratories at zonal level, intermediate laboratories at regional and district levels, and peripheral laboratories at health centers and dispensaries level (Figure 1). Tuberculosis laboratory services are managed through CTRL, which oversees the entire TB diagnostic network across the country. The primary role of the laboratories within the network is to provide quality TB diagnostic services and treatment monitoring for patient care. The laboratories have various testing capacities depending on location, infrastructure, and the roles and responsibilities assigned to each specific level of the network.
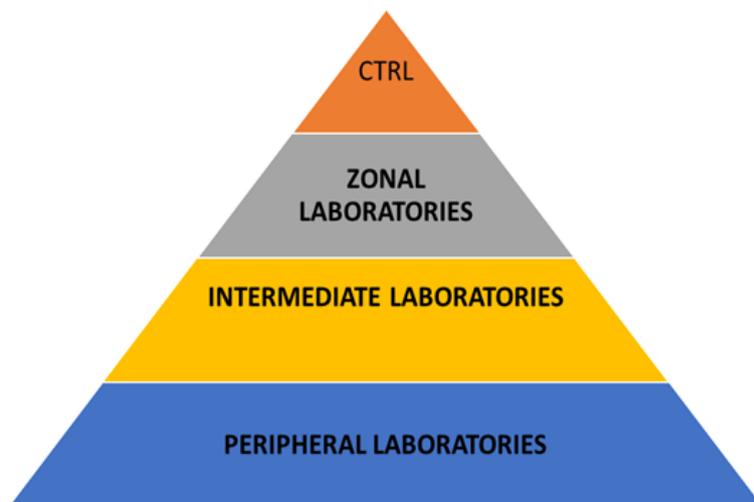
Figure 1: Organizational structure of the laboratories network in Tanzania

2.2 Roles and Responsibilities of the Network

The roles and responsibilities by level are outlined below. In addition, each level of the network is linked through a two-way system: the lower-level reports to the next higher level, and the higher level supervises the lower level.

2.3 Central TB Reference Laboratory

2.3.1 Diagnostic Services

- Offers TB diagnostic services using the following techniques: ZN Microscopy, FM Microscopy, LJ first- and second-line Drug Susceptibility Testing (DST), MGIT first and second line DST, LPA first- and second-line DST and GeneXpert MTB/RIF/ ultra

- Conducts appropriate TB bacteriology tests, including AFB smear microscopy, molecular tests, culture, susceptibility testing, and species identification tests on sputum specimens of new and retreatment patients received from districts and Zonal Tuberculosis Reference Laboratories (ZTRL)

- Spearheads evaluation of new TB diagnosis technologies being introduced in Tanzania

- Conducts slit skin smears for AFB smear microscopy for referred leprosy patients

2.3.2 Planning and Logistics Management

- Conduct quantification, forecasting, and distribution of TB laboratory reagents, supplies, and consumables for the entire network

- Provides strategic oversight to ensure the effective management of all tuberculosis laboratory resources

2.3.3 Quality Assurance and Control

- Performs external quality assurance (EQA) services for laboratories through onsite supervision, training, blinded rechecking and proficiency testing including production and distribution of Xpert PT

- Ensures periodic maintenance of diagnostic equipment by supporting equipment calibration, planned preventive maintenance and laboratory equipment repair

- Conducts mentorship and supervision to all facilities implementing Quality Management System across the network

2.3.4 Capacity building

- Prepares guidelines and/or manuals for guiding implementation of TB diagnostic across the entire network

- Conducts mentorship and supervision to zonal TB laboratories and other lower tiers to ensure attainment of key laboratory performance indicators
- Identifies human resources needs and conducts relevant training, supervision, and mentorship to improve laboratory personnel's competence in collaboration with zonal TB laboratories

2.3.5 Surveillance and Research

- Initiates, coordinates, and collaborates in operational research of relevant TB and leprosy control activities
- Conducts periodic TB prevalence survey in collaboration with the National Institute for Medical Research
- Plans and carries out TB drug resistance surveillance (TB-DRS)

2.3.6 Monitoring, Evaluation, and Learning (MEL)

- Collects, analyzes, and uses TB diagnostic data to inform decision making and planning for TB diagnosis activities across the network

2.3.6.1 Zonal TB Laboratories

Diagnostic Services

- Offer TB diagnostic services using the following techniques: ZN Microscopy, FM Microscopy, LJ culture, MGIT first-line DST, LPA first and second-line DST and Xpert MTB/RIF/ultra
- Receive specimens from their respective zones and perform tests for TB culture and LPA.
- Refer positive culture isolates to Central Tuberculosis Reference Laboratory for phenotypic drug susceptibility testing (DST)
- Conduct slit skin smears for AFB microscopy for referred leprosy patients

Planning and Logistics Management

- Provide information to CTRL on quantification and forecasting of TB laboratory supplies
- Provide strategic oversight to ensure the effective management and utilization of all tuberculosis laboratories resources in their respective zones

- Oversee distribution of TB laboratory commodities and supplies to their respective zones

Quality Assurance and Control

- Coordinate EQA services through onsite supervision, training, blinded rechecking, and proficiency testing in collaboration with CTRL
- Provide information to the CTRL on functionality of diagnostic equipment

Capacity Building

- Disseminate and enforces utilization of relevant TB diagnostic guidelines and/or manuals
- Conduct supervisions and mentorship and to ensure good performance of key laboratory performance indicators

Surveillance and Research

- Conduct routine surveillance of anti TB drugs, in collaboration with RTLCs and DTLCs
- Provide information needed for conducting operational research of TB and leprosy control activities
- Collect and report information needed for conducting national TB drug resistance surveillance (TB-DRS)
- Initiates, coordinates, and collaborates in operational research of TB and leprosy control activities

Intermediate TB Laboratories (regional/referral and district)

- Conducts Xpert MTB/RIF/Ultra tests according to the National guidelines
- Implements TB sample referral system
- Collects, reviews and report TB diagnostic data to the higher levels
- Ensures availability of laboratory reagents and other supplies, in collaboration with the RTLC/DTLC and RLT//DLT
- Implements quality control (QC) and quality assurance (QA) in accordance with available procedures.
- Participates in EQA programs (blinded rechecking, panel testing, supervisory visits).

2.3.6.2 Peripheral TB Laboratories

- Collects, stores, and transports TB specimens for GeneXpert, TB culture, and sensitivity testing at their higher-level reference laboratory, in collaboration with the DTLC
- Performs TB tests using Xpert MTB Rif and Smear Microscopy in compliance with the existing standards
- Performs and participates in EQA for TB tests
- Collects, reviews and report TB diagnostic data to the higher levels
- TB Laboratory Network Infrastructure and Functional Components

2.3.6.3 TB Diagnosis

TB diagnosis in Tanzania is done in line with the requirement and recommendation of the World Health organization (WHO). The complexity and placement of diagnostic technologies varies between higher- and lower-tier facilities, with higher tiers being equipped with advanced technologies. The following technologies are available in Tanzania: AFB Smear microscopy, Xpert MTB/RIF/Ultra, LPA for first- and second-line DST, MGIT first-line and second DST, and LJ first- and second-line DST. In the network, CTRL is equipped with all technologies available in the country. To enhance universal access to TB diagnosis services, reliable specimen referral mechanisms are crucial. The NTLP/CTRL uses a hub and spoke model to refer specimens from lower-tier facilities to higher ones. This system is detailed in the National Procedure Manual for Comprehensive Specimen Referral System.

2.3.6.4 Human Resource for the National TB Laboratory Network

The MOH through NTLP ensures the availability of qualified staff to offer TB diagnostic services at all levels. However, the development and maintenance of trained laboratory staff is one of the challenges for TB laboratory networks in the country. Public sector laboratories have high staff turn-over for staff, resulting in staffing shortages (Table 1). It is essential to undertake workload assessments to understand current human resource capacity and allocations, and well as to create future HR projections.

The WHO laboratory safety guideline recommends employee medical evaluations prior to employment and annually assessed, to ascertain both the risk level and baseline of health for each staff member. In most facilities medical evaluation is not frequently conducted. Health surveillance strategies should be enforced to monitor staff on a regular basis and follow-up with available diagnostic tests (X-ray, TST, and Xpert MTB/RIF/Ultra).

Table 1: Human resource capacity across 4 zonal laboratories (by number and cadre)

No	Cadre	Available	Required	Deficit
1	Laboratory Scientist	13	19	6
2	Laboratory Technologist	9	15	6
3	Bioengineer	0	1	1
4	Laboratory Technician	0	6	6
5	Supply Officer	1	7	6
6	ICT Personnel	0	7	7
7	Accountant	0	1	1
8	Statistician	1	1	0
9	Data Clerk	3	5	5
10	Administrator	0	1	1
11	Record Management Officer	0	6	6
12	Health Attendant	2	9	7
13	Driver	1	1	0

2.3.6.5 Management of Laboratory Commodities and Supplies

Proper management of laboratory commodities and supplies is an essential component of the program. The NTLP, through the CTRL, ensures continuous and uninterrupted availability of reagents and supplies for TB and leprosy diagnosis at all levels.

Laboratory commodities and supplies management involves procurement, distribution, storage and rational use. TB commodities management is based on six rights: the right goods, in the right quantities and right condition, delivered to the right place, at the right time, and at the right cost. Laboratory commodities are requested from the Medical Stores Department and distributed to MSD zonal offices and on to health facilities. Regional and

district laboratory coordinators in collaboration with pharmacists, are responsible for monitoring all laboratory commodities.

Procurement of laboratory reagents, and supplies is carried out in line with national health policy and guidelines and in tandem with international guidelines on TB and leprosy diagnosis and treatment. Specifications for procurement of supplies are provided by CTRL based on the international standards. Currently, laboratory commodities procurement follows two operational channels: 1) procurement done by the MSD and 2) procurement done by the NTLP in collaboration with implementing partners.

Reagents for culture, DST and molecular tests are not procured by MSD, hence they follow the NTLP procurement channel. However, all other laboratory commodities are procured centrally by MSD and distributed to zonal MSD branches (Seek for more clarity on the current practice from NTLP procurement unit). The zonal MSDs then distributes supplies to the district level and large hospitals. Faith-based hospitals and NGO can procure supplies and commodities directly from the MSD.

The Medical Stores Department is equipped with cold chain storage and delivery tools from the national to zonal offices, as well as an electronic management system used for managing the laboratory commodity ordering process. The supplies procured by the NTLP are distributed by the CTRL/NTLP in collaboration with partners through the RTLCs and the DTLCs.

The MoH, through the NTLP, quantifies laboratory reagents and supply requirements annually and submits its order to the MSD, which procures the items and stocks them in its warehouse. Health facility, district, and regional orders for reagents and supplies are based on the number of patients notified in the previous month/quarter. The health facility orders laboratory commodities and submits the request to District Laboratory Technologist (DLT) and Regional Laboratory Technologist (RLT), who submit to the central MSD. The central MSD distributes the allocated commodities to regions through zonal MSD centers.

Storage of laboratory commodities should focus on maintaining the quality of the received reagents in accordance with manufacturer recommendations. Reagents should be arranged by type according to first expiry, first out, and first in-first out, and recorded into ledgers and bin cards.

2.3.6.7 Laboratory Quality Management Systems

Laboratory quality management systems involve a range of activities that enable laboratories to achieve and maintain provision of high-quality laboratory diagnostic services in the country in accordance with the requirements of ISO 15189:2012. For a laboratory to be fully accredited, it has to be enrolled in the Stepwise Laboratory Management Towards Accreditation (SLMTA) program. The essential elements of a quality assurance system for TB laboratories include developing and standardizing policies, procedures, equipment management, participation in EQA and internal audit.

The implementation of quality management systems in TB diagnostic laboratories started in 2015 through the TB SLMTA approach with the purpose of supporting the accreditation process for TB zonal laboratories. During this process, six laboratories were involved in TB SLMTA (the CTRL, Mbeya Referral, Kibong'oto Hospital, Public Health Laboratory Pemba, Bugando Medical Centre, and Dodoma Hospital).

Thereafter the QMS implementation process aligned with the MoH accreditation plan with emphasis on ensuring that TB tests are part of the QMS implementation plan. Currently, five zonal laboratories are accredited and about 80% of accredited laboratories in the country include TB tests (GeneXpert and AFB smear) in their Schedule of Accreditation (SOA).

The EQA program for TB tests involves all three components: proficiency testing (PT), blinded rechecking for AFB smear microscopy, and on-site supervision visits. The total coverage of the laboratories participating in EQA range from 82–86% for blind rechecks for AFB smear microscopy and 93% for GeneXpert in 2021.

The PT providers for GeneXpert are Uganda SRL and CDC Atlanta USA. Also, Uganda SRL provides PT for AFB smear, culture, DST, and LPA. Blinded rechecking is performed for regional, district and peripheral TB diagnostic laboratories. The CTRL will develop guidelines for conducting TB tests EQA program. In 2022/2023, the CTRL anticipates preparing and distribute PT for GeneXpert in Tanzania to increase both EQA country coverage and sustainability.

2.3.6.6 Specimen Referral Systems for the TB Laboratory Network

The laboratory specimen referral system refers to the transportation of specimens from one facility to another facility that has the necessary diagnostic capacity and the return of results to the requesting facility. The organizational structure of the National Laboratory Specimen Referral and Results Feedback System (NLSRFS) follows the hub and spoke model as described in the national integrated Specimen Referral System (SRS) guidelines (Figure 2 from the National Procedure Manual for Comprehensive Specimen Referral System, page 5).
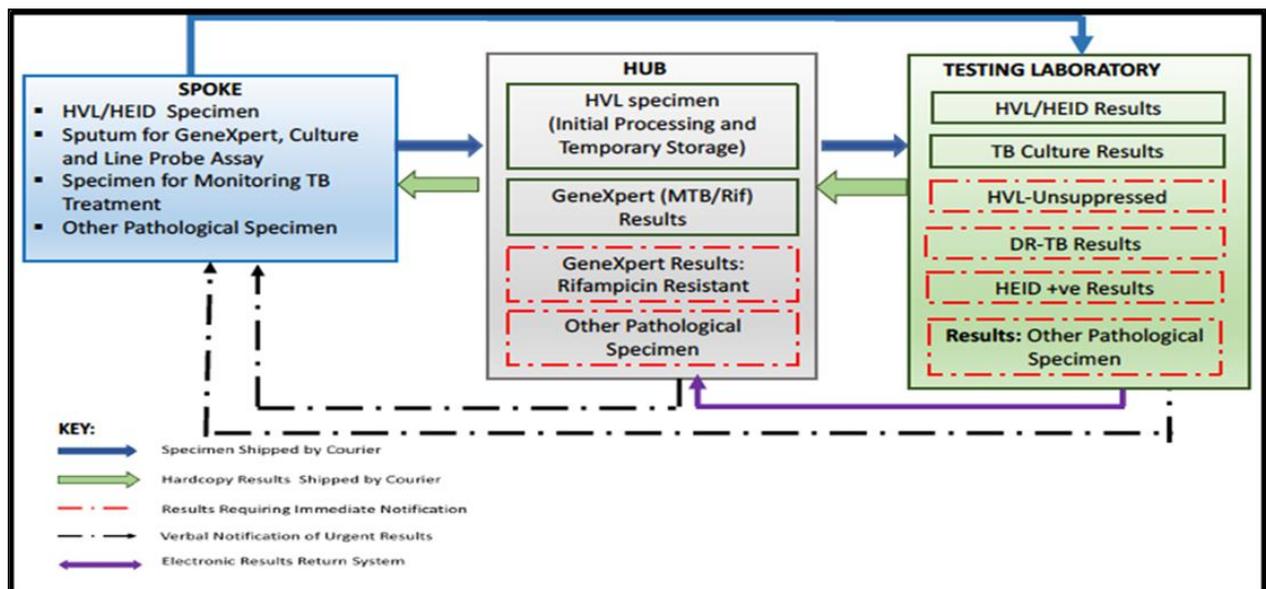
Figure 2: Laboratory specimen referral system

In 2020, the government of Tanzania formalized and scaled an integrated specimen transportation system under a national courier service (*EMS*) using a hub and spoke model. In addition, the TB program in collaboration with the IPs will continue to implement a community-based specimen referral system to collect specimens from accredited drugs dispensing outlet (ADDO) shops, traditional healers, and Community Health Volunteers (CHVs). These community actors have demonstrated the ability to successfully handle and refer specimens. The CHVs also facilitate linkages to Direct Observed Treatment centers (DOT), contact investigation, and adherence support.

In implementing this strategy, the program expects to reduce turnaround time for specimen referral and results feedback from 7 to 14 days in 2020 to a maximum of 4 days by 2023 (NSP VI). The country will also increase the number of district councils with reliable sputum

referral for TB diagnosis (at least 2 motorcyclists) from 154 councils in 2020 to all 189 councils by 2022.

The integrated specimen referral mechanism is based on a hub and spoke model, in which a number of health facilities (10–25 spokes which are either DOT centers or microscopy sites) sampled within a catchment area of about 30 to 40 kilometers send specimens to a collection point ("hub:" GeneXpert sites) where TB specimens are either initially tested with GeneXpert or aggregated before transportation to the testing laboratory (TB culture or LPA laboratories). At the end of 2020, approximately 7,239 health facilities were mapped to 301 GeneXpert laboratories countrywide. There is about one hub per district, for a total of 301 hubs covering the 7,239 health facilities (NSP V, 2015). Unlike HIV specimens TB specimens are not being tracked through the electronic sample referral system (eSRS).

2.3.6.8 Laboratory Information and Data Management

The Tanzania health information system is predominantly paper-based, with a few electronic-based applications. The paper-based information tools consist of forms and registers used at the facility, district, and national levels. The electronic-based system includes GxAlert, an application that manages GeneXpert data from lower-level facilities to the national level, the electronic TB and leprosy register (ETL) which is a component in DHIS2 is used to track and monitor TB patient cases, and the TBLIS at CTRL. In addition, the national system has the Data Intensive System and Applications (DISA) laboratory information system (LIS), which is used in some zonal TB laboratories (KIDH, BMC, and MZRH) as well as the HMIS in regional laboratories (DRRH) which is not yet linked and/or integrated with TB-LIS at CTRL and DHSI2/ETL. Figure 3 shows the reporting and feedback loop from the community to the NTLP/CTRL level.
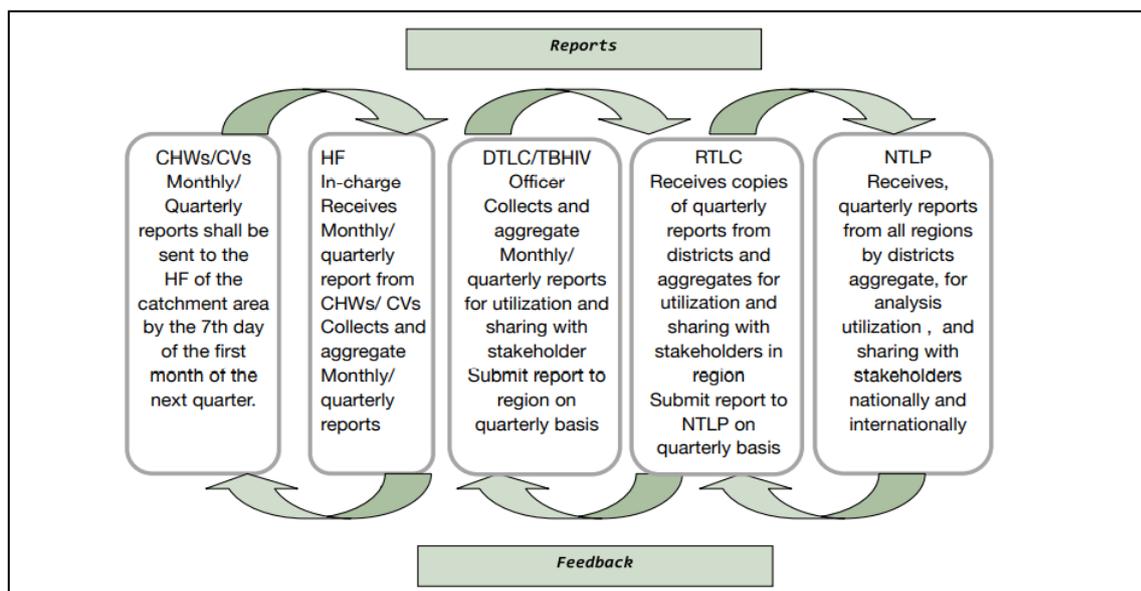
Figure 3: TB data flow chart

Source: *National Operational Guidelines for Community Based TB, TB/HIV and DR-TB Interventions, page 56*

TB laboratory diagnostic data is primarily collected using TB laboratory request forms and the TB 05 laboratory register. In 2014, Tanzania adopted the use of GxAlert as an electronic means of collecting TB diagnostic data. GxAlert is connected to GeneXpert machines and uploads results into a server in real time so that different levels of stakeholders can access and utilize the TB results. At the district level and higher, there is a DHIS2-ETL which collects all information on TB cases within their respective tiers The DHIS2-ETL is managed by data managers and TB coordinators. TB diagnostic data are collected monthly and flow from facilities to districts to regions to zones to CTRL and finally to NTLP which reports to the MoH. There is a need to decentralize DHIS-2 ETL beyond district level. This can be piloted in a few districts.

The current TB-LIS at CTRL is not linked with the TB laboratory network within the country, or with the patient-based data that is captured with other non-laboratory tools (clinical paper-based patient data at the facility level and electronic data at district, regional and national level (DHIS2). Efforts are underway to ensure all electronic systems are linked and connected to the Open Local Data Repository (Open LDR)—a central information system where all data will be posted.

2.3.6.9 Maintenance and Validation of TB Laboratory Equipment

Each level has specific requirements for infrastructure, biosafety and biosecurity which are defined by the various activities and diagnostic methods being performed in the laboratories. As the level of the laboratory increases, the technologies become more advanced and as a result the necessary skills, proficiency, and training requirements for laboratorians increase.

Laboratories require infrastructure development or upgrades to reach minimum standards of safety for conducting different tests such as culture and drug susceptibility testing. The responsibility of undergoing such upgrades is offered and coordinated at the national level. Additional consultants may be asked to provide guidance on how to design laboratories to ensure safe and efficient workflow.

Effective management of laboratory equipment and supplies is essential at every level of the network. The CTRL evaluates the quality, accuracy, and performance of equipment. Each laboratory (at all levels) should have a comprehensive list of equipment which shows their functionality status. Any materials or equipment provided directly to a laboratory by a donor or partner organization should be placed in this inventory and reported to the NTLP through the CTRL. According to the national policy on medical laboratory equipment, introduction of technologically new equipment should be approved by the Tanzania Medicines and Medical Devices Authority (TMDA), which is authorized to verify the suitability of new equipment.

The CTRL guides procurement of equipment based on international standard specifications. A national procedure guides procurement of equipment through MSD. Each laboratory is responsible for verification of any new equipment and/or technologies before routine use.

2.4 Situational Analysis and Rationale for Operational Planning

This operational plan was developed based on the findings from the baseline assessment from four zonal TB Laboratories capacity for/and quality of TB testing (April 2021), end-term review of National TB and Leprosy Strategic Plan V(2016-2020) in 2020 and recently completed Tanzania TB Diagnosis Network Assessment (TB-DNA 2021).

In April 2020, NTLP/CTRL conducted TB zonal laboratories assessments in collaboration with USAID-IDDS to determine the implementation status of quality management systems (QMS) and identify the steps needed to obtain accreditation of the laboratories in TB culture and line probe assay (LPA) tests. The zonal laboratories involved in this assessment were Mbeya (Southern Highlands Zone), Dodoma (Central Zone), Bugando (Lake Zone), and Kibong'oto (Northern Zone).

The findings from the baseline assessments highlighted the status of implementation of planned activities, challenges, and best practices toward improving capacity and quality of TB testing. Overall, while the total number of staff at each laboratory varied, the team found the number of staff allocated for TB testing was inadequate for the number of sections within the laboratories compared with workload and testing capacity at zonal laboratories. Also, training and competence records of the staff working in TB laboratory sections were unavailable for review in all laboratories.

TB laboratory test equipment for smear microscopy, GeneXpert MTB/RIF, and TB culture were available and functional in all four laboratories. The LPA was available and functional in Mbeya and Kibong'oto laboratories. There is no routine maintenance and servicing which may impact functionality in the future for instance biosafety cabinets (BSC) and LPA machines. As part of improving this, the government through the MoH signed a contract with Cepheid to service GeneXpert machines. One or more randomly selected TB culture reports in each of the four laboratories was assessed for compliance to ISO 15189:2012 requirements. In each of the assessed laboratories, the reports showed an average of 50% compliance to the requirements.

In February 2020, NTLP conducted an end-term review of the National TB and Leprosy Strategic Plan V 2016–2020 (NSP V). The NSP V laboratory activities focused on establishing a TB network, expanding the access and availability of diagnostics, capacity building, quality assurance, and information system strengthening.

In this review, it was found that implementation of QMS and accreditation of the zonal TB laboratories under ISO 15189:2012 for smear microscopy and GeneXpert tests had been achieved during the preceding period. There was also significant improvement in scaling up the coverage of molecular diagnostics such as GeneXpert across the network from four (4)

facilities in 2012 to 238 facilities in 2020. Despite these improvements, major challenges remained to be addressed to keep the country on course to attain national and international TB targets.

The challenges identified are highlighted below:

1. Planned Preventive Maintenance (PPM) and routine calibration of the equipment was not done regularly as per manufacturer recommendations.

2. Only one of four zonal TB laboratories have infrastructure suitable to accommodate tests such as LPA, TB culture, and phenotypic DST.

3. There is a significant shortage of laboratory staff in zonal TB laboratories.

4. There was no evidence that zonal TB laboratories were supervising their lower tiers.

5. There was not optimal utilization of electronic TB laboratory information systems.

6. There is no participation of EQA in some TB tests such as TB culture, LPA, and phenotypic DST.

7. No standard TB laboratory request forms are used across the diagnostic network.

8. At the time the February 2020 review was conducted, there was no national biosafety and biosecurity manual addressing TB biosafety and biosecurity requirements.

9. Late/erratic supply of reagents and consumables for TB diagnosis was observed in most TB laboratories.

The TB Laboratory Operational Plan 2022/23 addresses the challenges identified in the findings from the TB Zonal Laboratories Assessment (April 2021) and the end-term review of the NSP V and to maximize the contribution of the TB laboratory network towards attaining national and international TB targets.

The activities in this plan aim at strengthening and scaling up innovative approaches in the areas of TB laboratory quality improvements (QI), commodities management systems strengthening, and expanding utilization of new WHO-recommended rapid diagnostic technologies.

3.0 Purpose and Objectives of the TB Laboratory Operational Plan 2022/2023

The plan aims to support implementation of TB diagnostic interventions for strengthening, sustaining, and maximizing input of the TB laboratory network towards attaining national and international TB targets by enhancing capacity and quality of TB testing at zonal laboratories.

3.1 Objectives of the TB laboratory Operational Plan 2022/23

   i.   Objective

To expand access to quality TB diagnostic services, including adoption of new technologies.

   ii.   Key Intervention Areas

   1. To enhance access to TB diagnostic services.

   2. To strengthen the supply chain management for TB laboratory commodities at all levels.

   3. To strengthen quality assurance (QA) of TB diagnostic services across the network.

   4. To expand the coverage and utilization of phenotypic and genotypic drug susceptibility testing including use of LPA at all zonal laboratories. The budget summary for activities in the key intervention areas is summarized below;

Table 2: Budget summary

Key intervention area	Total (TZS)	Total (USD)
Enhance universal access to TB diagnosis services	415,395,000	180,607
Strengthen supply chain management for TB laboratory commodities at all levels	3,670,784,108	1,595,993
Strengthen quality assurance (QA) in TB diagnosis across the network	6,288,473,824	2,734,119
Expand the coverage and utilization of phenotypic and genotypic DST	1,421,867,371	618,203
Total	**11,796,520,303**	**5,128,922**

4.0 Key Intervention Areas

4.1. Enhance Access to TB Diagnostic Services

The intervention aims at ensuring every council has at least one GeneXpert machine, equivalent to one machine per 250,000 people on average, and councils which are geographically hard to reach have at least two machines equivalent to one machine per 150,000 people. While the intent is to minimize the use of smear microscopy as a primary diagnostic technology by 2025, most TB diagnosis in Tanzania is still visualization of AFB under the microscope. Microscopy investigation is also used for follow-up purposes. The program will ensure availability and utilization of GeneXpert technology and strengthening of specimen transportation mechanisms. The program, through its NSP VI, has also planned to roll out TrueNat technology in the diagnostic network to improve coverage of TB molecular diagnostic technologies.

As part of improving access to diagnostic services, availability of a well-functioning specimen referral system is required. The program is using an integrated specimen referral system (i.e., hub and spoke). The system needs to be evaluated periodically to ensure quality and efficiency. Additionally, community-based support for specimen transportation through various locally available means (e.g., community health workers conducting community-based specimen collection) will be enhanced to complement the hub and spoke system in areas where accessibility will be a limitation to this system.

4.2. Strengthen the Supply Chain Management of Laboratory Commodities at all Levels

To ensure that all TB diagnostic centers are providing high-quality and timely services, equipment maintenance is a priority of this objective. Building the capacity of HCWs will be emphasized and mentorship will be strengthened. Measures will be put in place for the maintenance of the adopted technologies and availability of laboratory commodities will be enhanced through electronic management information systems.

The NTLP/CTRL will procure and plan for calibration and maintenance services for laboratory commodities and supplies needed for rapid tests. Procurement of laboratory commodities, supplies, and equipment of new technologies will continue to be done vertically by program level. NTLP will incorporate procurement and supply of commodities needed for rapid tests

(LPA, GeneXpert) into the normal national procurement and supply system, as well as the eLMIS system.

4.3. Strengthen Quality Assurance (QA) across the TB Diagnostic Network

Quality assurance activities will be implemented at all levels. In addition, the accreditation processes will be continued for the CTRL and for the zonal TB laboratories to include LPA and TB culture tests. NTLP will make efforts to build in-country capacity for proficiency testing and genome sequencing.

At the heart of quality management is the availability of data for continued monitoring and evaluation. Hence, the NTLP will strengthen the existing information systems including TBLIS, DHIS2-ETL,GxAlert, and EQA reporting. Further, the improvement of the system will ensure interoperability and linkages with national (Ministry) databases. EQA services will be established at zonal laboratories to provide support to regions.

NTLP will develop guidelines, SOPs, and conduct training and mentorship to ensure quality implementation of the program activities and improved data flow and analysis at all levels. Infrastructure of EQA centers will be improved with provision of furniture, office equipment, stationery, and access to electronic means of communication.

Data management plans and procedures will be developed and disseminated to improve data flow and troubleshooting. Capacity for preventive maintenance and repair of GeneXpert will be increased through training of supervisors and provision of tools.

As a long-term plan to ensure EQA participation to GeneXpert sites, Uganda Supranational TB reference Laboratory is building capacity to the CTRL on TB EQA production for both GeneXpert and Smear Microscopy. CTRL in collaboration with the National Health Laboratory Quality Assurance and Training Centre (NHL-QATC) will then be able to produce and supply EQA materials.

In this plan, the CTRL and all zonal TB laboratories will increase the number of tests to be accredited. In addition, the laboratory network will aim to improve the standards of zonal laboratories to reach GLI standards needed for accreditation for TB culture and LPA.

4.4. Expand the Coverage and Utilization of Phenotypic and Genotypic Drug Susceptibility Testing

To increase DST coverage for all confirmed TB patients, this intervention focuses on increasing access to DST as per testing algorithms using conventional and molecular techniques. Activities include adoption of new technologies in diagnosis of TB, mapping and strengthening of TB data flow and patient results, building capacity of the TB laboratories staff, and ensuring even distribution and access to TB diagnostic molecular technologies. The NTLP will lead implementation of this intervention, with support from implementing partners.

New technology adoption will be guided by feasibility and acceptability studies to ensure alignment with the national guidelines and priorities. The use of Xpert Ultra cartridges, Xpert/MTB XDR, and more easily accessible molecular technologies such as TrueNat will be explored for adoption. LPA for second-line DST will be strengthened and scaled up to all zonal TB laboratories.

Appendices

- **Appendix 1: Activities, Allocated Budget, and Indicators**

Activity	Indicators	Means of verification	Assumptions	Linkages	Responsible		TOTAL BUDGET	Quarter			
								1	2	3	4
Objective 2.0 To expand access to quality TB services including the adoption of new diagnosis technologies											
Key priority intervention area/activities											
2.1 Enhance universal access to TB diagnostic services											
2.1.1 Recruit/re-allocate/second at least 2 skilled laboratory staff per each zonal laboratory	Number of laboratory staff recruited/re-allocated/ seconded	HR staff inventory showing new recruited/re-allocated/ seconded staff	Government approves recruitment/ re-allocation/ secondment of staff	MOHCDGEC/ PO-RALG/IPs	NTLP	MOHCDGEC / IPs	86,880,000				
2.1.2 Conduct one orientation/mentorship on TB culture and LPA to new laboratory personnel	Number of personnel oriented/mentored on LPA and TB culture	Availability of mentorship/orientation report	Availability of funds	MOHCDGEC /IPs	CTRL	MOHCDGEC / IPs	16,320,000				
2.1.3 Conduct quarterly supportive supervision to lower tiers	Number of tiers supervised at each level	Supervision reports	Availability of funds	MOHCDGEC/ PO-RALG/IPs	CTRL	MOHCDGEC /IPs	145,530,000				

2.1.4 Orient 200 community health workers on appropriate TB specimen collection, handling, transportation and use of TB diagnostic technology tools in view of COVID-19	Number of community Health workers trained	Training reports	Availability of funds	MOHCDGEC/ PO-RALG/IPs/CTRL	CTRL	MOHCDGE/IPs	129,125,000				
2.1.5 Conduct orientation/sensitization to RLTs, RTLCs, DTLCs, and DLTs to improve TB specimen referral system	Number RTLCs, RLTs, DTLCs and DLTs oriented on specimen referral	Orientation/sensitization report	Availability of funds	MOHCDGEC/ PO-RALG/IDPS	CTRL	MOHCDGE/IPs	37,540,009.60				

Activity	Indicators	Means of verification	Assumptions	Linkages	Responsible	Source of funds	TOTAL BUDGET	Quarter			
								1	2	3	4
Objective 2.0 To expand access to quality TB services including the adoption of new diagnosis technologies											
Key priority intervention area/activities											
2.2: Strengthen supply chain management for TB laboratory commodities at all levels											
Activity 2.2.1. Conduct workshop to review and update eLMIS to include all TB laboratory commodities	Updated eLMIS with all TB commodities	Workshop reports	Availability of funds	NTLP, PORALG & MSD	CTRL	MOHCDGEC & IPs	263,760,000				
Activity 2.2.2. Conduct training to regional and district laboratory coordinators on updated eLMIS for TB laboratory commodities.	Number of regional and district laboratory coordinators trained on updated eLMIS	Training reports	Availability of funds	NTLP, PORALG & MSD	CTRL	MOHCDGEC & IPs	90,000,000				
Activity 2.2.3. Conduct workshop to design and adapt specific tool for requesting and reporting of reagent and supplies between health facilities, Zonal laboratories and CTRL	Designed tool for requesting and reporting of reagent and supplies between zonal laboratories and CTRL	Workshop reports	Availability of funds	NTLP	CTRL	MOHCDGEC & IPs	90,380,000				
Activity 2.2.4. Conduct biannual review meeting on supply chain management and	Number of Review Meetings Conducted	Meeting minutes	Availability of funds	NTLP, PORALG & MSD	CTRL	MOHCDGEC & IPs	45,620,000				

forecasting on TB commodities											
Activity 2.2.5. Procure 2 Biosafety cabinets, 2 Incubators, 2 MGIT machine, 2 autoclaves, 2 freezers & 2 LPA machine for zonal laboratories	Number of Biosafety cabinets, Incubators, MGIT machine, Autoclaves, Freezers & LPA procured	Procurement documents	Availability of funds	NTLP	CTRL	MOHCDGEC & IPs	732,427,000				
Activity 2.2.6. Procure necessary reagents and supplies such as LPA reagents, GeneXpert Cartridges, culture reagents, eggs, PPE and triple package materials	Number of reagents & supplies procured	Procurement documents	Availability of funds	NTLP	CTRL	MOHCDGEC & IPs	2,343,528,000				
Activity 2.2.7. Conduct workshop to link (Interoperability) ETL with other system within the Facility/Clinical/ Pharmacy system and GxAlert	ETL linked with other LIS like GxAlert, TBLIS etc.	Workshop reports	Availability of funds	NTLP	CTRL	MOHCDGEC & IPs	150,000,000				
Activity 2.2.8. Procure reagents and supplies for Culture and DST Media preparation	Number of reagents & supplies procured	Procurement documents	Availability of funds	NTLP	CTRL	MOHCDGEC & IPs	163,094,108				
Activity 2.2.9. Upgrade cold room for storage of	Upgraded cold room	Upgraded cold room	Availability of funds	NTLP	CTRL	MOHCDGEC & IPs	50,000,000				

Media and Isolates at CTRL										

Activity	Indicators	Means of verification	Assumptions	Linkages	Responsible	Source of funds	TOTAL BUDGET	Quarter			
								1	2	3	4
Objective 2.0 To expand access to quality TB services including the adoption of new diagnosis technologies											
Key priority intervention area/activities											
2.3: Strengthen quality assurance (QA) across TB diagnostic network											
2.3.1 Procure/provide proficiency testing (PT) for GeneXpert, LPA, phenotypic DST, culture and microscopy tests to TB Laboratories.	Number of PTs procured/distributed	PT reports	Availability of funds and IPs readiness to support.	NTLP	CTRL	MOHCDGEC and IPs	421,001,544				
2.3.2 Conduct three days orientation to regional, district TB coordinators, controllers, and zonal laboratories staff on re-designed EQA for AFB smear microscopy system (blinded checking)	Number of coordinators oriented	Orientation reports	Availability of funds	NTLP and PO-RLAG	CTRL	MOHCDGEC and IPs	587,000,000				
2.3.3 Conduct three workshops (5 days each) to develop and disseminate national TB External Quality Assurance guideline.	Number of copies of EQA guideline disseminated.	EQA Guideline developed. Dissemination reports.	Availability of funds	MOHCDGEC and IPs, PO-RALG	CTRL	MOHCDGEC and IPs	100,095,000				
2.3.4 Capacitate reference and zonal TB laboratories to prepare	Number of lab staffs trained, number of PT	Report on capacity building	Availability of funds	MOHCDGEC and IPs	CTRL	MOHCDGEC and IPs	55,530,370				

and distribute PT/EQA materials	distributed											
2.3.5 Conduct quarterly workshops on EQA for AFB smear Microscopy and GeneXpert data review from zonal TB laboratories	Number of workshops conducted, number of EQA reports reviewed.	Meeting reports EQA report	Availability of funds	MOHCDGEC and PO-RALG	CTRL	MOHCDGEC and IPs	67,500,000					
2.3.6 Conduct national biannual workshop on EQA for AFB smear Microscopy and GeneXpert data review in the country	Number of workshops conducted	Workshop reports	Availability of funds	CTRL and Zonal Laboratories	CTRL	MOHCDGEC and IPs	264,400,000					
2.3.7 Conduct quarterly QMS mentorships to Zonal TB laboratories to facilitate accreditation for TB testing.	Number of mentorships conducted, number of TB tests enrolled into accreditation.	Mentorship report Accreditation assessment report	Availability of funds	MOHCDGEC and IPs	CTRL	MOHCDGEC and IPs	63,520,000					
2.3.8 Conduct quarterly QMS mentorship to TB diagnostic centers to facilitate accreditation of GeneXpert and microscopy	Number of mentorships conducted, number of TB tests enrolled into accreditation.	Mentorship report Accreditation assessment report	Availability of funds	CTRL & Zonal Lab	CTRL	MOHCDGEC and IPs	197,600,000					

2.3.9 Payment of accreditation annual fees for reference and zonal TB laboratories	Number of laboratory paid annual fees.	Annual fees paid receipt.	Availability of funds	CTRL	CTRL	MOHCDGEC and IPs	360,000,00 0					
2.3.10 Conduct laboratory annual management review meetings for TB culture as per ISO 15189 requirements	Number of laboratories conducting meeting	Meeting report	Availability of funds	CTRL	CTRL and Zonal Labs	MOHCDGEC and IPs	30,670,000					
2.3.11 Conduct three workshops (5 days each) to develop and disseminate National TB Biosafety and Biosecurity Manual	Number of copies for BSS developed and disseminated	Available developed BBS manual Dissemination report	Availability of funds	CTRL, Zonal Laboratori es	CTRL and Zonal Labs	MOHCDGEC and IPs	100,915,00 0					
2.3.12 Conduct orientation on BBS to national, zonal and regional laboratory staffs	Number of staff orientated.	Orientation reports	Availability of funds	CTRL and Zonal Labs	CTRL	MOHCDGEC and IPs	34,535,000					
2.3.13 Conduct gap assessment on QMS implementation to TB diagnostic laboratories.	Number of laboratories assessed	Assessment reports	Availability of funds	CTRL, Zonal TB Laboratori es	CTRL	MOHCDGEC and IPs	5,080,000					
2.3.14 Conduct QMS internal auditors orientation to zonal laboratories.	Number of auditors oriented	Orientation reports.	Availability of funds	CTRL, Zonal TB Laboratori es	CTRL	MOHCDGEC and IPs	15,355,000					

2.3.15 Conduct TB equipment service maintenance and calibration to central and zonal laboratories.	Number of equipment calibrated and serviced	Maintenance and calibration reports	Availability of funds	CTRL, Zonal TB Laboratories	CTRL	MOHCDGEC and IPs	318,500,000				
2.3.16 Procure quality control material for TB.	Number of quality control materials procured.	Availability of procurement receipt/documents	Availability of funds	CTRL, Zonal Laboratories	CTRL	MOHCDGEC and IPs	1,300,000				
2.3.17: Conduct biannual supervision visits to five Zonal Laboratories	Number of supervision conducted	Availability of supervision reports	Availability of funds and collaboration with other supporting partners	NTLP	CTRL	MOHCDGEC and IPs	298,350,000				
2.3.18: Conduct Supportive supervision and mentorship to Laboratories with low performance in EQA	Number of low performing laboratories supervised/mentored	Mentorship/supervision reports	Availability of funds	NTLP	CTRL	MOHCDGEC and IPs	206,485,000				
2.3.19. Conduct quarterly TB laboratory TWG meetings	Number of meetings conducted	Meeting reports	Availability of funds	NTLP	CTRL	MOHCDGEC and IPs	113,400.00				

Activity	Indicators	Means of verification	Assumptions	Linkages	Responsible	Source of funds	TOTAL BUDGET	Quarter			
								1	2	3	4
Objective 2.0 To expand access to quality TB services including the adoption of new diagnosis technologies											
Key priority intervention area/activities											
2.4: Expand the coverage and utilization of phenotypic and genotypic DST											
2.4.1 Procure and distribute 6 Xpert MTB XDR to all zonal laboratories	Number of Xpert MTB/XDR machine procured.	Procurement documents and machines available.	Availability of funds	MOHCDGEC, MOF and IPs	NTLP	MOHCDGEC and IPs	235,840,800				
2.4.2 Conduct training to users on GeneXpert MTB XDR technology.	Number of GeneXpert users trained.	Training report	Availability of funds.	MOHCDGEC, MOF and IPs	NTLP	MOHCDGEC and IPs	20,375,000				
2.4.3 Conduct method verification for procured Xpert MTB XDR	Xpert MTB XDR technology verified	Verification report	Availability of funds	MOHCDGEC, CTRL, IPs	NTLP	MOHCDGEC and IPs	70,000,000				
2.4.4 Conduct two workshops to Map and redistribute molecular diagnostic technologies appropriately.	Number of molecular technologies mapped and re-distributed	Redistribution list and mapping report	Availability of funds.	MOHCDGEC, MOF and IPs,	NTLP	MOHCDGEC and IPs	30,160,000				
2.4.5. Connect and maintain to all GeneXpert machines to electronic information systems.	Number of GeneXpert machines connected to LIS	Xpert machines reporting electronically	Availability of funds	MOHCDGEC, MOF and IPs	NTLP	MOHCDGEC and IPs	111,688,679				

2.4.6. Connect existing TB laboratory information systems with DHIS2-ETL to ensure interoperability of laboratory and clinical information systems	Number of GeneXpert machines connected to LIS	Availability of connected machines report	Availability of funds to procure GxAlert router	MOHCDGEC, MOF, /TBA, Partners, /Facilities	NTLP	MOHCDGEC and IPs	25,000,000					
2.4.7 Conduct ToT training to CTRL staff on second line DST using new WHO recommended drugs	Number of ToT trained on second line DST using new WHO recommended drugs	Availability of training report	Availability of funds	MOHCDGEC and IPs	NTLP	MOHCDGEC and IPs	22,250,000					
2.4.8 Conduct training and mentorship to at least 4 staff from each zonal laboratory on DHIS2 ETL	Number of trained zonal Laboratory staff on DHIS-2-ETL	Training reports and training certificates	Availability of funds				20,470,000					
2.4.9. Evaluate and adapt new WHO recommended TB molecular diagnostic testing such as GeneXpert ultra-cartridges, Truenat and GeneXpert XDR	Number of new WRD evaluated and adapted	Availability of evaluation report	Availability of funds to conduct evaluation	MOHCDGEC, MOF, /TBA, Partners, /Facilities	NTLP	MoHCDGEC and IPs	21,100,000					
2.4.10 Procure new WHO recommended TB molecular diagnostic testing	Number of machines procured	Availability of procurement report	Availability of funds	MOHCDGEC, MOF, /TBA, Partners, /Facilities	NTLP	MoHCDGEC and IPs	383,573,946.50					

2.4.11 Conduct meeting to disseminate guideline for new TB diagnostic technologies to regional and district coordinators.	Number of guidelines copies disseminated	Dissemination report.	Availability of funds	MoHCDGEC, MoF and IPs	NTLP	MoHCDGEC and IPs	41,875,000				
2.4.12 Printing and dissemination of specimen referral guideline to all diagnostic facilities in all tiers of the network.	Number of copies of specimen referral guidelines printed	Availability of specimen referral guidelines, disseminated report	Consultancy, availability of funds	MOHCDGEC, MOF, /TBA, Partners, /Facilities	NTLP	MoHCDGEC and IPs	40,300,000				
2.4.13 Procure 6 computers and provide annual internet bundles.	Number of computers procured and connected to internet.	Availability of procurement documents	Availability of funds	MOHCDGEC, MoF and IPs	NTLP	MOHCDGEC, MoF, and IPs	24,720,000				
2.4.14 Upgrade zonal laboratories infrastructure to accommodate phenotypic and genotypic DST performance.	Number of zonal laboratories upgraded	Upgrading reports	Availability of funds, Partners prioritization	MoHCDGEC, MoF, /TBA and IPs	NTLP	MoHCDGEC and IPs	404,673,946				

Appendix 2: TB Laboratory Network Operational Plan 2021–2022 Development Workshop Participant List

No	Name	Title	Institution
1	Dr. Riziki Kisonga	Program Manager	NTLP
2	Mr. Reginald Julius	Head of Laboratory Services	MoHCDGEC
3	Dr. Alex Magesa	Deputy Director Diagnostic Services	MoHCDGEC
4	Dr. Andrew Kilale	Principal Research Scientist	NIMR
4	Mr. Emmanuel Nkiligi	M&E Officer	MoHCDGEC
5	Mr. Edgar Luhanga	Laboratory Diagnostic Network Coordinator	MoHCDGEC
6	Dr. Leobrate Mleo	Deputy Program Manager	NTLP
7	Mr. Amri Kingalu	Laboratory Manager	CTRL
8	Dr. Siril Kullaya	Team Lead	USAID-IDDS
9	Mr. Samwel Mulungu	TB Diagnostic Specialist	USAID-IDDS
10	Ms. Mary Emmanuel	Senior Program Assistant	USAID-IDDS
11	Mr. Nicodem Mgina	Assistant GeneXpert Focal Person	CTRL
12	Mr. Said Mfaume	GeneXpert Focal Person	CTRL
13	Mr. Jabir Muhsin	Quality Officer	CTRL
14	Ms. Daphne Mtunga	Laboratory Technologist	CTRL
15	Ms. Maryjesca Mafie	Laboratory Technologist	CTRL
16	Ms. Naima Mkingule	Head Of Laboratory Services	MZRH
17	Ms. Tulalumba Lwesya	Laboratory Scientist	MZRH
18	Ms. Jacquiline Mwombeki	Laboratory Scientist	MZRH
19	Mr. Regan Mmasi	Laboratory Scientist	MZRH
20	Mr. Husein Mvugalo	TB Zonal Laboratory Scientist	Dodoma
21	Ms. Linah Ndumizi	Quality Officer	Dodoma
22	Ms. Yuritha Barnabas	Laboratory Manager	Dodoma
23	Mr. Japhet Shigella	Laboratory Scientist	NPHL

No	Name	Title	Institution
24	Mr. Geofrey Japhet	Laboratory Scientist	BMC
25	Mr. John Dafi	Laboratory Manager	BMC
26	Ms. Sabrina Mhagama	TB Zonal Laboratory Scientist	BMC
27	Ms. Sarapia Paul	Laboratory Scientist	Kibong'oto
28	Mr. Mpoki Jonas	TB Zonal Laboratory Scientist	Kibong'oto
29	Mr. Richard Kinyaha	Quality Officer	Kibong'oto

Appendix 3: Agenda for the Workshop to Develop TB Laboratory Network Operational

Day 3: Wednesday, August 25,2021

Plan 2021–2022

Day 1: Monday, August 23, 2021		
Time	**Description**	**Faculty**
8:00–8:30	Registration	IDDS
8:30–8:45	Opening remarks and welcoming speech	MOHCDGEC
8:45–9:15	Workshop objectives: ● Strategic versus operational planning ● Review of National TB/Leprosy & TB Laboratory Strategic plans	Amri Kingalu/Dr. Siril Kullaya
9:15–10:00	Overview of zonal TB Laboratory baseline assessment findings and proposed actions towards expanding accreditation scope	Samwel Mulungu
10:00-10:30	**Tea/Coffee**	**Organizers**
10:30–12:00	Roles and responsibilities zonal TB laboratories-contribution National Strategic plan and to achieving National and International Targets	Samwel Mulungu
12:00–1:00	Questions and answers, how to develop operational plan and formulation of working groups	**All**
1:00–2:00	**Lunch**	**Organizers**
2:00–3:00	Group work 1: situational analysis	All
3:00–3:30	**Tea/Coffee**	**Organizers**
3:30–5:00	Group work presentation-situational analysis	**Amri Kingalu**
Day 2: Tuesday, August 24, 2021		
8:00–8:30	Recap of Day 1	Participants
8:30–9:30	Group work 2: formulation of goals and objectives	Samwel Mulungu
9:30–10:30	Group work presentation-goals and objectives	
10:00–10:30	**Tea/Coffee**	**All**
10:30–1:00	Group work 3: formulation and presentation of activities and sub activities	Dr. Andrew Kilale
1:00–2:00	**Lunch**	**All**
2:00–3:30	Group work 4: costing of the sub activities	All
3:30–3:45	**Tea/Coffee**	**Organizers**
3:45–5:00	Group presentation of the work plan budget	Group leads

08:30 AM	09:00 AM	Day 2 recap	Selected members for day 2
09:00 AM	10:00AM	Final report presentation and discussion	Dr. Kilale
10:00 AM	**11:00AM**	**Nutritional Break**	**All**
11:00 AM	11:30 AM	Presentation of laboratory operation plan status	Edgar Luhanga/Amri Kingalu
11:30 AM	13:00 PM	Group work	All
13:00PM	**14:00 PM**	**Nutritional Break**	**All**
14:00PM	16:00 PM	Group work	All
Day 4: Thursday, August 26, 2021			
8:30 AM	09:00 AM	Day 3 recap	Selected members for day 3
09:00 AM	10:00 AM	Group work finalization	All
10:00 AM	**10:30 AM**	**Nutritional Break**	**All**
10:30 AM	13:00 PM	Group work presentation and discussion	All
13:00 PM	**14:00 PM**	**Nutritional Break**	**All**
14:00 PM	17:00 PM	Group work presentation and discussion	All
Day 5: Friday, August 27,2021			
8:30 AM	9:00 AM	Day 4 recap	Selected members for day 4
9:00 AM	10:00 AM	Operational plan compilation and finalization	Dr Kilale
10:00 AM	11:00 AM	Nutritional Break	All
11:00 AM	13:00 PM	Final Operational plan presentation and discussion	Dr Kilale
13:00 PM	14:00 PM	Nutritional Break	All