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MINISTRY OF HEALTH

NATIONAL TUBERCULOSIS AND LEPROSY PROGRAM

Tuberculosis Diagnostic Network Assessment report

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LIST OF ABBREVIATIONS

AFB	Acid-fast Bacilli
BSC	Biosafety Cabinet
CHMT	Council Health Management Team
CTRL	Central Tuberculosis Reference Laboratory
DDH	Designated District Hospital
DST	Drug Susceptibility Testing
DTLC	District TB and Leprosy Coordinator
EQA	External Quality Assessment
ETL	Electronic TB and Leprosy Register
FL	First Line
GIS	Geographic Information System
GLI	Global Laboratory Initiative
HCW	Health Care Worker
IDDS	Infectious Disease Detection and Surveillance
IPC	Infection Prevention and Control
IQC	Internal Quality Control
IRL	Intermediate Reference Laboratory
KPI	Key Performance Indicator
LF-LAM	Lateral Flow Lipoarabinomannan
LIS	Laboratory Information Management System
LPA	Line Probe Assay
M&E	Monitoring and Evaluation
MDR-TB	Multidrug-resistant Tuberculosis
MOH	Ministry of Health
MSD	Medical Stores Department
MTB	Mycobacterium Tuberculosis
NLSP	National Tuberculosis Laboratory Strategic Plan
NSP	National Tuberculosis and Leprosy Strategic Plan
NTLP	National Tuberculosis and Leprosy Program
NTLP	National Tuberculosis and Leprosy Program
QMS	Quality Management System
QMS	Quality Management System
RHMT	Regional Health Management Team
RHMT	Regional Health Management Team
RIF	Rifampicin
RR	Rifampicin Resistant
RRH	Regional Referral Hospital

RTLC	Regional TB and Leprosy Coordinators
SL	Second Line
SOP	Standard Operating Procedure
TAT	Turnaround time
TB	Tuberculosis
USAID	United States Agency for International Development
WHO	World Health Organization
ZIHHTLP	Zanzibar Integrated HIV, Hepatitis, TB, and Leprosy Program

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EXECUTIVE SUMMARY

Introduction

Tuberculosis (TB) remains a disease of public health importance and is one of the top 10 causes of death worldwide. In 2019, 10 million people fell ill with TB, and 1.4 million died from the disease (including 208,000 people living with HIV). Multidrug-resistant TB, which is a laboratory diagnosis, remains a public health crisis and a health security threat. The World Health Organization (WHO) estimates that in 2019 alone, there were 465,000 new cases with resistance to rifampicin—the most effective first-line drug, of which 78 percent had multidrug-resistant TB. An estimated 58 million lives have been saved through TB diagnosis and treatment between 2000 and 2018 (WHO, 2020).

TB continues to be a major public health problem in the United Republic of Tanzania. The country is among the 30 high-burden TB countries in the world. The national TB prevalence survey conducted in November 2012 revealed higher TB burden, with a prevalence of 295 cases per 100,000 among adults older than 15 years of age. However, the most recent WHO modeled estimates show that the prevalence of all forms stands at 528 per 100,000, with incidence of 327 per 100,000 and case detection rates determined at 79 percent. In 2019, a total of 81,000 cases of all forms were notified, which is an increase of 5,155 cases or 6 percent, compared to 2018. An estimated 56,000 cases went unnotified in 2019 (WHO, 2020).

The National TB and Leprosy Program (NTLP) has launched a new National TB and Leprosy Strategic Plan (NSP), covering the period 2021–2025, which coincides with the implementation of the Health Sector Strategic Plan V. The NSP builds upon the previous NSP and offers a patient-centered plan to end the two diseases in Tanzania (Ministry of Health [MOH], 2018). A strong TB laboratory network will be a key to successfully accomplishing the objectives of the new NSP.

Objectives

The main objectives of the assessment were to review the diagnostic network, current practices, and algorithms; identify challenges that prevent the overall diagnostic network from performing efficiently and effectively; and propose evidence-based interventions to improve the overall ability of the TB diagnostic network to meet the goals and targets of the NSP.

Methods

The assessment included consultations with the MOH, NTLP, Central TB Reference Laboratory (CTRL), and other stakeholders at the national level, and included site visits to a total of 35 TB diagnostic and clinical facilities in 12 geographical regions. Regions, districts, and facilities were selected by the NTLP and the CTRL, with the aim of including a range of laboratories at varying levels of the health system. The assessment used an assessment tool (TB-Net Tool) that uses semi-quantitative scoring to identify the stage of various aspects of the diagnostic network to describe current capabilities and identify key areas for improvement. The assessment team reviewed the self-assessed staging conducted by the program, visited various facilities, and consulted numerous stakeholders to assess the functionality and performance of the national TB diagnostic network from the perspective of its ability to meet the needs of the country's NSP.

General Findings

- An organized and structured TB diagnostic network is in place with clearly defined tiers with specific roles and responsibilities and led by a strong CTRL, which performs essential clinical and public health functions.
- Collaboration between the HIV and TB programs is working very well and leading to excellent linkage to testing and care for patients. The detection of TB among people living with HIV could be improved by widespread use of the lateral flow lipoarabinomannan test.
- The laboratory network has many suitable and up-to-date policies and guidelines, but they are not fully implemented at all levels of the diagnostic network.
- TB diagnostic tests are provided for free in public sector facilities for people being evaluated for TB, although patients may pay for chest X-rays. In some settings, there did not appear to be a functional linkage of persons with an abnormal chest X-ray to TB diagnostic services.
- Standardized forms are used to collect information on key quality measures and performance indicators, but the data are not routinely reviewed, analyzed by the laboratory staff, and used for improving laboratory testing. There was a lack of dedicated staff for data management in some levels, as well as a lack of training on data management for laboratory staff.

- Specimen referral systems play a critical role in ensuring access to laboratory services. However, it was observed that proper triple packaging was not used for all specimen referrals, and there were frequent stockouts of packaging materials. Standard operating procedures for specimen referral processes were not fully available, the quality of specimens received at the testing laboratory was a challenge in some settings, and there were delays in the return of results from zonal laboratories, which led to a prolonged turnaround time for Xpert testing (average of four to seven days).
- During verification visits, there were reports of stockouts in reagents for acid-fast bacilli, culture, first-line and second-line line probe assays, and chemistry tests as well as triple packaging materials and GeneXpert cartridges. Also, laboratories do not routinely conduct lot- to-lot verification to ensure the quality of reagents.
- A national biosafety and biosecurity manual which addresses TB safety issues was not available, and biosafety cabinets at regional and local levels were out of repair or not recently certified. Biosafety officers at local facilities reported having minimal training. Many facilities did not have a program for routine screening (at least yearly) of workers for signs and symptoms of TB.
- The diagnosis of pediatric TB was challenging in many settings because there was a lack of capacity for, and training in, collecting specimens from children.
- Most laboratories reported having an adequate number of staff; however, there is no national staffing plan supported by workforce projections. Many facilities reported a lack of refresher training for staff and that there was not a system in place to assess and document the competency of staff.

Recommended Key Interventions and Priority Actions

The assessment team recommends that the NTLP and the CTRL prioritize and consider immediate action to implement the following key recommendations. Specific, detailed recommendations are provided for each diagnostic network core capability in the report.

1. **Establish/operationalize a reliable specimen referral system.**

   Specimen referral systems play a critical role in ensuring access to laboratory services by allowing patients to receive care and treatment at one location, while their specimens are transferred to various levels of a tiered laboratory system for testing. Referral systems can efficiently increase access to diagnostics in areas where testing is not available, prevent the need and associated costs for patients to travel, and lead to equity in access to health care. Many sites visited had specimen referral systems at least partially in place for HIV/TB. To build on this, the country should further develop national guidelines for an integrated specimen transport and referral system for TB, HIV,

and, where possible, other diseases. These guidelines should include a monitoring and evaluation framework with standardized indicators to routinely monitor and evaluate to ensure that the system is meeting the needs of both TB and HIV programs. The country should also ensure that all persons involved in specimen transport are trained on standard operating procedures for specimen collection, packaging, referral, and documentation and that all facilities have adequate supplies of proper triple packaging materials.

2. **Strengthen policies, procedures, and practices to ensure the safety of workers.**
   Ensuring safe working conditions in TB laboratories begins with developing national biosafety and biosecurity policies, manuals and enforcing the policies at all levels of the laboratory network. The MOH, the NTLP, and the CTRL should accelerate finalization and dissemination and training to all biosafety officers throughout the network.

   An important aspect of worker safety, which was lacking in many of the facilities visited, is screening for laboratory- or hospital-acquired TB infections. A program for conducting annual screening of health care workers for signs and symptoms of TB and documenting results in personnel files should be instituted in all TB facilities.

3. **Improve the supply chain.**
   Reliable supply of quality-assured laboratory commodities is essential in a well-functioning laboratory system. During verification visits, there were reports of stockouts in reagents for acid-fast bacilli, culture, first-line and second-line line probe assays, and chemistry tests as well as triple packaging materials and Xpert cartridges. Laboratories do not routinely conduct lot-to-lot verification to ensure the quality of reagents. The network should formalize reporting of stockouts and expiration and initiate corrective actions to identify the root cause of the challenges and determine whether they are regional or systemic. The NTLP should work on strengthening capacity for quantification and forecasting of TB diagnostic commodities at all levels (adopt use of electronic quantification tool), as well as fast tracking clearance process of the imported TB diagnostic commodities in close collaboration with the Medical Stores Department and the Government Procurement Services Agency. The NTLP should secure enough funds for covering diagnostic TB commodities.

4. **Expand the use of quality data to improve program performance.**
   The appropriate and consistent use of quality data will strengthen the capacity of the program, including understanding TB diagnostic needs across populations and sectors; evaluating the competency of various cadres of staff; monitoring resources, equipment, and supplies; and tracking progress and areas for improvement.

Standardized forms were used to collect information on key quality indicators and performance indicators, but the data were not routinely reviewed and analyzed by the laboratory staff.

Key performance indicators should be tracked and monitored for all aspects of laboratory testing at all levels of the laboratory system to improve program performance. Laboratory staff should be empowered to review and analyze key performance indicators to enable them to monitor their testing and promptly initiate corrective action as needed. The use of electronic data systems (e.g., GxAlert) for collecting data and monitoring key performance indicators should be expanded.

5. **Strengthen the clinical-laboratory interface.**
   Clinical activities, from screening of persons for signs and symptoms of TB to collecting specimens, are important aspects of the diagnostic cascade. in some settings, there did not appear to be a functional linkage of persons with abnormal chest X-rays to TB diagnostic services, and some sites mentioned in adequate training on chest X-ray interpretation. Collaboration should be established between facilities with trained X-ray experts and those without at all levels so that they could provide training and technical assistance in the interpretation of chest X-ray findings to the facilities lacking X-ray experts.

6. **Ensure availability of well-trained, competent laboratory workers.**
   Most laboratories reported having an adequate number of staff; however, there was no national staffing plan supported by workforce projections. Many facilities reported a lack of refresher training for staff and that there was no system in place to assess and document the competency of staff. Priority actions should include developing a national staffing plan for TB laboratories supported by workforce projections and developing a comprehensive program to provide refresher training to all laboratory workers and to assess and document staff competency.

   Implementation of the recommended key interventions and priority actions should be guided by several cross-cutting principles. These include the following:
   - Developing aggressive, bold policies and interventions in alignment with the End TB Strategy and mobilize commensurate resources
   - Finding efficiencies, optimizing test utilization, and improving access to existing services, to build a strong foundation for the rapid scale-up of laboratory and other diagnostic testing

- Analyzing existing services and deploying what is available now, while planning and continuing to evaluate new tools and approaches (e.g., phenotypic and molecular drug- susceptibility testing, next generation sequencing)
- Shifting the focus of diagnostic TB services from the health system to the patient, including the complete cascade from screening to treatment completion
- Emphasizing translation of policies into action and putting in place comprehensive systems with adequate resources to closely monitor implementation
- Managing change within diagnostic network and laboratory personnel to ensure the acceptance and effective implementation of the strengthened diagnostic network

Next Steps

The findings and recommendations from the assessment are extensive and will require the MOH, the NTLP, and the CTRL to lead and coordinate efforts among all stakeholders, including technical partners and donors. Recommended activities or interventions should be prioritized by establishing a detailed action plan with time-bound deliverables and specified roles and responsibilities of various stakeholders. The implementation of this plan should be reviewed periodically and adjusted as needed.

The recommended key interventions and priority actions described in this report will assist Tanzania to reach its TB diagnostic goals with the aim of eliminating TB by 2030.

1.0 INTRODUCTION

1.1 Tuberculosis Burden in the United Republic of Tanzania

Tuberculosis (TB) remains a disease of public health importance and is one of the top 10 causes of death worldwide. In 2019, 10 million people fell ill with TB, and 1.4 million died from the disease (including 208,000 people living with HIV). Multidrug-resistant TB (MDR-TB), which is a laboratory diagnosis, remains a public health crisis and a health security threat. The World Health Organization (WHO) estimates that in 2019 alone, there were 465,000 new cases with resistance to rifampicin (RIF)—the most effective first-line drug—of which 78 percent had MDR-TB. An estimated 58 million lives have been saved through TB diagnosis and treatment between 2000 and 2018 (WHO, 2020).

TB also continues to be a major public health problem in the United Republic of Tanzania. The country is among the 30 high-burden TB countries in the world. The national TB prevalence survey conducted in November 2012 revealed higher TB burden, with a prevalence of 295 cases per 100,000 among adults older than 15 years of age. However, the most recent WHO modeled estimates show that the prevalence of all forms stands at 528 per 100,000 with incidence of 327 per 100,000 and case detection rates determined at 79 percent. In 2019, a total of 81,000 cases of all forms were notified, which is an increase of 5,155 cases or 6 percent, compared to 2018. An estimated 56,000 cases went unnotified in 2019 (WHO, 2020).

1.2 The National TB Strategic Plan

The National TB and Leprosy Program (NTLP) launched a new National TB and Leprosy Strategic Plan (NSP), covering the period 2021–2025, which coincides with the implementation of the Health Sector Strategic Plan V. The NSP builds upon the previous NSP and offers a patient-centered plan to end the two diseases in Tanzania (Ministry of Health [MOH], 2018).

The country has adopted WHO-recommended diagnostics, including Ziehl-Nelsen Microscopy, Xpert Mycobacterium tuberculosis (MTB)/RIF, line probe assay (LPA), and culture. The main challenge to attaining universal access to drug susceptibility testing (DST) is the limited access to rapid diagnostic tests using Xpert MTB/RIF and underutilization of available GeneXpert machines, and hence the risk of initiating resistant TB cases on first-line TB medicines.

The NSP has nine specific objectives:

7. To increase TB treatment coverage from 53 percent in 2018 to 90 percent by innovatively addressing barriers to access, utilization, and the needs of the key and vulnerable populations for TB care and prevention services.
8. To expand access to quality TB diagnostic services, including the adoption of new diagnostic technologies.
9. To maintain the proportion of childhood TB among the notified cases at 15 percent, increasing the ratio of TB incident cases for ages 0–4:5–14 to 1.5.

10. To increase rifampicin-resistant (RR)/MDR-TB cases detected and enrolled for treatment from 48 percent to 90 percent of the estimated cases among notified cases.
11. To strengthen management of comorbidities, including collaborative TB/HIV activities and prevention of persons at high risk.
12. To strengthen TB services to miners and their families.
13. To reduce leprosy prevalence in all endemic councils.
14. To ensure the availability of supportive systems and strengthened program management and coordination for the implementation of TB and leprosy services.
15. To ensure the implementation of evidence-based interventions through institutionalized efficient monitoring and evaluation systems and coordination of research.

1.3 National TB Laboratory Strategic Plan

The objectives of the current National TB Laboratory Strategic Plan (NLSP) are to:

- Increase access to quality-assured acid-fast bacilli (AFB) microscopy.
- Improve the diagnosis of TB among AFB-negative cases, especially among people living with HIV.
- Increase access to rapid laboratory diagnosis among presumptive and TB patients considered at risk for MDR-TB and extensively drug-resistant TB.
- Establish laboratory quality management systems. Targets of the NLSP include the following:
- 90 percent of new and relapse TB patients tested using WHO-recommended rapid tests at time of diagnosis.
- 90 percent of notified new and relapse TB cases with bacteriological confirmation.
- 100 percent of laboratories showing adequate performance in external quality assessment (EQA) for smear microscopy among the total number of laboratories that undertake smear microscopy during the reporting period.

1.4 TB Diagnostic Network

A comprehensive, high-quality TB diagnostic network is essential to diagnose TB accurately and rapidly and to link confirmed TB patients to appropriate and timely treatment. Laboratories and laboratory services are key components of a well-functioning diagnostic network; however, a laboratory test is just one part of the diagnostic process (Figure 1).

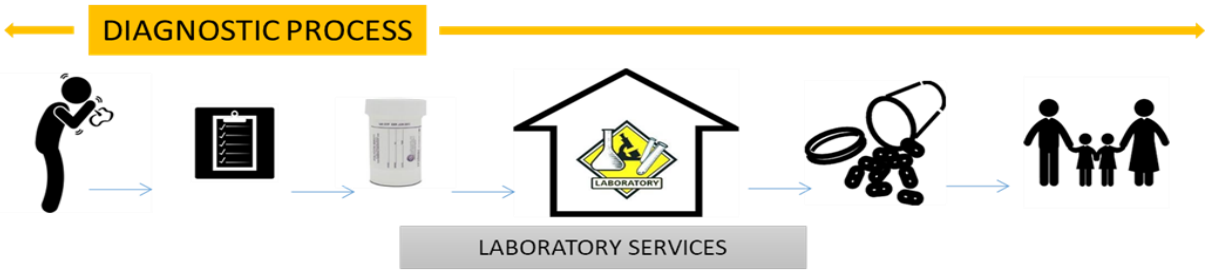


Figure 1. The TB diagnostic cascade

The diagnostic process starts with a person experiencing symptoms and deciding 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 a TB program and all levels of TB or general laboratories. The network encompasses all points through which community members seek care—both in the public and private sectors and among formal and informal providers.

1.3.1-Tiered Network of TB Laboratories

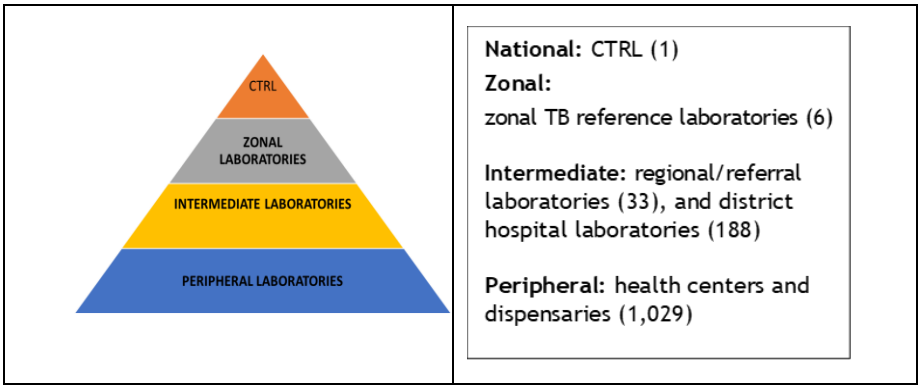


Figure 2. Organization of TB laboratory services in Tanzania

The network includes the CTRL and six zonal TB laboratories serving six zones in the country (Southern Highlands Zone, Lake Zone, Northern Zone, Eastern Zone, Central Zone, and Zanzibar). The CTRL also serves as a zonal laboratory for Eastern Zone. There are 221 intermediate laboratories at regional and district levels and 1,029 peripheral-level laboratories. All intermediate and peripheral laboratories perform sputum smear microscopy. Rifampicin resistance-TB (RR-TB) cases diagnosed on the GeneXpert platform are referred for culture and DST at zonal laboratories and the CTRL.

The CTRL and some zonal laboratories are equipped with both culture and LPA. The CTRL oversee the implementation of EQA at all levels within the network. The CTRL is also linked to the Supra-National Reference Laboratory in Uganda for supervisory and technical support. The zonal-level laboratories supervise and provide technical support to intermediate-level laboratories and peripheral laboratories.

Rollout of Xpert MTB/RIF for diagnosis of TB and MDR/RR-TB under the NTLP has succeeded in placing 254 GeneXpert systems in 218 facilities, covering the public, private, Faith Based Organization (FBO) and military health facilities at all levels. To improve access to rapid and accurate detection of TB, an integrated specimen transportation system has been developed.

2.0 NATIONAL TB DIAGNOSTIC NETWORK ASSESSMENT

The MOH in collaboration with the United States Agency for International Development (USAID), invited a group of laboratory, diagnostic network, and TB program experts to assess the TB diagnostic network in Tanzania.

2.1 Rationale

The NSP identified the following as the major challenges for the TB diagnostic network:
Attaining full test scopes on ISO15189:2012 accreditation at the CTRL and the zonal laboratories. Meeting biosafety and biosecurity standards at all levels. Achieving universal access to WHO-recommended TB diagnosis. Receiving timely diagnosis and results feedback due to a fragmented specimen transportation system.

2.2 Objectives

This assessment comprehensively evaluated the TB diagnostic network, including policies and guidance, laboratory infrastructure, and placement and use of diagnostic technologies, data management, and quality management systems (QMS) in the laboratories. It assessed the functionality and performance of the national TB diagnostic network from the perspective of its ability to meet the needs of the country's NSP. The assessment did not assess the performance of individual laboratories and facilities.

The key objective of the assessment was to evaluate the current practices, policies, and algorithms and propose evidence-based, short- to medium-term interventions to improve access, capacity, and quality of the TB diagnostic network to increase detection of TB, TB/HIV, MDR-TB, and TB in children.

2.3 Expected Outputs

Two major outputs were expected to be delivered by the team at the end of the assessment: Evidence of the strengths and limitations of the TB diagnostic network at all levels of the health system to contribute to NSP priorities and reach the NSP targets. Evidence-based and results-oriented recommendations that can be operationalized for a strengthened TB diagnostic network. The deliverable includes a final detailed report of recommendations in line with the NSP to inform the development of a TB diagnostic network operational plan that serves as the roadmap for the MOH, the NTLP, the CTRL, the subnational level program, donors, and technical partners.

2.4 Assessment Team

The assessment was conducted by a group of external TB laboratory and diagnostic network experts (i.e., persons not associated with the TB program or diagnostic network being evaluated), as well as internal program and laboratory experts associated with the national program or laboratory network of Tanzania (Table 1). Consultants were chosen to represent the range of diagnostic network components including laboratory services and testing algorithms, quality assurance, clinical linkages, public/private.

Integration, diagnostic data management, specimen referral, commodity and logistics management, and biosafety. External consultants came from a variety of organizations or were independent. Internal (i.e., NTLP-affiliated) assessors represented the many levels of the NTLP, including the national program, CTRL, technical agencies and organizations, and private hospitals. All efforts were made to ensure that there were no conflicts of interest for any of the assessors.

Table 1. TB diagnostic network assessment team members

Name	Organization	Name	Organization
Sode Matiku	Consultant	Onna Panga	MOH
Salim Bossy	CTRL	Edward Shogolo	CTRL
Bryson Malewo	CTRL	Reginald Julius	MOH
Siril Kullaya	USAID-IDDS	Davis Lumisha	Consultant
Peter Torokaa	MOH	Herbert Mutunzi	Consultant
Samwel Mulungu	USAID-IDDS	Nicholaus Mnyambwa	Consultant
Zubeida Salum	MOH	Raymond Shirima	CTRL
Zablon Nkika	Consultant	Salum Ali	Ministry ofHealth Zanzibar
Peter Mashosho	President's Office, Regional Administration and Local Government Tanzania	Ester Shija	MOH
Method Mutakyamilwa	MOH	Liberate Mleoh	NTLP
Fredrick Kangave	Consultant	Basra Doulla	CTRL
Edgar Luhanga	NTLP	Amri Kingalu	CTRL

2.5 Sites and Facilities Visited

The assessment covered the NTLP and other stakeholders at the national level, the CTRL, regional referral laboratories, district hospitals, and peripheral laboratories. A total of 35 facilities in 12 geographical regions (Table 2). Regions, districts, and facilities were selected by the NTLP and the CTRL, with the aim of including a range of laboratories at varying levels of the health system, including private sector and non-governmental organization TB diagnostic facilities. The sites visited are listed in Annex 1.

Table 2. Summary of sites visited during assessment of the TB diagnostic network

Team	Region	Laboratories Visited
A	Mbeya	• Mbeya Zonal Referral Hospital • Mbeya Regional Referral Hospital
	Kagera	• Amenye Dispensary (private) • Ruanda Health Centre • Zamzam Health Centre • Nyakahanga District Hospital • Kayanga Health Centre
	Dar es Salaam	• St. Theresa Health Centre (private) • Central TB Reference Laboratory • Ukonga Dispensary (prison facility)
B	Morogoro	• Morogoro Regional Referral Hospital • Sabasaba Health Centre • St. Francis Turian Designated District Hospital
	Dar es Salaam	• Regency Lancet Laboratory
	Zanzibar	• Mnazi Mmoja Regional Referral Hospital • Al-rahma Private Hospital • Kivunge District Hospital • Mpendaye Health Centre • Pemba Public Health Laboratory • Abdallah Mzee Hospital • Chake District Hospital
C	Dodoma	• Dodoma Regional Referral Hospital
	Singida	• Singida Regional Referral Hospital • Sokoine Health Centre • Tumaini Health Centre
	Mwanza	• Sekouture Regional Referral Hospital • Bugando Medical Centre
D	Tanga	• Mombo Health Centre
	Kilimanjaro	• Kibong'oto Infectious Disease Hospital
	Arusha	• Arusha Regional Referral Hospital • Shree Hindu Charitable Hospital • Selian Lutheran Hospital
	Manyara	• Mererani Health Centre • Simanjiro Health Centre
	TOTAL	**35**

The following topics were assessed:

1. Overall placement, quantity, and use of appropriate diagnostic technologies.
2. Availability and use of correct diagnostic algorithms, guidelines, and policies, including testing for HIV-positive patients and pediatric patients.
3. Laboratory infrastructure and appropriate biosafety measures.
4. Specimen transportation and results feedback mechanisms.
5. Equipment validation and maintenance.
6. Management of laboratory commodities and supplies.

7. Laboratory/diagnostic network information and data management systems.
8. Laboratory QMS.
9. Quantity and quality of trained staff throughout the network.
10. Supervision, monitoring, and quality assurance.

Assessment of these topics and the TB diagnostic network relied on the use of the TB Diagnostic Network Assessment Tool.

3.0 TB DIAGNOSTIC NETWORK ASSESSMENT TOOL

3.1 Background

The TB Diagnostic Network Assessment Tool (TB-Net Tool) was developed to assess the functionality of a national TB diagnostic network from the perspective of its ability to meet the needs of the country's NSP for TB. The tool uses semi-quantitative scoring to identify the "capability" stage of various aspects of the diagnostic network to describe current capabilities and help identify key areas for improvement.

3.2 Diagnostic Network Standards, Core Capacities, and Components

The foundation of the TB-Net Tool is a set of standards that provides a measure of the quality and capabilities of a diagnostic network. The standards are based on the national TB diagnostic network standards and assessment tools developed and piloted by the Global Laboratory Initiative (GLI) and partners;

1. Which were based on an earlier GLI assessment tool focusing on TB microscopy laboratory networks.

2. For each standard, core capacities and components are used to define essential features and functions of a national diagnostic network designed to detect, assess, notify, and respond to TB (Annex 2). The core capacities and components are adapted from the original nine LABNET1 core capacities, which were developed for evaluating national laboratory networks in Africa with respect to achieving global health security targets.

[1] Ondoa, P., et al. A new matrix for scoring the functionality of national laboratory networks in Africa: introducing the LABNET scorecard. African Journal of Laboratory Medicine, 5, Oct. 2016. http://www.ajlmonline.org/index.php/ajlm/article/view/498/712.

3.3 Questions and Stages

In the TB-Net Tool, standardized questions are used to assess to what degree each component is present to meet the diagnostic network standard. Attributes of each component are used to define six stages of capability, from "completely absent" to "fully compliant with international standards." The stages, based on a Capability Maturity Measurement Model,[2] are quantified using a scoring system (0–5) to provide a semi-quantitative measure of the stepwise progression toward complete fulfillment of each component of a core capacity:

- Stage 0: Absence of attributes that are considered key to the development of inputs and processes needed for the implementation of a functional diagnostic network
- Stage 1: Foundational level includes attributes that are considered key to the development of inputs and processes needed for the implementation of a functional diagnostic network
- Stage 2: Moderate level attributes include inputs and processes needed to build or maintain the diagnostic network
- Stage 3: Strong technical or managerial or organizational capacity and a high level of performance of the diagnostic network with defined public health output and outcomes
- Stage 4: Advanced level; performance of the network is continuously measured and achieves national standards of capability
- Stage 5: Attainment of international standards; systems of revision are in place for continuously improving the diagnostic network

The questions and stages by core capacity and associated components used in the assessment are listed in Annex 3.

3.4 Determining the Capability Stage and Progress toward Achieving Core Capacities

A capability stage is determined for every question of a component (Figure 3).

Core Capacity 4. Diagnostic Algorithm								
No.	**Questions**	**Stage**						
		0	**1**	**2**	**3**	**4**	**5**
Component 4.1. Algorithm							
4.1.1	Is a national TB diagnostic algorithm available that is responsive to the epidemic, patient-centered, and based on international best practice?				☐		
4.1.2	Does the algorithm address the laboratory goals of the End TB strategy to increase access to rapid detection of TB and to reach universal access to DST?					☐	
4.1.3	Does the algorithm focus on the whole diagnostic cascade, from screening to treatment completion?						☐

[2] Watts H. Characterizing the software process. A maturity framework. Technical report CMU. SEI-87TR- 11. ESD-TR-87-112. June 1987.

4.1.4	Are health care workers provided with standardized sensitization content (e.g., algorithm diagrams, brochures, training materials)?		□				
4.1.5	Are diagnostic tests ordered according to standard diagnostic algorithms and based on national policy and patient factors?			□			

Figure 3. Determining a capability stage for each question

This qualitative analysis can provide a quick visual assessment of the status of individual components and identify areas that need strengthening. To provide an assessment of the progress toward achieving a strong diagnostic network, progress toward reaching Stage 5 (or 100 percent capability) is calculated for each core capacity.

Figure 4 is an example of how to determine progress toward achieving 100 percent capability for the core capacity of diagnostic algorithm and laboratory-clinical interface:

- Translate each question's capability stage into points. For example, question 1 contributes
- points, question 2 contributes 4 points, etc.
- Add up the points for all of the questions in the core capacity. In the example, the total is 22 points.
- Calculate the capability percentage as: [(total number of points for all questions in a core capacity) / (total number of questions x 5)] x 100. In the example, the percentage is: [22 / (8 x 5)] x 100 = 55%.

Core Capacity 4. Diagnostic Algorithm	**Component**	**Stage**
Standard: Testing is performed in a manner and in facilities that guarantee safety for the staff, the customers, the community, and the environment. Sufficient materials, means, and skills are available throughout the system to ensure safe and secure procurement, handling, storage, transportation, and disposal of specimens and materials, both in routine as well as in emergency circumstances.	Algorithm: Question 1 Question 2 Question 3 Question 4 Question 5	 3 4 5 2 1
	Detection of TB: Question 1	 3
	Detection of drug-resistant TB Question 1 Question 2	 3 1
	Total	22

Figure 4. Determining progress toward 100 percent capability for a core capacity

This type of analysis will provide practical information on the actions required to achieve 100 percent capability in each core capacity. Note that reaching 100 percent for every core capacity may not be appropriate for all countries.

3.5 Assessment Process

The key objectives of the assessment of the TB diagnostic network were to:

- Review holistically the diagnostic network, current practices, and algorithms.
- Identify challenges that prevent the diagnostic network from performing efficiently and effectively.
- Propose evidence-based interventions to address the identified challenges and the objectives, interventions, and targets of the NSP, to improve the overall ability of the diagnostic network to meet the goals and targets of the NSP.

The assessment was conducted in four stages:

- Pre-assessment data collection and analysis
- Self-assessment of TB diagnostic network core capacities using the TB-Net Tool
- Review of self-assessment and in-country verification by the assessment team
- Review of the findings of the assessment, identification of strengths and weaknesses, and development of evidence-based interventions to improve the TB diagnostic network

3.5.1 Pre-assessment Data Collection and Analysis

National and subnational data on diagnostic and laboratory variables were provided by the CTRL before the assessment. An external consultant compiled, analyzed, and presented the data to the assessment team before the site visits.

Official NTLP and CTRL documents and reports were reviewed prior to the assessment and included the NSP, the most recent annual report, the draft NSP, diagnostic algorithms, and other recording and reporting forms.

Because there were many facilities and sites to visit, where possible, the assessment planned to have facility and site-specific data collected and key variables analyzed and compiled in a usable format for the assessment team prior to the site visits.

3.5.2 Self-assessment Scoring of TB Diagnostic Network

The country used the TB-Net Tool to perform a desk review self-assessment of their capacities in key diagnostic network areas by identifying their capability stage according to predefined criteria (components and questions) for each core capacity (Table 4). The self-assessment was performed about one month prior to the in-country external assessment by a small technical group consisting of the NTLP, the CTRL, and other national-level laboratory experts.

3.5.3 Review of Self-assessment and In-country Verification by the Assessment Team

From June 14 to 25, 2021, the assessment team reviewed and verified the country's self-assessment stages for each component. Data for verification were gathered during visits to predetermined program staff and diagnostic facilities at each level of the TB diagnostic network (CTRL, zonal TB reference and peripheral laboratories) and compiled by the team after the site visits.

A standard list of verification questions for each core capacity and component guided the process (Table 3). To ensure that the assessment team received enough detail on specific diagnostic network components, the verification process included a limited number of topic-specific checklists to supplement the verification questions.

Table 3. Assessment checklists

Verification Checklist	Audience	Purpose
NTLP	National TB program manager	To verify the self-assessed stages
National laboratory	CTRL manager	To verify the self-assessed stages
Intermediate laboratory	Intermediate reference laboratory (IRL) managers	To verify the self-assessed stages
Peripheral laboratory	Peripheral laboratories (e.g., Xpert or microscopy testing sites)	To verify the self-assessed stages
Program	Provincial or district TB program officers	To verify the self-assessed stages
TB clinic	Staff at health facilities and TB clinics	To verify the self-assessed stages
HIV clinic	Staff at HIV clinics and laboratories	To verify the self-assessed stages
Additional checklists		
Specimen referral checklist	Laboratories that refer or receive specimens for testing	To evaluate specimen referral, transport, and results return
Diagnostic data management checklist	National reference laboratory and intermediate reference laboratory staff	To assess data management processes
Clinical-laboratory interface checklist	Clinical and laboratory staff	To assess the interactions of clinical and laboratory staff in the diagnostic cascade
Chest X-ray checklist	Clinical and program staff	To assess the availability and use of chest X-ray in the diagnosis of TB
Private sector checklist	Staff at private sector laboratories and health facilities	To assess the involvement of private sector laboratories and health facilities in the TB diagnostic network
Checklist for ancillary testing for patient monitoring	Staff at TB and HIV clinics and health facilities	To assess the availability of the ancillary testing that is needed for patient care
Pediatric TB checklist	Laboratory and clinical staff involved in diagnosing TB in children	To assess the ability of the network to provide the laboratory testing needed to diagnose TB in children

Each field team was provided a set of tools (including the main assessment tool and accompanying checklists) specific for the types of facilities and individuals planned to be assessed or interviewed in their allocated state or region. The consultants were responsible for collecting the data and verifying the collected information.

Members of the assessment team interviewed national level staff and agencies. The information was collected according to the main assessment tool and supplemental checklists.

3.5.4 Review of the Findings of the Assessment and Development of Recommendations

Feedback on findings from each region was compiled, and a set of key findings and priority interventions were developed by group consensus among the external consultants. A mixed methods approach was used, including qualitative and quantitative data. Findings from both the regional-level and national-level assessments informed the team's final findings and recommendations.

Site- or region-level reports were compiled by the assessment teams based on data gathered using the various assessment tools and informed key findings and recommendations (Annex 4).

4.0 FINDINGS AND RECOMMENDATIONS

The assessment team analyzed national, intermediate, and peripheral-level data and information for each facility. This section includes information on the following:

- Pre-assessment data analysis results
- National TB diagnostic network scorecard results
- Key findings, interventions, and priority actions
- Detailed findings and recommendations by capacity and thematic area
- General considerations for strengthening the diagnostic network and thematic areas Site-specific key findings and recommendations by facility are described in Annex 4.

4.1 Pre-assessment Data Analysis Results

The pre-assessment data analysis results are still pending and will be distributed later as a supplement to this diagnostic network assessment report.

4.2 National TB Diagnostic Network Assessment Results

The capability stages identified for the components of each core capacity during the self-assessment and by the assessment team following the field visits and discussions with key stakeholders are shown in Table 4. Table 5 provides the progress towards 100 percent capability for each core capacity, calculated both for the self-assessment and team assessment. Figure 5 illustrates the comparison of results between the self-assessment and team assessment.

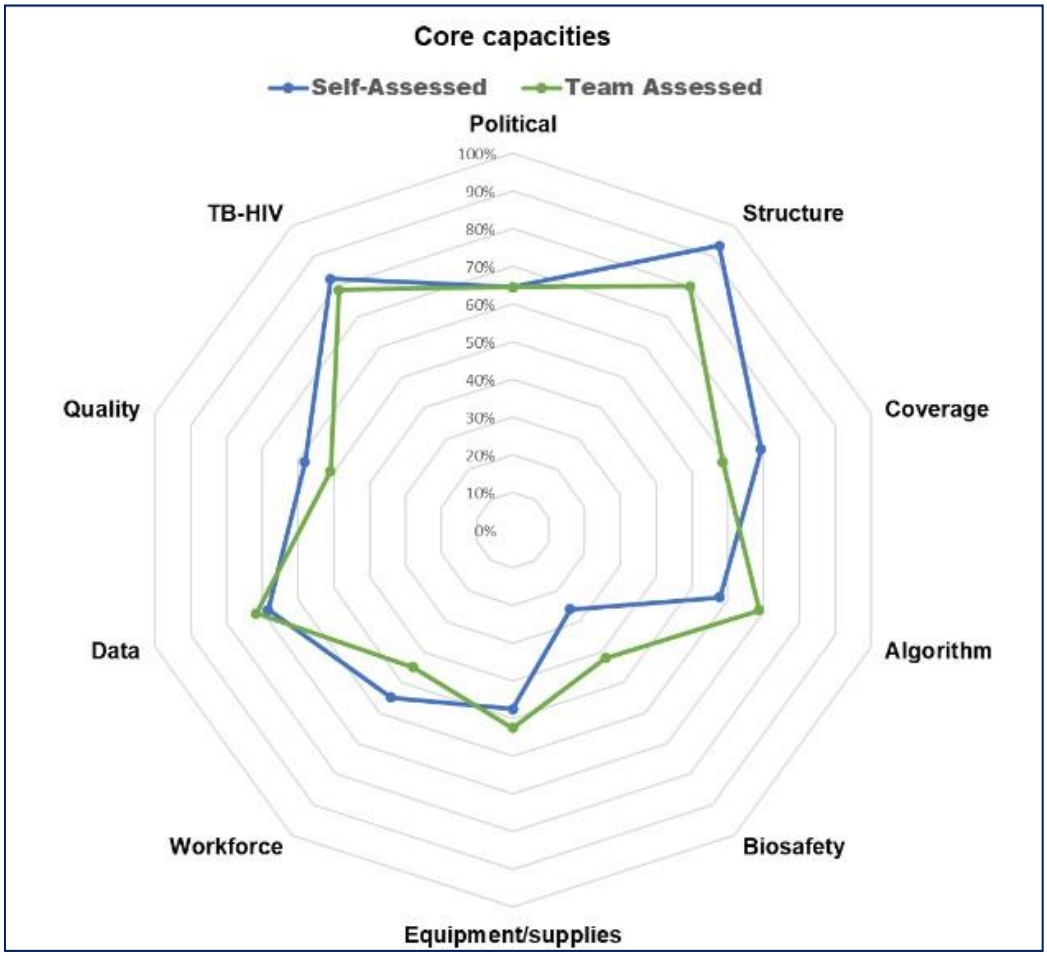
Table 4. Capability stages identified in the self-assessment and team assessment

Core Capacity		Stage		Stage Determining Factors Considered by the External Assessment Team
#	Component	Self	Team	
Capacity 1. Political, legal, regulatory, and financial framework				
1.1	Legislation and policies	4	3	Many policies in place but not implemented at all levels of network.
1.2	National TB policies and plans	1	2	A national TB laboratory policy is available as part of the NLSP (not yet approved).
1.3	Governance	5	4	There is inter-ministerial coordination at the MOH and the President's Office, Regional Administration and Local Government Tanzania.
1.4	Financing and budgets	2	2	Chest X-ray is not free.
Capacity 2. Structure and organization of the diagnostic network				
2.1	Diagnostic network	3	3	Some private, nongovernmental organization, academic, or military laboratories perform TB clinical diagnostic and public health functions.
2.2	Coordination and management	5	3	There is formal communication available but not on a regular basis.
2.3	Programmatic and operational research	5	3	Few studies at the lower level are done to inform decision-making.
Capacity 3. Coverage				
3.1	Diagnostic network coverage	3	2	Lists are available in the Health Facility Registry portal under the MOH but did not list diagnostic tests available at each site.
3.2	Specimen referral system	4	2	Only 38 of 52 facilities reported that standard operating procedures were available and adhered to by all persons involved in specimen transport.
3.3	Linkages	4	4	38 of 40 sites reported that there were formal procedures in place to ensure efficient linkage of persons with presumptive TB to TB laboratory testing.
3.4	Emergency preparedness	0	1	19 of 38 facilities had plans, but most were informal and not written.(Specify facilities and sites-Samwel)
Capacity 4. Diagnostic algorithm				
4.1	Algorithms	1	2	37 of 44 facilities report that training was available.
4.2	Detection of TB	3	4	57 of 62 facilities reported that WHO-Recommended rapid TB diagnostic tests were available to all symptomatic persons.
4.3	Detection of drug-resistant TB	2	3	44 of 62 sites reported that rapid DST available for fluoroquinolones and Amikacin. The CTRL is establishing capacity to test all drugs used in country (i.e., a full panel).
Capacity 5. Biosafety				
5.1	Facilities	3	2	No maintenance plan and power backup available at lower-level facilities.
5.2	Biosafety and biosecurity manual	0	1	Biosafety manuals were available in some visited sites.
5.3	Biosafety systems	2	2	Only 21 of 36 facilities reported screening workers for TB annually.
5.4	Waste management	1	2	Only 2 of 29 facilities did not have access to autoclaves or an incinerator.

Capacity 6. Equipment and Supplies				
6.1	Supply chain management	2	2	13 of 25 sites reported stockouts in the past year.
6.2	Equipment management	1	2	Maintenance plan is available at national level and some lower levels for essential equipment.
Capacity 7. Workforce				
7.1	Education and training	3	2	Pre-service training available, but regular reviews and competence assessment are not done.
7.2	Staffing	0	1	General staffing plan is available but not implemented.
7.3	Human resources strategies and plans	4	2	Key issues are addressed but not regularly reviewed to accommodate needs.
7.4	Competency-based job descriptions	3	3	18 of 30 sites reported having competency-based job descriptions, but competency testing was not routinely done.
Capacity 8. Diagnostic Data Management				
8.1	Data collection forms	4	4	Standardized test forms used in 62 of 64 sites, but only 28 of 36 sites regularly review the data.
8.2	Reporting	3	3	31 of 54 sites had an electronic system for reporting results to clinicians.
8.3	Data connectivity and remote monitoring	4	3	Diagnostic connectivity (GxAlert and Electronic TB and Leprosy Register) available in 19 of 30 sites.
8.4	Data analysis and sharing	3	3	Laboratory data unit available at the national level.
8.5	Surveillance and epidemiology	1	4	Engagement of the CTRL in conducting routine TB surveillance.
Capacity 9. Quality of the Diagnostic Network				
9.1	Documents and document control	1	2	National standard operating procedures available in 23 of 36 facilities.
9.2	Quality assurance	2	2	28 of 36 facilities monitor and evaluate quality indicators.
9.3	Quality management system	3	3	13 of 31 laboratories implementing QMS.
9.4	Certification and accreditation	4	1	There is enforced certification and accreditation program, but it is limited due to budget constraints.
Capacity 10. TB-HIV				
10.1	Legislation and policies	5	4	There is inter-ministerial coordination.
10.2	Structure and organization of the network	5	5	Existence of quarterly TB/HIV technical working group meetings. 55 of 67 sites report a TB/HIV shared specimen referral system.
10.3	Coverage	4	4	Collaborative TB/HIV implementation guideline. Procedures in place in 19 of 20 facilities visited.
10.4	Diagnostic algorithm	0	0	Lateral flow lipoarabinomannan is not being used.
10.5	Workforce	4	4	Appropriate cross-training available in 55 of 64 sites visited.
10.6	Diagnostic data management	3	4	56 of 64 sites reported that TB test request forms contain fields for HIV status.

Table 5. Progress toward 100 percent capability

Core Capacity	Capability Percentage	
	Self-assessed	Team-assessed
1. Political, legal, regulatory, and financial framework	64%	64%
2. Structure and organization of the diagnostic network	93%	80%
3. Coverage	69%	59%
4. Diagnostic algorithm	58%	69%
5. Biosafety	26%	42%
6. Equipment and supplies	48%	53%
7. Workforce	55%	45%
8. Diagnostic data management	58%	72%
9. Quality of the diagnostic network	58%	51%
10. TB-HIV	83%	79%



4.3 Key Findings, Interventions, and Priority Actions

The team assembled the composite data and information from the assessment into six key findings with associated recommended interventions and priority actions.

Key Finding #1:

Specimen referral systems play a critical role in ensuring access to laboratory services by allowing patients to receive care and treatment at one location, while their specimens are transferred to various levels of a tiered laboratory system for testing. Referral systems can efficiently increase access to diagnostics in areas where testing is not available, prevent the need and associated costs for patients to travel, and lead to equity in access to health care.

The assessment team's key findings on the specimen referral system were as follows:

- Proper triple packaging was not fully observed for all specimen referrals, and there were frequent stockouts of packaging materials.
- Standard operating procedures (SOPs) for specimen collection, labeling, packaging, and transport referral are not fully available to all persons involved in specimen transport.
- The quality of specimens received at the testing laboratory was a challenge but for various reasons (quantity, quality, specimen type, leakage).
- Delays in the return of results or feedback from zonal laboratories were observed.

Intervention: **Establish a reliable specimen referral system.**

Priority Actions:

- Ensure that triple packaging materials are available at all sites.
- Ensure the availability and use of SOPs on specimen collection, packaging, referral, and documentation at all levels.
- Provide training on specimen collection, labeling, packaging, and transport referral for all persons involved in specimen transport.
- Document and collect accurate turnaround times (TAT) for all steps of referral and reporting.
    - Emphasize need for prompt return of results to the point of referral.
    - Encourage critical results reporting by phone or electronically using secure official channels—particularly to reduce the TAT for Xpert testing.
- Develop national guidelines for an integrated specimen transport and referral system, including TB, HIV, and possibly other diseases.
- Monitor and evaluate whether the specimen referral system is meeting the needs of the TB program using standardized indicators in a monitoring and evaluation (M&E) framework embedded in national guidelines.

Key Finding #2:

Ensuring safe working conditions in TB laboratories begins with developing national TB biosafety policies and manual and implementing and enforcing the policies at all levels of the laboratory network.

However, a national biosafety manual was not available. Biosafety cabinets (BSCs) at regional

and local levels were out for repair or not recently certified. Biosafety officers at local facilities reported having minimal training. HCWs who come in contact with TB patients and those who work in the TB laboratory are at increased risk of acquiring an MTB infection. Many facilities did not have a program for routine screening (at least yearly) of workers for signs and symptoms of TB.

Intervention: **Strengthen policies, procedures, and practices to ensure the safety of workers.**
Priority Actions:

- Accelerate development and dissemination of a national TB biosafety manual.
- Provide training for all biosafety officers.
- Use the in-country capacity of the National Health Laboratory Quality Assurance and Training Centre, National Calibration Centre, and certified biomedical engineers to regularly certify the BSCs.
- Institute a program for annual screening of HCWs for signs and symptoms of TB and document results in personnel files.

Key Finding #3:

Reliable supplies of quality-assured laboratory commodities are essential in a well-functioning laboratory system. During verification visits, reports were received of stockouts in reagents for AFB, culture, first- line/second-line LPAs, and chemistry tests, as well as triple packaging materials and GeneXpert cartridges. Laboratories do not routinely conduct lot-to-lot verification to ensure the quality of reagents.

Intervention: **Improve the supply chain.**

Priority Actions:

- The CTRL and the NTLP work on quantification and forecasting of TB diagnostic reagents and supplies, including triple packaging materials, as well as fast tracking clearance process of the imported TB consignment in close collaboration with the Medical Stores Department (MSD) and the Government Procurement Services Agency.
- Formalize reporting of stockouts and expiration. Initiate corrective actions to identify the root cause of the challenges and if they are regional or systemic.
- Regional health management teams, council health management teams, and facilities, in collaboration with the NTLP, procure triple packaging materials for specimen transportation.
- Ensure that laboratories perform lot-to-lot verification of reagents. For some consumables (e.g., Xpert MTB/RIF cartridges), lot verification may be done at the national level.

Key Finding #4:

Standardized forms are used to collect information on key quality indicators and performance indicators, but the data are not routinely reviewed and analyzed by the local laboratory staff. Test requisition forms are often not completely filled in, resulting in incomplete laboratory registers. There is no dedicated laboratory staff for TB data management below the national level. Electronic data systems can facilitate patient transactions, data collation, monitor key performance indicators (KPIs), and provide actionable data to all levels of the laboratory network.

Intervention: **Expand the use and analysis of quality data to improve program performance.**

Priority Actions:

- Establish a set of KPIs and targets to be monitored, analyzed, and reported at all levels.
- Track and monitor KPIs for all aspects of laboratory testing at all levels of the laboratory system to improve program performance
- Monitor, evaluate, and improve the timeliness, completeness, and correctness of laboratory data reported to the CTRL.
- Empower laboratory staff to collect and analyze KPIs to enable them to monitor their testing and promptly initiate corrective action as needed. Include these duties in job descriptions.
- Ensure the proper skills and resources are in place for data collection and analysis and that there are adequate resources to carry out collection and analysis.
- Reactivate GxAlert for real-time reporting and quality monitoring at all GeneXpert hubs and harmonize and implement TB laboratory information management systems (LIS) at all facilities with proper and well-coordinated linkages between the CTRL, regional referral hospitals, district hospitals, and peripheral laboratories.

Key Finding #5:

Clinical activities, from screening of persons for signs and symptoms of TB to collecting specimens, are important aspects of the diagnostic cascade. It was observed that the diagnosis of pediatric TB was challenging in many settings because there was a lack of capacity for, and training in, collecting specimens from children. Also, in some settings, there did not appear to be a functional linkage of persons with an abnormal chest X-ray to TB diagnostic services. Some sites mentioned a lack of training on X-ray interpretation.

I*ntervention*: **Strengthen the clinical-laboratory interface.**

Priority Actions:

- Mobilize resources to train and equip facilities to collect suitable specimens from children.
- Provide training on chest X-ray interpretation and strengthen referral system for patients who receive abnormal chest X-rays.
- Establish collaboration between zonal and regional levels so that X-ray experts at zonal-level hospitals could provide technical assistance in the interpretation of X-ray findings at the regional level.

Key Finding #6:

Most laboratories reported having an adequate number of staff; however, there is no national staffing plan supported by workforce projections. Many facilities reported a lack of refresher training for staff and that there was not a system in place to assess and document the competency of staff.

Intervention: **Ensure availability of well-trained, competent laboratory workers.**

Priority Actions:

- Develop a national staffing plan for TB laboratories supported by workforce projections.
- Develop a system to assess and document staff competency. Assessments should be done yearly.
- Develop a comprehensive program to provide refresher training to all laboratory workers.

4.4 Detailed Findings and Recommendations by Capacity and Thematic Area

Because the objective of the assessment was to evaluate the current laboratory and program diagnostic practices and identify issues that may limit the overall diagnostic network from performing efficiently and effectively, this section presents detailed findings and recommendations for each of the 10 capacities that encompass the standards of a comprehensive diagnostic network (Annex 2). One thematic area (specimen referral systems) is included in addition to the 10 capacities.

Note that there is overlap among the capacities—for example, findings and recommendations on optimal utilization of Xpert is both a network structure/organization issue and a network coverage/access issue.

Capacity 1. Political, legal, regulatory, and financial framework

Components: Legislation and policies, national policies and plans, governance, financing

Standard 1. The TB diagnostic network is built on a foundation of political, legal, and regulatory frameworks that supports the achievement of the NSP, organizes and controls all public and private diagnostic services to support the NSP, and provides sufficient, dedicated, and available funding at all levels of the network. Policies are in places that enable continuous, country-wide availability of free, quality-assured TB diagnosis according to the national guidelines.

The assessment found that policies, plans, regulations, and legislation exist for most components of TB diagnosis. There is a comprehensive NSP and a draft NLSP that is aligned with NSP targets and End TB targets. However, policies are not consistently implemented thorough the network.

Specific findings and recommendations are as follows:

Key Findings	Recommendations
• A draft NLSP is available. • Overall, well-structured laboratory network with many policies and guidelines developed. • There was limited awareness of the TB strategic plan and guidelines or adherence to best practices listed in the guidelines at all the visited facilities. • TB diagnostic tests are mostly free, but persons being evaluated for TB often must pay for the chest X-ray, and the role of chest X-ray in the diagnosis of TB is unclear. • In some settings, there did not appear to be a functional linkage of persons with an abnormal chest X-ray to TB diagnostic services. • Some clinical facilities reported a lack of training on the use and interpretation of chest X-rays.	• The CTRL should fast track the approval of the draft NLSP. • Emphasize implementation of policies and guidelines. Do not let guidelines and policies just sit on the shelf. • Develop and disseminate national TB guidelines and tools to ensure that best practices listed in the national TB strategic plan are shared and disseminated in private and public health facilities. An effective way of doing this could be by ensuring that there is a known web page or by leveraging social platforms to link all TB focal persons with key national TB guidelines and new updates in a real-time manner. • Develop and implement a national policy on the use of chest X-ray in the diagnosis of TB, and ensure the availability of quality radiology free of cost. • Establish collaboration between zonal and regional levels so that X-ray experts at zonal-level hospitals could provide technical assistance in the interpretation of X-ray findings at the regional levels.

Although many key documents are available, implementation of policies and guidance are not uniform throughout the diagnostic network.

Chest X-ray is an important entry point into many diagnostic algorithms, especially with respect to triaging presumptive TB patients for further testing. Easily accessible, free-to-the-patient, high quality X- ray services will be essential. A technical working group of programmatic, clinical, and laboratory experts to review the use, costs, and access of chest X-ray services and develop national policies and guidance on the use of chest X-ray in the diagnosis of TB.

Capacity 2. Structure and organization of the diagnostic network

Components: Network structure, coordination and management

Standard 2. A sustainable, rational, and efficient TB diagnostic network provides integrated, essential, quality diagnostic services for patient care and public health. The TB diagnostic network is coordinated by a national reference or public health laboratory and includes the public and private sector as well as community-level diagnostic services. All facilities have clearly defined terms of reference and are adequately supervised.

This core capacity focuses on the structure and management of the TB diagnostic network. Additional aspects of the TB diagnostic network are included in other core capacities (e.g., Capacity 3. Coverage). The tiered TB diagnostic network in Tanzania has defined terms of reference and an agreed-upon mandate for most of the public sector clinical services providers to provide services for the NTLP as part of an integrated TB diagnostic network.

Specific findings and recommendations are as follows:

Key Findings	Recommendations
• An organized and structured TB diagnostic network is in place with clearly defined tiers with specific roles and responsibilities. • The network is led by a strong CTRL that performs essential clinical and public health function. • Engagement of the private sector is growing, but more participation is needed.	• To improve communication between tiers, the CTRL should reactivate regular TB laboratory technical working group meetings at the national and regional levels. • Consider decentralization of CTRL activities to zonal laboratories, such as establishing phenotypic DST capacity at the zonal laboratories to reduce the long TAT for DST. • Consider including private facilities in supportive supervision to strengthen the relationship between private and public laboratories.

The structure of the network and the testing packages available at each level of the network should be tailored to meet the needs of the community and the local epidemiology of TB (i.e., demand-based rather than population-based targets). The roles and responsibilities of each laboratory in the diagnostic network must be clearly defined, preferably in written terms of reference.

Further engagement of the private sector will be important for ensuring that all TB patients are reported to the national program and that all receive quality care.

Capacity 3. Coverage

Components: Diagnostic network coverage, sample referral system, rapid response and preparedness

Standard 3. The national TB diagnostic network provides complete coverage and universal access to TB diagnostic services to the entire population of the country. Referral mechanisms

exist to rapidly and safely refer samples to the appropriate level for testing and to provide timely results to enable initiation of appropriate treatment.

Tanzania's current diagnostic network makes rapid TB diagnostics available to the majority of the population; however, there are gaps in coverage in some regions. In almost all sites visited, there were procedures in place to ensure the linkage of patients to testing and to care.

Understanding the coverage of testing is challenged by the lack of a comprehensive list of TB laboratories that includes geographic information system (GIS) coordinates and descriptions of available equipment and services. Few facilities had continuity of operations plans in case tests could not be performed.

Specific findings and recommendations are as follows:

Key Findings	Recommendations
• Rapid molecular tests for TB and detection of rifampicin resistance were available in most districts. • 38 of 40 facilities reported having procedures in place to ensure efficient linkage of persons with presumptive TB to TB diagnostic service. • 62 of 64 facilities reported having procedures in place to ensure efficient linkage of persons diagnosed with TB or RR-TB to appropriate care and treatment. • Maps or lists of facilities with locations, contact information, available equipment, and services were not available at many facilities. • Only 19 of 33 facilities had continuity of operations plans in case testing could not be performed. Most were informal arrangements without a written plan.	• Create and disseminate an up-to-date list of all TB facilities that includes GIS coordinates, contact information, and a current inventory of diagnostic tests and equipment. • The CTRL should assist facilities to develop written plans for continuation of services in case of emergency situation.

An inventory of GIS-mapped TB laboratories (including current inventory of diagnostic tests and instruments) should be useful to the program for strategic planning, allocating resources, and planning for continuation of TB services in case of service disruptions. For example, the inventory of laboratories and current GeneXpert instruments and test volumes may identify under-utilized and over-utilized instruments and opportunities to redistribute instruments to improve the efficiency of testing.

Thematic area: Specimen referral and results reporting system

The majority of sites visited had specimen referral systems in place for HIV/TB, but coverage for lower- and higher-level referrals was not 100 percent. At most sites, there was a good collaboration and integration between the HIV referrals and TB referrals. Challenges with specimen referral (e.g., lack of triple packaging materials, delays in return of results) were reported.

Specific findings and recommendations are as follows:

Key Findings	Recommendations

• On the Tanzania mainland, the specimen referral systems for HIV and TB are well integrated.
• In Zanzibar, two parallel system exist in for TB and HIV specimen referral: one in which TB specimens are being transported to diagnostic centers along with HIV specimens, and the second in which specimens are being transported by health care providers to testing laboratories.
• In some settings, persons being evaluated for TB were referred to the laboratory instead of collecting a specimen and sending the specimen to the laboratory. This has cost implication to the patients and increased risks for transmission.
• 56 of 64 facilities reported that specimen referral systems were in place.
• However, only 27 of 59 facilities reported using proper triple packaging for specimen transport.
• SOPs for specimen referral were available in 38 of 52 facilities.
• There were challenges with specimen referral (i.e., delay of results, lack of triple packaging in referring sites, delay of results for DST sent to the CTRL).
• Reports of stockouts of specimen packaging materials were common.
• Specimen referrals to zonal laboratories or the CTRL were being done by the TB clinic without involvement of the local laboratory. Reports were returned only to the referring facility.
	• Develop national guidelines for an integrated specimen referral system, including TB, HIV, and other diseases.
	• Monitor and evaluate whether the specimen referral system is meeting the needs of the TB program using standardized indicators in an M&E framework embedded in national guidelines.
	• Ensure that triple packaging materials are available at all sites.
	• Ensure the availability and use of SOPs on specimen collection, packaging, referral, and documentation at all levels.
	• Provide training on all aspects of specimen referral to all persons involved in the referral process.
	• Document and collect accurate TATs for all steps of referral and reporting.
	  • Emphasize the need for prompt return of results to the point of referral.
	  • Encourage critical results reporting by phone or electronically to reduce the overall testing TAT.
	• Establish a system for documenting and evaluating the frequency of and reasons for rejection of specimens and any corrective actions taken.
	• Expand use of the Electronic TB and Leprosy Register (ETL) for timely results submission and tracking of specimens. Facilities should be able to register specimens that they refer for testing into the system, and the receiving laboratory should be alerted of the specimen in transit. The facilities should be able to view the status or progress of each specimen.
	• Feedback from the CTRL for referred specimens should be provided to the local and zonal laboratories, as well as the referring facility.

An efficient specimen referral and results reporting system can help:

- Optimize access to services and improve promptness of testing, use of instruments, biosafety and biosecurity, maintenance of proficiency, and quality assurance.
- Provide the program with a degree of control over specimen flow and referral pathways.
- Facilitate linkage to care and capture of all detected patients in the TB surveillance system.
- Provide solutions adapted to the local geography and epidemiology.

The GLI Guide for TB Specimen Referral Systems[3] and the GLI Specimen Referral Toolkit[4] are good sources of information for designing, implementing, and monitoring specimen referral and results reporting systems.

Capacity 4. Diagnostic algorithm and laboratory-clinical interface

Components: Algorithms, TB diagnosis, drug-resistant TB, linkages, surveillance, research

Standard 4. A national TB diagnostic algorithm that is responsive to the epidemic, patient-centered, includes appropriate use of diagnostic technologies, and is based on the current structure of the health system is enforced at all levels of the TB diagnostic network (see Annex 5). A minimum package of tests and quality standards is defined for each level of the network. Laboratorians, health care workers, and TB program staff are trained in the application of the algorithm, and an efficient diagnostic-clinical interface allows for appropriate diagnostic tests to be ordered and performed and ensures the timely linkage of diagnosed patients to appropriate care and treatment.

Tanzania's current diagnostic algorithm includes rapid molecular diagnostic testing for the majority of persons being evaluated for TB. The testing in the current network focuses on adult pulmonary TB, and there are gaps on the availability of laboratory testing for pediatric TB. Also, the current algorithm does not include the use of the WHO-recommended urine lateral flow lipoarabinomannan (LF-LAM) test for people living with HIV.

[3] GLI Guide to TB Specimen Referral Systems and Integrated Networks. 2017. http://www.stoptb.org/wg/gli/gat.asp
[4] GLI Specimen Referral Toolkit. 2017. http://www.stoptb.org/wg/gli/srt.asp

Specific findings and recommendations are as follows:

Key Findings	Recommendations

• 57 of 62 facilities reported that rapid molecular tests were available onsite or by referral for the detection of TB and resistance to rifampicin for all persons with signs and symptoms of TB.
• 43 of 62 sites reported that rapid DST for isoniazid and fluoroquinolones was available onsite or by referral for persons with bacteriologically confirmed TB.
• Only 38 of 64 facilities reported that the current national TB diagnostic algorithm was available.
• 35 of 62 sites reported that DST for a full panel of second-line drugs was available.
• The CTRL does not yet have the capacity to conduct DST for all drugs used for treating TB in Tanzania.
• The role of LF-LAM is not well defined in the algorithm and is not optimized. Only 3 of 66 sites reported that the urine LF-LAM test was available.
	• Ensure dissemination and use of the current TB diagnostic algorithms in all diagnostic centers.
	• Review the placement of GeneXpert instruments to ensure that all instruments are efficiently utilized and that access to Xpert testing is optimized.
	• Consider the adoption of other molecular WHO-recommend diagnostic tests for TB:
	  • High-throughput, moderate complexity, automated nucleic acid amplification tests for detection of TB and resistance to isoniazid and RIF
	  • Truenat MTB tests for detection of TB and rifampicin resistance, particularly the use of the battery-operated instruments in hard-to-reach facilities or areas with unstable power supply
	• Build capacity of the CTRL to conduct DST for the newer drugs in liaison with Uganda's Supra-National Reference Laboratory.

• The diagnosis of pediatric TB was challenging in many settings because there was a lack of capacity for, and training in, collecting specimens from children.	• Incorporate the most recent WHO recommendations for LF-LAM testing into the testing algorithm. Expand the number of facilities that provide the LF-LAM test. • Sensitize pediatricians and nurses to the laboratory testing to support the diagnosis of childhood TB. • Train and equip facilities for the collection of suitable specimens from children.

Tanzania has adopted a diagnostic algorithm that meets the goals and recommendations of WHO and the End TB Strategy with respect to the use of the Xpert test as the initial diagnostic test for TB. Further improvements in the algorithm could be made by fully incorporating the latest WHO recommendations for the use of the LF-LAM test and considering the use of other rapid molecular tests, such as the Truenat MTB test.

Adherence to the diagnostic algorithm could be improved by ensuring that all laboratory and clinical staff (public sector and private sector) have access to printed copies of the algorithm, the latest guidelines, and sensitization materials, as well as training on the algorithm, ordering tests, and interpreting results.

Capacity 5. Biosafety

Components: Facilities, biosafety manual, biosafety systems, specimen storage, waste management

Standard 5. Testing is performed in a manner and in facilities that ensure safety for the staff, the customers, the community, and the environment. Sufficient materials, means, and skills are available throughout the system to ensure safe and secure procurement, handling, storage, transportation, and disposal of samples and materials, both in routine as well as in emergency circumstances.

Adherence to biosafety standards in TB testing facilities is critical for ensuring the safety of laboratory staff and patients and for protecting the environment. National biosafety policies and procedures specific for TB should be available and adhered to at all levels of the diagnostic network. It is critical that all laboratories meet the biosafety requirements for safely working with specimens containing MTB bacteria.

Specific findings and recommendations are as follows:

Key Findings	Recommendations
• A national TB biosafety manual is not in place. • In 9 of 36 facilities, a biosafety officer was not available. • Only 18 of 25 biosafety officers had received a refresher training recently. • 28 of 29 facilities reported that personal protective equipment was available. • BSCs were available in many facilities, but often the servicing and certification of the BSCs was overdue. • Adequate methods were used to safely dispose of infectious waste in 32 of 36 facilities. • Only 21 of 38 facilities reported that workers had been screened for the signs and symptoms of TB in the past year.	• Accelerate the development and dissemination of a national TB biosafety manual. • Ensure that all facilities have a biosafety officer and provide regular refresher trainings for biosafety officers. • Conduct zonal biosafety workshops to train biosafety officers and review biosafety guidelines, including any updates. • Use the in-country capacity of the National Health Laboratory Quality Assurance and Training Centre, National Calibration Centre, and certified biomedical engineers to regularly certify the BSCs. • Institute a program for annual screening of HCWs for signs and symptoms of TB and document results in personnel files.

Ensuring safe working conditions in TB laboratories begins with developing national TB biosafety policies and manuals and implementing and enforcing the policies at all levels of the laboratory network. The CTRL and zonal laboratories must lead by example and ensure that they adhere to all biosafety requirements (physical facilities, administrative controls, safe working practices, personal protective equipment) related to the TB testing that they conduct.

HCWs who come in contact with TB patients and those who work in the TB laboratory are at increased risk of acquiring an MTB infection. As such, there must be a routine HCW screening program (at least yearly) for signs and symptoms of TB.

Capacity 6. Equipment and supplies

Components: Supply chain management, equipment

Standard 6. Testing is performed with state-of-the-art and well-maintained equipment and an uninterrupted supply of quality reagents and consumables.

Procurement of TB commodities is coordinated by the MOH/Pharmaceutical Services Unit, which is mandated to coordinate all pharmaceutical services, including supply chain of health services. Procedures for procurement and supply chain management are well stated in the NTLP policy.

Procurement of TB commodities is funded by the Global Fund through NTLP coordination. The MSD— through a special unit that is dedicated to handling public health programs—is responsible for storing and distributing TB commodities through zonal MSDs. Funds through the Global Fund as well as the President's Emergency Plan for AIDS Relief are used to procure cartridges.

Specific findings and recommendations are as follows:

Key Findings	Recommendations
• 25 of 38 facilities reported stockouts during the past year, including supplies for AFB, culture, first-line/second-line LPA, specimen packaging, and chemistry tests, as well as for Xpert cartridges. • Frequent stockouts remain a major challenge and are mainly caused by delays in processing import permits and port clearance procedures. • Only 13 of 29 facilities conducted lot-to-lot verification of commodities. • 18 of 25 had SOPs for reporting complaints about numerous laboratory supplies.	• Formalize reporting of stockouts and expiration. Initiate corrective actions to identify the root cause of the challenges and whether they are regional or systemic. • The CTRL and the NTLP to work on quantification and forecasting of TB reagents and supplies, as well as fast tracking clearance process of the imported TB consignment, in close collaboration with the MSD and the Government Procurement Services Agency. • Strengthen quality assurance of laboratory supplies by empowering all laboratories to perform lot-to-lot verification of reagents.
• Maintenance plans were available at the national level and some lower levels for essential equipment. • 21 of 36 facilities reported that a national maintenance plan was available for all laboratory equipment.	• Develop and disseminate an SOP for reporting complaints on the quality of laboratory supplies and develop SOPs for corrective actions. • Develop comprehensive maintenance plans for all equipment, and establish KPIs and targets in agreements with all service providers. • Finalize the NTLP/Cepheid service-level agreement through cartridge surcharge. • Train more GeneXpert focal persons or super-users on first-line preventative maintenance.

Building capacity at the national and local levels for monitoring consumables and managing procurement and equipment maintenance should improve the functionality, reliability, and robustness of the supply chain.

Capacity 7. Workforce

Components: Education and training, staffing, human resources development strategy

Standard 7. Adequate numbers of competent, well-trained, and motivated technical and managerial staff are available at all levels of the diagnostic network.

Laboratory staff is well-trained on technical aspects of testing but less well-trained on laboratory management and quality assurance. All public and private sector laboratory and clinical staff need to be included in the trainings for efficient functioning of the diagnostic network.

Specific findings and recommendations are as follows:

Key Findings	Recommendations
• There is no national staffing plan for TB laboratories supported by workforce projections. • Most (29 of 38) laboratories reported that the available workforce is sufficient for diagnostic testing, but some reported that they did not have adequate staff for data management or QMS activities. • Competency-based job descriptions were lacking at 12 of 30 sites. • Annual competency testing was lacking at 16 of 36 sites. • Many facilities reported a lack of refresher training for staff. • Central and regional laboratory managers have received training in laboratory management and QMS, but some managers of lower-level laboratories have not.	• Develop a national staffing plan for TB laboratories supported by workforce projections. • Address any staffing shortages and build capacity of zonal, regional, and peripheral laboratories on data management, documentation, and other QMS activities. • Develop and disseminate standardized competency-based job descriptions. • Develop a system to assess and document staff competency. Assessments should be done yearly. • Develop a comprehensive program to provide refresher training to all laboratory workers. • Develop a training plan in laboratory management and QMS for all laboratory managers.

Shortages of trained personnel will threaten the ability to provide the laboratory services needed for implementation of the NSP. Training must focus on the skills and knowledge needed to meet NSP targets and must include competency assessment. Ensure that standardized training is available to all laboratory and clinical staff at all tiers of the diagnostic network. Expand access to QMS training.

Implementing QMS is a cost-effective approach to improving the quality and reliability of diagnostic testing, which in turn improves patient outcomes.

Capacity 8. Diagnostics data management

Components: Data collection, data analysis and sharing, reporting, surveillance/epidemiology, **security and confidentiality of information**

Standard 8. Interoperable and interconnected electronic recording and reporting systems are in place that generate reliable data that are monitored and analyzed in real time. These systems comply with international standards to allow the rapid exchange of information in standardized formats at national and subnational levels. A laboratory information management system provides up-to-date information about the status of the laboratories and is linked to the health management information system of the country.

This standard relates to Indicator 4 of the WHO framework of indicators and targets for laboratory strengthening under the End TB Strategy, which has a 2020 target that 100 percent of testing sites using a WHO-recommended rapid TB diagnostic test have a data connectivity system established that transmits results electronically to clinicians and to an information management system.

Reporting of diagnostic data for both clinical and programmatic management is primarily paper-based, and currently there is limited connectivity of GeneXpert instruments. About half of laboratories use an electronic LIS. Electronic data systems can facilitate patient transactions, data collation, and monitoring of KPIs, and provide actionable data to all levels of the laboratory network.

Specific findings and recommendations are as follows:

Key Findings	Recommendations
• 62 of 64 facilities reported that standardized test request forms were used. • Test request forms were often incompletely filled in, resulting in incomplete laboratory registers. • Standardized forms were used to collect laboratory statistics and performance data, but the data were not routinely reviewed and analyzed by the laboratory staff. • There were no dedicated laboratory staff for TB data management below the national level, and training in data management has been lacking. • 27 of 38 facilities report the use of an electronic system for reporting data to local and national programs.	• Provide refresher training to laboratory and clinical staff to emphasize the need to fill in test requisition forms completely. • Build capacity of zonal, regional, and peripheral staff on data management and analysis ensure that there are adequate resources to carry out collection and analysis. • Ensure that data that are collected are analyzed, reviewed, and used for decision-making at all tiers of the network. • Empower laboratory staff to collect and analyze laboratory data and promptly initiate corrective action as needed. Include these duties in job descriptions. • Monitor, evaluate, and improve the timeliness, completeness, and correctness of laboratory data reported to the CTRL.

• 31 of 54 facilities report the use of an electronic system (e.g., LIS) for reporting diagnostic data to clinicians.
• In some peripheral laboratories, the lack of internet connectivity prevented the use of the ETL.
• A variety of electronic systems are used, including ETL and TB LIS at the CTRL, the Government of Tanzania—Hospital Management Information System at some facilities, and a LIS at some facilities that did not include TB or HIV.
• 19 of 30 sites reported that a diagnostics connectivity solution (e.g., GxAlert) had been implemented.
• 16 of 30 sites reported that SOPs for the backup and retrieval of data were fully implemented.
	• Implement electronic information systems at all facilities with proper linkages between the CTRL, regional referral hospitals, district hospitals, and peripheral laboratories.
	  • Ensure that TB tests are integrated into the existing LIS.
	  • Harmonize or strengthen the interface between existing systems (ETL, TB-LIS, Government of Tanzania—Hospital Management Information System).
	• Activate or reactivate GxAlert for real-time reporting and quality monitoring at all GeneXpert hubs.
	• Establish a connection between GxAlert and existing systems, such as ETL and TB LIS, to avoid duplication of efforts and duplicate errors in the system.

Connected solutions in health systems are becoming the expected norm to identify, monitor, and address challenges.5 Automated data collection relieves the burden on staff to collect data and allows more time to use data for action, as well as providing novel questions and answers unavailable in paper-based systems. Potential gains include the following:

- Many human resource hours saved and increased data accuracy
- Improved test/case linkage and follow up of TB-positive cases
- Automated TAT for various network activities, including specimen/result referral
- Electronic equipment monitoring and rapid identification of failures
- Ability to monitor adherence to algorithms and testing protocols
- Improved data quality for better trust-based intelligent decisions
- Real-time stock and consumption monitoring
- Real-time alerts and notifications for all TB cases and RR cases

Gains would be made in which the program harmonizes its LIS investments onto platforms that are networked to work together. There was a desire for LIS across multiple sites visited; however, prerequisites for an LIS investment must have power that is consistently available for at least 90 percent of the working hours and reliable Internet connections. Otherwise, paper-based systems will continue to be used as the de facto standard.

Capacity 9. Quality of the diagnostic network

Components: Quality assurance, QMS, certification and accreditation

Standard 9. High-quality diagnostic services producing accurate and reliable results are available throughout the network. Continuous quality improvement targets all facilities in the

[5] GLI Quick Guide to TB Diagnostics Connectivity Solutions. 2016. http://stoptb.org/wg/gli/gat.asp

network and includes quality indicator monitoring, external quality assurance, and regular onsite supervision. A system of national certification is in place for all public and private laboratories in the network, and reference and referral level laboratories are accredited according to national or international standards.

A comprehensive and systematic quality assurance program should be implemented to enable laboratories to achieve and maintain high levels of accuracy and proficiency in testing, to ensure the reliability and reproducibility of results, and thus to inspire confidence in clinicians and patients who are users of the laboratory's services. A comprehensive quality assurance system includes standardized procedures (i.e., SOPs), document control, quality indicator monitoring, internal quality controls, EQA, proficiency testing, regular onsite supervision, and timely feedback, corrective actions, and follow-up.

Specific findings and recommendations are as follows:

Key Findings	Recommendations
• 31 of 36 laboratories have a quality officer. • 13 of 31 facilities reported that quality management activities were implemented in a structured approach. • 30 of 36 laboratories use standardized documents and records, but only 13 had a document control system in place. • National SOPs and job aids were available in 23 of 36 laboratories. • 29 of 36 laboratories reported participating in EQA programs; however, there were issues related to inconsistent EQA program participation and delays in or a lack of feedback reports from the EQA provider. • 20 of 36 laboratories reported having standardized internal quality control (IQC) procedures in place for all tests. • 22 of 36 laboratories reported that KPIs were regularly reviewed and used for decision-making.	• Accelerate QMS implementation at all levels of the diagnostic network. • Enroll laboratories in a structured QMS program, such as Strengthening Laboratory Management Towards Accreditation or TB-Strengthening Laboratory Management Towards Accreditation. • Implement a document control system that ensures that all documents are up-to-date and complete and that all laboratory staff have read and understood the documents. • Disseminate national SOPs and job aids for all laboratory activities to all diagnostic centers. • Ensure that all laboratories enroll and regularly participate in EQA programs for each test they conduct. • Strengthen the EQA feedback system such that it reaches all facilities in a timely manner and corrective actions are taken promptly. • Ensure that IQC is performed for all tests and that IQC results are documented in laboratory registers. • Establish a set of KPIs and targets to be monitored, analyzed, and reported. • Empower laboratory staff to collect and analyze KPIs and promptly initiate corrective action as needed. Include these duties in job descriptions.
•	• Track and monitor KPIs for all aspects of laboratory testing at all levels of the laboratory system to improve program performance.

The quality of testing and the network functions can be strengthened by the following:

- Ensuring that updated standardized documents developed at the national level are available and disseminated to the testing sites, including SOPs (microscopy, Xpert testing, maintenance of GeneXpert instruments, EQA procedures, biosafety, etc.); equipment maintenance and room temperature logs; job aids; standardized training and competency assessment packages; checklists for onsite assessments; etc.
- Implementing a comprehensive quality assurance system that includes standardized documents, competency testing, IQCs, EQA, onsite supervision, continuous quality improvement processes, documentation, etc.
- Employing an M&E system that assesses the impact of the quality assurance system using KPIs of testing and network functions.
    - KPIs for TB tests and specimen referral are described in the GLI Guide to Laboratory Strengthening[6] and the GLI Guide to TB Specimen Referral Systems.[7]
    - KPIs for diagnostic networks include patient-to patient TATs, loss to follow-up, timeliness of information flow, and completeness of reporting.
- Deploying electronic data systems (especially remotely monitored systems) to improve the efficiency of data reporting, management of the diagnostic network, and resource use by targeting onsite interventions to facilities that can most benefit from the interventions.

Capacity 10. TB/HIV

Components: Legislation and policies, structure and organization of the network, coverage, diagnostic algorithm, workforce, diagnostic data management

Standard 10. A comprehensive approach is needed to combat the twin epidemics of HIV/AIDS and TB. All persons being evaluated for TB should receive free HIV testing and, if found positive, referred to appropriate counseling and care. All HIV-positive persons should be screened for TB and linked to appropriate diagnostic testing. Coordination and communication between the National AIDS Control Program and the National TB Control Program are essential. The TB diagnostic network should collaborate with the HIV diagnostic network regarding laboratory and diagnostic services (e.g., specimen transport, shared diagnostic platforms, referrals for testing).

[6] GLI Guide to Laboratory Strengthening. 2017. http://www.stoptb.org/wg/gli/srt.asp
[7] GLI Guide to TB Specimen Referral Systems and Integrated Networks. 2017. http://www.stoptb.org/wg/gli/gat.asp

Tanzania has a dedicated organizational unit in charge of coordination between the TB laboratory network and the HIV/AIDS laboratory network. Coordination between the National AIDS Control Programme and the NTLP is strong, and there is an excellent joint national policy for isoniazid preventive therapy for HIV-positive individuals. HIV testing and TB testing are free in all public facilities and private laboratories associated with HIV and TB laboratory networks. The TB diagnostic network and HIV diagnostic network collaborate extensively regarding specimen transport and referrals for testing. TB, HIV, and TB-HIV statistical data are reported, analyzed, and used for decision-making purposes at the national level, and there is a surveillance system for TB/HIV.

Specific findings and recommendations are as follows:

Key Findings	Recommendations
• The role of LF-LAM is not well defined in the algorithm and is not optimized. Only 3 of 66 sites report that the urine LF-LAM test was available. • 55 of 67 facilities reported that specimen referral systems for TB testing and HIV testing shared and coordinated.	• Incorporate the most recent WHO recommendations for LF-LAM testing into the testing algorithm. Expand the number of facilities that provide the LF-LAM test. • Enhance integration and coordination of TB and HIV specimen referrals at all levels (see discussion of thematic area on specimen referral).

Diagnostic services for people living with HIV who are being evaluated for TB could greatly benefit from the implementation of latest WHO recommendations for the use of the LF-LAM test to aid in the diagnosis of TB.

The programs are encouraged to take advantage of the interest of implementing partners in coordinating activities, leveraging knowledge and resources, and working together to address the needs of HIV and TB laboratory testing in a streamlined, efficient manner.

4.5 General Considerations for Strengthening the Diagnostic Network and Thematic Areas

Implementation of the recommendations should be guided by several cross-cutting principles. These include the following:

- Developing aggressive bold policies and interventions in alignment with the End TB Strategy and mobilizing commensurate resources
- Finding efficiencies, optimizing test utilization, and improving access to existing services to build a strong foundation for the rapid scale-up of laboratory testing
- Deploying what is available now, while planning for the future, and continuing to evaluate new tools and approaches
- Shifting the focus of diagnostic TB services from the health system to the patient, including the complete cascade from screening to treatment completion

- Emphasizing translation of policies into action and putting in place comprehensive systems with adequate resources to closely monitor implementation
- Linking indicators of laboratory and diagnostic network strengthening with NSP goals and targets
- Managing change in the diagnostic network and laboratory personnel to ensure the acceptance and effective implementation of the strengthened diagnostic network

4.6 Next Steps

The findings and recommendations from the assessment are extensive and will require the NTLP and the CTRL to lead and coordinate efforts among all stakeholders, including technical partners and donors. Recommended activities or interventions should be prioritized by establishing a detailed action plan with time-bound deliverables and specified roles and responsibilities of various stakeholders. The implementation of this plan should be reviewed periodically and adjusted as needed.

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ANNEXES

Annex 1. Sites Visited

Team	Region	District	Facility Name	Facility Category
Team A	Mbeya	Mbeya City Council	Mbeya Zonal Referral Hospital	Culture/district laboratory
		Mbeya City Council	Mbeya Regional Referral Hospital (RRH)	Intermediate reference laboratory (IRL)
		Mbeya City Council	Ruanda Health Centre	Peripheral laboratory
		Mbeya City Council	Amenye Dispensary	Private peripheral laboratory
	Kagera	Bukoba Municipal Council	Zamzam Health Centre	Peripheral laboratory
		Karagwe District Council	Nyakahanga Designated District Hospital	Peripheral laboratory
		Bukoba Municipal Council	St. Theresa Health Centre	Peripheral laboratory
Team B	Morogoro	Morogoro Municipal Council	Morogoro RRH	IRL
		Morogoro Municipal Council	Sabasaba Health Centre	Peripheral laboratory
		Mvomero District Council	St. Francis Tirian Designated District Hospital	Peripheral laboratory
	Dar es Salaam	Kinondoni Municipal Council	Regence Lancet Laboratories	IRL private
		Kinondoni Municipal Council	Upanga Health Centre	Peripheral laboratory
		Kinondoni Municipal Council	Central Tuberculosis Reference Laboratory	National culture/drug susceptibility testing (DST) laboratory
	Zanzibar	Urban Unguja	Mnazi Mmoja RRH	IRL
		Urban Unguja	Al Rahma Hospital	Peripheral hospital
		North Uguja	Kivunge District Hospital	Peripheral laboratory
		Southwest Pemba	Abdallah Mzee RRH	IRL
		Chake Chake	Pemba Public Health Laboratory	Culture/DST laboratory
Team C	Tanga	Korogwe District Council	Mombo Health Centre	Peripheral laboratory
	Kilimnajaro	Siha District Council	Kibongoto Infectious Disease Hospital	Culture/DST laboratory
	Arusha	Arusha City Council	Shree Hindu Charitable Hospital	Peripheral laboratory
		Meru District Council	Meru District Hospital	Peripheral laboratory
		Arusha City Council	Selian Lutheran Hospital	Peripheral laboratory
		Arusha City Council	Arusha RRH	IRL

Team	Region	District	Facility Name	Facility Category
		Simanjiro	Simanjiro Health Centre	Peripheral laboratory
	Manyara	Manyara	Tumaini Health Centre	Peripheral laboratory
Team D	Dodoma	Dodoma City Council	Dodoma RRH	Culture/DST laboratory
	Singida	Singida Municipal Council	Singida RRH	IRL
		Singida District Council	Sokoine Health Centre	Peripheral laboratory
	Mwanza	Mwanza City Council	Bugando Medical Centre	Culture/DST Laboratory
		Mwanza City Council	Sekouture RRH	IRL

Annex 2. Diagnostic Network Standards, Core Capacities, and Components

The Tuberculosis Diagnostic Network Assessment Tool's foundation is built around a set of standards that provide a qualitative measure of quality or attainment of a comprehensive TB diagnostic network. "Core capacities" and "components" of the tool are linked to each of the standards and refer to the overarching capabilities of a national TB diagnostic network to detect, assess, notify, and respond to TB. Components are used to describe the essential functions of the diagnostic network across the core capacities.

Standard 1. The country has a fully endorsed political, legal, and regulatory framework in place that supports the achievement of the National TB and Leprosy Strategic Plan and that organizes and controls all public and private diagnostic services to support the National TB and Leprosy Strategic Plan, with sufficient dedicated funding available. Policies are in place that enable continuous, country-wide availability of free, quality-assured diagnosis according to the national guidelines.

- **Core Capacity:** Political, legal, regulatory, and financial framework
- **Components:** Legislation and policies, national policies and plans, governance, financing, and budgeting

Standard 2. A sustainable, rational, and efficient TB diagnostic network provides integrated, essential, quality diagnostic services for patient care and public health. The TB diagnostic network is coordinated by a national reference or public health laboratory and includes the public and private sector as well as community-level diagnostic services. All facilities have clearly defined terms of reference and are adequately supervised.

- **Core Capacity:** Structure and organization of the diagnostic network
- **Components:** Diagnostic network, coordination and management, programmatic and operational research

Standard 3. The national TB diagnostic network provides complete coverage and universal access to TB diagnostic services to the entire population of the country. Referral mechanisms exist to rapidly refer specimens to the appropriate level for testing and to provide timely results to enable initiation of appropriate treatment. An efficient diagnostic-clinical interface allows for appropriate diagnostic tests to be ordered and ensures the timely linkage of diagnosed patients to appropriate care and treatment.

- **Core Capacity:** Coverage
- **Components:** Diagnostic network coverage, specimen referral system, linkages, emergency preparedness

Standard 4. A national TB diagnostic algorithm that is responsive to the epidemic, patient-centered, includes appropriate use of diagnostic technologies, and is based on the current structure of the health system is enforced at all levels of the TB diagnostic network. A minimum package of tests and quality standards is defined for each level of the network. Laboratorians, health care workers, and TB program staff are trained in the application of the algorithm.

- **Core Capacity:** Diagnostic algorithm
- **Components:** Algorithms, detection of TB, detection of drug-resistant TB

Standard 5. Testing is performed in a manner and in facilities that ensure safety for the staff, customers, community, and environment. Sufficient materials, means, and skills are available throughout the system to ensure safe and secure procurement, handling, storage, transportation, and disposal of specimens and materials, both in routine as well as in emergency circumstances.

- **Core Capacity:** Biosafety
- **Components:** Facilities, biosafety and biosecurity manual, biosafety systems, waste management

Standard 6. Testing is performed with state-of-the-art and well-maintained equipment and an uninterrupted supply of quality reagents and consumables using standardized testing methods throughout the country.

- **Core Capacity:** Equipment and supplies
- **Components:** Supply chain management, equipment management

Standard 7. Adequate numbers of competent, well-trained, and motivated technical and managerial staff are available at all levels of the diagnostic network.

- **Core Capacity:** Workforce
- **Components:** Education and training, staffing, human resources strategies and plans, competency-based job descriptions

Standard 8. Interoperable and interconnected electronic recording and reporting systems are in place that generate reliable data that are monitored and analyzed in real time. The systems comply with international standards to allow the rapid exchange of information in standardized formats. A laboratory information management system provides up-to-date information about the status of the laboratories and is linked to the health management information system of the country.

- **Core Capacity:** Diagnostics data management
- **Components:** Data collection forms, reporting, diagnostics connectivity and remote monitoring, data analysis and sharing, surveillance and epidemiology, security and confidentiality of information

Standard 9. High-quality diagnostic services producing accurate and reliable results are available throughout the network. Continuous quality improvement targets all facilities in the network and includes quality indicator monitoring, external quality assurance, and regular onsite supervision. A

system of national certification is in place for all public and private laboratories in the network, and reference and referral level laboratories are accredited according to national or international standards.

- **Core Capacity:** Quality of the diagnostic network
- **Components:** Documents and document control, quality assurance, quality management system, certification and accreditation

Standard 10. A comprehensive approach is needed to combat the twin epidemics of HIV/AIDS and TB. All persons being evaluated for TB should receive free HIV testing and, if found positive, referred to appropriate counseling and care. All HIV-positive persons should be screened for TB and linked to appropriate diagnostic testing. Coordination and communication between the National AIDS Control Program and the National TB Control Program are essential. The TB diagnostic network should collaborate with the HIV diagnostic network regarding laboratory and diagnostic services (e.g., specimen transport, shared diagnostic platforms, referrals for testing).

- **Core Capacity:** TB/HIV
- **Components:** Legislation and policies, structure and organization of the network, coverage, diagnostic algorithm, workforce, diagnostic data management

Annex 3. Questions and Stages by Core Capacity and Components

Capacity 1. Political, legal, regulatory, and financial framework

Question number	Questions	Stages					
		0	1	2	3	4	5
Component 1.1. Legislation and policies							
1.1.1	Are the following key areas related to TB control and diagnostic networks enforceable? - Roles and responsibilities of the NTP and health sector and links with other sectors (including financial flows) - TB notification - Drug-resistant TB - Private sector engagement - Biosafety and waste management - Disease surveillance - TB control in prisons, migrants, refugees, cross-border populations, etc. - Occupational health	No policy, plan, regulation, or legislation exists for any of the key areas.	Policies, plans, regulations, or legislation exists for 1 or 2 key areas.	Policies, plans, regulation, or legislation exists for 3 or 4 key areas.	Policies, plans, regulation, or legislation is in place for all key areas.	Policies, plans, regulations, or legislation are in place and enforced.	Legislation in place, enforced and regularly updated to reflect international standards.

Component 1.2. National TB policies and plans							
1.2.1	Is there a national TB laboratory policy, guideline or strategic plan? Is it 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? Does the national TB laboratory plan prioritize the development of a network of TB laboratories that use modern diagnostics, have efficient referral system; use standard operating procedures and	There is no national TB laboratory policy, guideline, or plan	There is a national TB laboratory policy, guideline or plan but it is not approved and aligned with national laboratory policy and TB NSP.	The national TB laboratory policy, guideline or plan is approved and aligns with the national laboratory policy and TB NSP. The plan describes development of	All of before and up to date and partially implemented. The plan prioritizes the development of an efficient TB laboratory network and clinical	Fully implemented and the plan prioritizes the development of a comprehensive TB laboratory network that encompasses both private-sector and	Implemented and aligned with overall health strategic plan. Revised at least once.

Question number	Questions	Stages					
		0	1	2	3	4	5
	appropriate quality assurance processes; have adequate biosafety and sufficient human resources; and promoter the clinical-laboratory interface?			ATB laboratory network.	Laboratory interface.	public-sector laboratories.	
1.2.2	Is there a current national TB plan describing how to operationalize the national TB laboratory strategic plan (NLSP) towards the achievement of the TB laboratory plan? Are indicators and annual targets described to monitor progress of implementationofthe strategic and operational plan related to TB laboratory services?	There is no current (yearly) national TB laboratory operational plan either as standalone or as part of the NLSP. There are no sub-national TB laboratory operational plans (e.g., at the regional or state level).	There is an operational plan or an operational section of the NLSP but it does not describe the how or the timelines or the associated budget required for the implementation of the NLSP.	The operational plan or operational section of the NLSP provides information on the how, the timelines and the budget associated with the implementation of the NLSP. Indicators and annual targets are described.	All of before and the plan describes milestones, indicators and annual targets to measure progress.	All of before and the plan is partly implemented (i.e., not distributed and used down to district level) and some indicators and annual targets are being monitored.	All of before, and the plan is fully implemented, prioritizing some or all of the core capabilities, based on the NLSP, and all indicators and annual targets are being routinely monitored.

1.2.3	Is there a licensing mechanism for TB laboratories in place?	No	One-time licensing is provided with registration and is legally required for all laboratories in the health sector. Licensing requirements are different for public versus	One-time licensing is in place and with similar requirements for all public and private TB laboratories in the health sector.	One-time licensing in place and enforced for public or private TB laboratories for health.	Licensing and re-licensing of all public and private TB laboratories for health are legally required.	Re-licensing is based on national certification standards and is legally required for all TB laboratories.

Question number	Questions	Stages					
		0	1	2	3	4	5
			private laboratories.				
1.2.4	Is there a policy or legislation mandating laboratories to report the detection of TB and DR-TB patients to the local and national programs or a policy requiring that laboratory registers are regularly (e.g., monthly) reviewed to ensure that all patients detected in the laboratory are reported to the program? Is the policy implemented? Do laboratories inform the local and national programme of persons with TB detected in their laboratory or are there procedures in place to review laboratory registers regularly (e.g., monthly)?	No policy exists for either reporting TB patients by the laboratory or for regular review of laboratory registers. AND Laboratories do not report data on TB detection.	There is a policy that laboratories must report aggregate data on the numbers of TB patients detected but there is no policy that laboratories must report TB patients or regularly review laboratory registers to identify TB patients. Laboratories routinely report aggregate data (e.g., number of patients detected). Any reporting of patients or review of registers is Infrequent and on an ad hoc	A policy has been approved to require laboratory reporting of TB or DR-TB patients to the local or national TB program or to require the regular review of laboratory registers to identify TB patients. Informing the local or national TB programme is done directly by the TB laboratory at some tiers or some regions by public sector laboratories.	Stage 2 and regular informing of the TB program at all tiers by public sector TB laboratories.	Stage 3 and the policy informing the TB programme occurs at all tiers in the public sector and by some private sector TB laboratories. Laboratory registers are regularly reviewed to ensure to ensure that all patients detected in the laboratory are reported to the program.	Stage 4 with all tiers in the public and private sectors.

			basis.				
Component 1.3. Governance							
1.3.1	Does the Ministry of Health (MoH) or other responsible ministry have a dedicated organizational unit in charge of laboratory coordination?	No	There are several entities involved in	Dedicated entity but not at senior management	Stage 2 plus coordination mechanisms with disease	Stage 3 plus the entity is a directorate or a department,	All of before, with inter-ministerial coordination.

Question number	Questions	Stages					
		0	1	2	3	4	5
			laboratory coordination.	level within the MoH. There is an official mandate, defined terms of reference and setting of targets.	specific vertical programs and public health-related committees.	representing laboratory services at top management level of the MoH with the private sector included in oversight.	
Component 1.4. Financing and budgets							

1.4.1	Are budgets with sufficient resources for the TB diagnostic network available at all levels of the laboratory system, including public and private sector service provision under NTP? The budget covers TB laboratory testing, clinical diagnostic services, public health functions and network management functions.	No	Only for the national TB reference laboratory(ies).	For the national TB reference laboratory and next level laboratories (intermediate or regional or state reference laboratories) and the budget at least partially covers the costs of laboratory testing, public health, clinical diagnostic, and network management functions.	At the national and intermediate levels, the budget completely covers the costs of laboratory testing, public health, patient diagnostic, and network management functions. Resources at the peripheral level only partially cover cost of laboratory testing and clinical diagnostic	Stage 3 and sufficient resources are available for TB laboratory activities and clinical diagnostic services at all levels of the TB laboratory system (NRLs, IRLs, peripheral laboratories). The budget completely covers the costs of laboratory testing, public health, patient diagnostic, and network management	Sufficient resources are available for TB laboratories at all levels of the network and including public and private sector facilities providing services under NTP.

					functions.	functions.	
1.4.2	Is the budget for TB laboratory and clinical diagnostic services covered by	The budget does not include any	Government and local funding	Stage 1 plus funding of basic supplies and	Stage 2 plus funding for supplies for	Government and local funding	Stage 4 and 100% of the

Question number	Questions	Stages					
		0	1	2	3	4	5
	Sustainable government funding and other local funding sources?	Government or local funding sources.	contribution to TB laboratory and clinical services includes only basic infrastructure and staff costs.	Reagents for some TB diagnostics (e.g., smear microscopy).	advanced TB diagnostics and other costs (e.g., training, QA, equipment, maintenance etc.).	represent 100% of the total TB laboratory and clinical budget.	budget spent in the last 3 years.
1.4.3	Is there a national policy which enables free diagnosis for all people being evaluated for TB, including all laboratory tests and X-ray as stipulated in the national algorithm?	No	Only limited diagnostics (e.g., smear microscopy) are provided free of charge in parts of the public sector only.	Several TB laboratory tests are available free of charge or reimbursed in public sector.	All TB laboratory tests are available free of charge or reimbursed in the public sector and some private sector facilities. Chest X-ray is free of charge or reimbursed in limited locations.	All laboratory tests are available free of charge or reimbursed in the public and private sector. Chest X-ray is available free of charge or reimbursed in the public sector and only in limited private sector facilities.	All TB diagnosis is free or reimbursed for all people being evaluated for TB in the public or private sector. Required ancillary testing (e.g., liver function tests) are free of charge or reimbursed.

Capacity 2. Structure and organization of the diagnosticnetwork

Question number	Questions	Stages					
		0	1	2	3	4	5
Component 2.1. Diagnostic network							
2.1.1	Is there a tiered TB diagnostic network in the country? Does each laboratory within the tiered TB diagnostic network have defined terms of reference and an agreed upon mandate to provide services for the NTP under the MoH as part of an integrated TB diagnostic network?	No	Only division into reference and other laboratories. The roles. responsibilities and mandate of the reference laboratory are clearly defined.	There is a TB diagnostic network with at least 3 tiers in the country without clearly defined roles and responsibilities for the different tiers.	There is a TB diagnostic network with at least 3 tiers in the country with partially defined roles and responsibilities and written terms of reference (TORs).	There is a TB diagnostic network for public health functions OR for clinical functions with clearly defined tier-specific roles and responsibilities and written terms of reference.	There is a TB diagnostic network for public health functions AND for clinical functions with clearly defined tier-specific roles and responsibilities for routine situations.

2.1.2	Do laboratories other than NTP or MoH laboratories (e.g., private, NGO, academic, prison, military) provide clinical diagnostic and public health functions for the national TB laboratory network?	MoH/NTP laboratories perform TB clinical functions OR perform TB public health functions for the national TB diagnostic network. Non-MoH/NTP laboratories do not perform clinical or public health functions as part of the national TB diagnostic network.	MoH/NTP laboratories perform TB clinical functions AND perform TB public health functions for the national TB diagnostic network. Non-MoH/NTP laboratories do not perform clinical or public health functions as part of the national TB diagnostic network	Stage 1 AND some private, NGO, academic or military laboratories perform TB clinical functions for the national TB diagnostic network	Stage 2 AND some private, NGO, academic or military laboratories perform TB public health functions.	All laboratories in the public and private sector perform TB clinical diagnostic and public health functions for the national TB diagnostic network but not fully integrated.	All laboratories in the public and private sector areintegratedin the TB diagnostic network with formalized linkages.
2.1.3	Does the organizational structure of the TB diagnostic network include decentralization of diagnostic services such as screening or sample collection to the community level?	No networks in place	The organizational structure of the TB diagnostic network does	A selection of basic TB laboratory and clinical diagnostic	Basic TB diagnostic services are decentralized to the community	Community services are regularly monitored for quality and cost	Stage 4 with demonstrated quality and cost-effectiveness is scaled up

Question number	Questions	Stages					
		0	1	2	3	4	5
			not include community level.	services (e.g., screening or sample collection) are decentralized to the community level in some districts.	level in most districts, including public sector and some private sector community-based providers. A process of formalizing linkages between community level and national health system has been initiated.	effectiveness AND for contribution to the rapid detection of TB. This approach is being scaled up in many districts with public sector community providers and some private sector integration.	nationwide and is incorporated into the organizational structure of the diagnostic network.

2.1.4	Have tier-specific TB laboratory minimum testing packages been defined and implemented in public sector laboratories and private sector laboratories that are part of the TB diagnostic network.?	No tier-specific minimum TB testing packages have been defined.	Minimum TB testing packages are defined for some tiers of laboratories in the public sector.	Minimum TB testing packages are defined for all tiers of laboratories in the public sector and implemented in some laboratories at some tiers.	Minimum testing packages are defined for all tiers laboratories in the public sector and for some private sector laboratories that are incorporated in the TB network and implemented in all public sector laboratories and some private sector laboratories.	Stage 3 with minimum testing packages for TB in all public and private sector laboratories in the TB diagnostic network and implemented in all public and private sector laboratories.	All of before and the testing packages have been revised at least once.
Component 2.2. Coordination and management							
2.2.1	Is there a formalized system of communication within the TB diagnostic network?	No	Formal communicatio n from the top level to the lower tiers is in place	Formal communication between tiers on an ad hoc basis	Formal communication between tiers at a specified, regular basis	Formal communicatio n between and within tiers on an ad hoc basis	Formal communicatio n between and within tiers at a regular basis
2.2.2	Is there a designated national TB reference laboratory (NRL) in the	No	An NRL has been designated.	An NRL has been designated	An NRL coordinates	Stage 3 and the links with the	Stage 4 and formalized links

Question number	Questions	Stages					
		0	1	2	3	4	5
	country? In large countries, there may be more than one designated laboratory that functions as an NRL, each with an assigned jurisdiction. - Is there a focal point at the national level that is responsible for managing the network of NRLs? - Do coordination meetings of the NRLs occur at least once a year if there is more than 1 NRL?		OR More than one NRL has been designated and each NRL has a clearly defined jurisdiction.	with clear TOR to coordinate public health functions of the national TB laboratory network. OR Each NRL has a clearly defined terms of reference.	public health functions of the national TB laboratory network and has informal links with the NTP (or other national agencies focusing on public health). OR A national-level unit is responsible for coordinating the activities of the network of NRLs.	NTP (or other national agencies) are formalized through MoUs or similar. AND if more than one NRL, coordination meetings of the NRLs occur at least once-a year	with a supranational (international) lab.
2.2.3	Does the NRL provide essential TB public health functions? 1) support for disease prevention, control and surveillance, 2) integrated data management, 3) reference and specialized testing, 4) laboratory improvement, 5) policy development, 6) public health preparedness and response,7) public health related research, 8) training and education; partnership and 9) communication.	The NRL is not designated or does not provide any of the essential TB public health functions.	<3 essential TB public health functions, including at least support for TB disease prevention, control and surveillance.	Between 3-5 essential TB public health functions, including at least support for TB disease prevention control and surveillance	Between 6-8 essential TB public health functions, including at least support for TB disease prevention control and surveillance	NRL performs all essential TB public health functions and supports all public sector laboratories and some private sector laboratories	Stage 4 with support for all public and private sector laboratories in the network included.

2.2.4	Does the TB diagnostic network collaborate with other disease-specific diagnostic networks (e.g. HIV) regarding laboratory and diagnostic services (e.g., specimen transport, shared diagnostic platforms, etc.)?	No	There is limited collaboration between TB and non-TB diagnostic networks either at the NRL level or program level.	Formal collaboration occurs on an ad hoc basis.	Formal collaboration and coordination mechanisms between TB and non-TB diagnostic networks take place at least annually.	Coordination mechanisms of TB and non-TB diagnostic networks occur at least once a year. A national level unit coordinates collaboration between TB and non-TB diagnostic networks.	Formal collaboration between TB and non-TB diagnostic networks and regular coordination meetings held. Review and analysis of collaboration on regular basis.

Question number	Questions	Stages					
		0	1	2	3	4	5
Component 2.3. Programmatic and operational research							
2.3.1	Is programmatically relevant operational research and research on new TB diagnostics or algorithms conducted in the country? Are data used from such research to inform national policy on the diagnostic network? Does research lead to adopting new diagnostics tools or algorithms, policy revision and implementation?	No	Limited high-quality research is conducted in the country and is not used to inform national policy.	High-quality research is conducted at reference and referral level only, and in few settings. Data are used to inform policy on an ad hoc basis.	Stage 3 plus some studies at lower levels of the network and various geographical settings. Data are used to inform national policy on an ad hoc basis.	Stage 4 plus all levels of the network and various geographical settings and some priority populations. Data are often used to inform national policy.	National policies on TB diagnosis are always informed by high quality research conducted in the country which reflects all levels of the network, various settings, and priority populations.

Capacity 3. Coverage

Question number	Questions	Stages					
		0	1	2	3	4	5
Component 3.1. Diagnostic network coverage							
3.1.1	At the national level, is there a current list or map of laboratories that fall under the national TB diagnostic network? Does this list or map include a current inventory of TB diagnostic tests (microscopy, Xpert MTB/RIF, culture, DST, etc.) and instruments within the existing diagnostic network?	No map or list is available at the national level.	A list or map exists of some laboratories in the public sector that offer TB services.	A list or map exists of ALL laboratories in the public sector that offer TB services.	A list or map exists of all laboratories in the public sector that offer TB services AND the map or list includes current inventory of diagnostic tests and instruments.	All of the before and includes incomplete GIS mapping of laboratories.	All of the before with complete GIS mapping and includes private, academia or military laboratories.
3.1.2	Are there sufficient TB diagnostic facilities to meet the estimated needs for the basic TB testing package available in all districts? TB diagnostic facilities may include community-based health facilities that screen patients, collect samples, and refer	No, because no TB testing package has been defined or no mapping was conducted.	TB diagnostic facilities to meet the estimated needs are not available at a distance ≤ 5 km OR at a maximum of 1-	TB diagnostic facilities to meet the estimated needs are available at a distance ≤ 5 km OR at a maximum of 1-	In 50-99% of the districts.	Full coverage to meet the estimated needs and with continuous services in parts of the districts.	Full coverage and with continuous services accessible in all districts.

	samples to TB laboratories for testing.		hour travel time for 80% of the population in any district.	hour travel time for 80% of the population in a district in less than <50% of the districts.			
3.1.3	Is there access to rapid TB testing (e.g., country-approved or WHO-approved rapid diagnostic tests [WRDs]) in all districts?	There is no laboratory onsite testing or referral services for rapid diagnostic testing (e.g., WRDs) in any of the districts.	Onsite testing or referral services for rapid diagnostic testing (e.g., WRDs) is available for some defined priority populations in <10% of the districts in the country.	All of the before in 10-49% of the districts in the country.	All of the before in ≥50 % of the districts. OR Onsite testing or referral services for rapid testing is available for all priority populations in ≥25% of districts	Onsite testing or referral services for rapid diagnostic testing (e.g., WRDs) is available in all districts for all defined risk groups. Onsite testing or referral services for rapid testing for all presumptive TB	Onsite testing or referral services for rapid diagnostic testing (e.g., WRDs) available in all districts for all defined risk groups. AND Onsite testing or referral services for rapid testing for all presumptive TB

Question number	Questions	Stages					
		0	1	2	3	4	5
						cases is available in some districts.	cases is available in all districts.
Component 3.2. Specimen referral system							
3.2.1	Are all persons involved in TB specimen referral trained in specimen referral processes and procedures (e.g., specimen, collection, storage and packaging; recording and reporting; transport; biosafety and spill procedures; etc.) as appropriate to their duties and responsibilities?	No	Training is available but does not include all processes and procedures relevant to the duties of each category of worker. OR Training only covers only a few categories of workers.	Training in specimen referral processes and procedures is available in the public sector for some categories of workers at some levels of the diagnostic network.	Training in specimen referral processes and procedures is available for all categories of workers and is sanctioned by competency testing and a certificate. AND Training and regular refresher training are available at some levels of the diagnostic network.	Initial training and regular refresher training with occasional repeat competency testing are available for all workers and at all levels in the public sector and in some private sector sites.	Stage 4 and regular competency testing and supervision at all levels in the public sector and in most private sector sites.
3.2.2	Is triple packaging used for all national and international TB specimen transportation?	Concept of triple packaging is unknown OR triple packaging material not available at any tier.	Triple packaging is only used for international specimen transportation.	Triple packaging material is used at SOME tiers BUT there are regular stock outs.	Triple packaging material is used at ALL tiers BUT there are regular stock outs.	Triple packaging is used at all tiers with continuous supply of material.	No potentially infectious specimen for TB diagnostic testing is transported nationally or internationally if it is not triple packaged.

3.2.3	Are there standard operating procedures (SOPs) for national and international TB specimen transportation (including defined roles and responsibilities)?	No standardized procedures for TB specimen transportation are in place.	Partially standardized procedures for TB specimen transportation are in place at some levels but roles and responsibilities are not defined.	Partially standardized procedures for TB specimen transportation in place at most sites with role and responsibilities defined. AND SOPs available in some sites that	Completely standardized procedures for TB specimen transportation in place at all sites with tier-specific roles and responsibilities defined. AND SOPs are available in most sites that	Completely standardized procedures for TB specimen transportation in place at all tiers with tier-specific roles and responsibilities defined. AND SOP available in all sites that are	Completely standardized procedures for national and international TB specimen transportation in place with tier-specific roles and responsibilities defined and regular rounds of

Question number	Questions	Stages					
		0	1	2	3	4	5
				are involved in specimen transport	are involved in specimen transport	involved in specimen transport	monitoring and improvement.
3.2.4	Are TB specimen referral and transportation systems in place at the local, regional and national levels?	No system in place for transporting specimens between tiers. Only ad hoc transportation takes place.	A non-structured specimen referral system exists between some tiers in some parts of the country.	A specimen referral system is in place to transport TB specimens from lower to appropriate higher tier laboratories in less than 50% of the districts.	A specimen referral system is in place to transport TB specimens from lower to appropriate higher tier laboratories in 50-80% of the districts.	A specimen referral system with national (>80% of the districts) coverage is in place to transport TB specimens from all lower to appropriate higher tier laboratories.	An integrated specimen referral system with national coverage is in place for TB specimens, connecting all tiers of the network with appropriate higher levels.
3.2.5	Is there a system in place that allows for a sample to be tracked from the submitting laboratory to the receiving laboratory and for the results and reports to be tracked to the original submitting laboratory?	No	Tracking system for referral is informal, irregular and not consistent.	Formal tracking system for referred samples exists at the national level only.	Stage 2 also at some lower levels or in some parts of the country.	Stage 3 also at all levels. Tracking system for referred samples provides reports on a timely basis.	Online real-time tracking system for referred samples provides reports on a timely basis and referred data are routinely or regularly reviewed.

3.2.6	Are there 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 and for importation of quality assessment and control materials?	No	MTAs and/or MoUs are in place for TB specimens, QC or other similar materials.	MTAs and/or MoUs and international specimen referral systems are in place for TB specimens, QC or other similar materials.	MTAs and/or MoUs are in place for routine and emergency situations for TB specimens, QC or other similar materials.	MTAs and/or MoUs and international specimen referral systems are in place for routine and emergency situations for TB specimens, QC or other similar materials.	All of before and a tracking system is in place for all international TB specimen referrals OR all TB specimens can be tested and confirmed in the country.
Component 3.3. Linkages							
3.3.1	Are procedures in place to ensure efficient linkage of persons with presumptive TB to TB diagnostic services (e.g., chest X ray, and laboratory testing)?	No	No formalized procedure; linkage is on an informal and irregular basis.	Formalized procedure is in place for some facilities at some	Formalized procedure is in place for all facilities at all tiers	Stage 3 with all public sector and some private sector facilities	Stage 4 with all public and private, with assessment of impact and

Question number	Questions	Stages					
		0	1	2	3	4	5
				tiers of the network.	in the public sector		review of procedures
3.3.2	Are procedures in place to ensure efficient linkage of persons diagnosed with TB or DR-TB to appropriate care and treatment?	No	No formalized procedure; linkage is on an informal and irregular basis.	Formalized procedure is in place for linking diagnosed patients with care at some tiers of the network.	Formalized procedure is in place for linking diagnosed patients with care at all tiers in the public sector AND procedures are in place to track patients to reduce patient dropout from the diagnostic and treatment cascade.	Stage 3 with all public sector and some private sector facilities.	Stage 4 with all public and private, with assessment of impact and review of procedures
3.3.3	Are there transfer-in and transfer-out forms available for patient's referral and linkage?	No	No formalized procedure; Transfer-in and out done based on patients and HCWs willing, informal basis.	Formalized procedure and form are in place for transfer-in and out at national level but not implemented at regional, district and peripheral level.	Formalized procedure and form are in place for transfer-in and out at national level. Forms and procedures implemented in some public facilities at regional level.	Formalized procedure and form are in place for transfer-in and out at national level. Forms and procedures implemented in all public facilities at regional and peripheral level.	Formalized procedure and form are in place for transfer-in and out at national level. Forms and procedures implemented in all public and private facilities at regional, peripheral level and regularly monitored.

3.3.4	Do clinical and laboratory staff regularly (at least quarterly) meet to troubleshoot gaps in laboratory-clinical linkages, including specimen referral, results interpretation and reporting?	No	Meetings occur infrequently on an ad hoc basis.	Regular meetings (at least quarterly) occur at some facilities in some tiers with public sector providers.	Regular meetings (at least quarterly) occur at all facilities in some tiers with public sector providers.	Regular meetings (at least quarterly) occur at all facilities in all tiers.	Stage 4 with joint planning and impact assessment conducted, with regular reviews.
Component 3.4. Emergency preparedness							
3.4.1	Are there plans for continuation of TB diagnostic services in case testing cannot be performed (e.g.,	No	Plans to ensure continuity of	Plans have been developed but are incomplete or not	Plans are in place and budgeted for implementation in	Stage 3 plus all public sector and	Stage 4 plus all public and private sector. Plans and

Question number	Questions	Stages					
		0	1	2	3	4	5
	equipment outages, stockouts or emergency situations such as commandeering of laboratory facilities by other disease programs, earthquake, floods, health worker strike, etc.)?		service are under development.	approved. Essential resources (staff, materials, budget) are lacking for full implementation.	parts of the public sector.	some private sector facilities.	budgets are reviewed on a regular basis.
3.4.2	At the local level is there a current list of laboratories that provide TB diagnostic services? Does this list include contact information, available TB diagnostic tests and instruments? Note: Such a list is useful for communication and coordination of testing during an emergency.	No list is available.	A list exists of some public sector laboratories in the local area that offer TB services.	A list exists of all public sector laboratories in the local area that offer TB services. AND the list includes contact information.	Stage 2 and the list includes some private laboratories in the local area that offer TB services. AND the map or list includes current inventory of diagnostic tests and instruments.	Stage 3 and the list includes all private, academia or military laboratories in the local area that offer TB services.	Stage 4 and there is complete GIS mapping of facilities that offer TB testing in the local area,

Capacity 4. Diagnostic algorithm

Question number	Questions	Stages					
		0	1	2	3	4	5
Component 4.1. Algorithm							
4.1.1	Is a clear national TB laboratory testing algorithm available that is responsive to the epidemic, patient-centered, based on international best practice and appropriate to the current structure of the health system?	A national TB laboratory testing plan is not available or does not adequately address all components of an appropriate TB diagnostic algorithm.	National laboratory testing algorithms for TB are available at some laboratories but are not current or complete.	National TB laboratory testing algorithms are available at all facilities in the public sector but are not current or complete.	Current national TB laboratory testing algorithms are available at most but not all public facilities including laboratories and clinical facilities.	Current national TB laboratory testing algorithms are available at all public facilities and some private facilities including laboratories and clinical facilities.	Current national TB laboratory testing algorithms are available at all public and private facilities and regularly reviewed and updated.
4.1.2	Does the TB laboratory testing	No	The national	The national TB	The national TB	The national TB	The national TB

	algorithm address the laboratory goals of the WHO End TB strategy to increase access to rapid and accurate detection of TB and to reach universal access to DST?		TB laboratory testing algorithm incorporates the use of rapid diagnostics to detect TB in some patients in some settings.	laboratory testing algorithm incorporates the use of rapid diagnostics to detect TB or rapid DST for patients in some high priority groups (e.g., those at risk of multidrug-resistant TB (MDR-TB), HIV/TB, or	laboratory testing algorithm incorporates the use of rapid diagnostics to detect TB or rapid DST for all TB patients in all high priority groups (e.g., those at risk of MDR-TB, HIV/TB, or pediatric TB).	laboratory testing algorithm incorporates universal access to rapid diagnostics to detect TB and rapid DST for all TB patients.	laboratory testing algorithm incorporates universal access to rapid diagnostics to detect TB and rapid DST for all TB patients and all persons being evaluated for TB.

				pediatric TB).			
4.1.3	Does the national TB diagnostic algorithm focus on the whole diagnostic cascade, from screening to treatment completion and define the role of symptom screening, clinical presentation, patient history, and X-ray in the diagnostic cascade? Note: The 'national TB diagnostic algorithm' may include separate algorithms that address TB screening and medical evaluation, laboratory testing, TB	No	The TB diagnostic algorithm focuses only on the laboratory testing but is not current or complete.	The algorithm focuses on the laboratory testing and does not address the whole diagnostic cascade, from screening to treatment completion. National guidelines for evaluating patients and using	The algorithm at least partially addresses the whole diagnostic cascade, from screening to treatment completion. National guidelines for evaluating patients and using	The algorithm addresses the whole diagnostic cascade, from screening to treatment completion. National guidelines for evaluating patients and using X-ray findings are	The algorithm addresses the whole diagnostic cascade, from screening to treatment completion and regularly updated. National guidelines for evaluating patients and using

Question number	Questions	Stages					
		0	1	2	3	4	5
	treatment and monitoring. These should be available in the NSP.			patients and using X-ray findings are available.	X-ray findings are followed by some clinicians in the public sectors	followed by all clinicians in the public sector and some clinicians in the private sector.	X-ray findings are followed by all clinicians in the public and private sectors.
4.1.4	Is comprehensive training on diagnostic algorithms, testing methods, specimen collection, test requisition forms and specimen referral provided to all laboratorians, clinicians and other providers (including non-NTP) and TB program staff? Are health care workers provided with standardized sensitization content (e.g., algorithm diagrams, brochures, training materials, customer handbook)?	No	Some training provided to some laboratorians, clinicians and providers in public sector in some districts but is not current or complete. Sensitization content is available at some facilities but not current or complete.	Training is provided to all laboratorians and some clinicians and providers in the public sector but is not current or complete. Sensitization content is available at all facilities in the public sector, but not current or complete.	Current and complete training is provided to all laboratorians, clinicians and providers in the public sector in some districts. Up-to-date sensitization content is available, but not at all public facilities.	Stage 4 with training provided to all laboratorians, clinicians and providers in the public sector and some private sector. Up-to-date sensitization content is available at all public facilities and some private labs.	All laboratorians, health care workers and TB program staff are trained in the application of the algorithm, which is regularly reviewed and updated. Up-to-date sensitization content is available at all public and private facilities and regularly reviewed and updated.

4.1.5	Are diagnostic tests ordered according to standard diagnostic algorithms and based on national policy and patient risk factors and history? (as opposed to individual clinicians deciding which tests to order based on their own criteria and patient preference)	No	National TB diagnostic algorithm is followed by some clinicians in the public sector for some patient categories.	National TB diagnostic algorithm is followed by some clinicians in the public sector for all patient categories.	National TB diagnostic algorithm is followed by all clinicians in the public sector in some districts for all patient categories.	Stage 3 with all public sector in all districts and some private sector.	Stage 4 with all public and private sector clinicians.
Component 4.2. Detection of TB							
4.2.1	Is diagnostic testing (either onsite testing or by referral) available for all tests prescribed in the national TB laboratory testing algorithm in all tiers of the laboratory network? Is access to TB laboratory testing available for all patient categories within the NSP, including pediatric, extrapulmonary, PLHIV and high-risk populations (miners, slum dwellers, diabetics, etc.)?	Testing not available for any of the tests.	Diagnostic testing required by the TB laboratory testing algorithm is taken into account in the definition of the tier-specific minimal testing	Stage 1 and the national laboratory network (all districts) has the capability to provide all of the diagnostic testing required by the national TB laboratory testing algorithm. The	Stage 2 and the required diagnostic testing is available onsite or by referral for all priority and high-risk patient categories in all districts.	Stage 3 plus access to testing is available for all patients in all districts.	For all public and private sector labs and continuously fulfilling international standards and requirements.

Question number	Questions	Stages					
		0	1	2	3	4	5
			package of the diagnostic network.	required diagnostic testing is available onsite or by referral for some priority and high-risk patient categories in some districts.			
4.2.2	Is the country transitioning from using the Xpert MTB/RIF test to the Xpert Ultra test as the WHO-recommended rapid TB diagnostic test?	The national TB plan does not address the transition from the Xpert MTB/RIF assay to the Xpert Ultra test.	A plan for transitioning from the Xpert MTB/RIF test to the Xpert Ultra test has been approved and is being implemented.	The Xpert Ultra test has replaced the Xpert MTB/RIF test for all testing or for testing of priority risk groups (e.g., TB-HIV, pediatric TB, smear-negative TB) in <10% of the Xpert testing sites.	All of before in 10- 49% of the Xpert testing sites.	All of before in ≥50 % of the Xpert testing sites.	The Xpert Ultra test has replaced the Xpert MTB/RIF test for all testing in all Xpert testing sites.
Component 4.3. Detection of drug-resistant TB (DRTB)							
4.3.1	Is DST for rifampicin available on site or by referral for all bacteriologically confirmed TB patients? Is DST for	DST for rifampicin or isoniazid is	DST for rifampicin is available on	DST for rifampicin is available on site or by referral for	Stage 2 plus rapid tests are used for DST for	Stage 3 plus all bacteriologically confirmed	Stage 4 plus all bacteriologically confirmed

	other key first-line anti-TB drugs (at least DST for isoniazid) available on site or by referral for all bacteriologically confirmed TB patients?	not available.	site or by referral in reference laboratories for some patients.	bacteriologically confirmed TB patients at risk of having MDR-TB.	rifampicin. AND DST for isoniazid is available on site or by referral for bacteriologically confirmed TB patients at risk of having INH-resistant TB.	patients in the public sector are tested for rifampicin resistance. AND Rapid DST for isoniazid is conducted for some bacteriologically confirmed TB patients at risk of having INH-resistant TB.	patients in the public and private sectors are tested for rifampicin resistance. AND Rapid DST for isoniazid is conducted for all bacteriologically confirmed TB patients at risk of having INH-resistant TB.
4.3.2	Is DST for key second-line drugs (at least fluoroquinolones [FQs]) available on-site or by referral for all patients with RR/MDR-TB and for FQs for all patients with isoniazid-resistant and rifampicin-susceptible	No second-line (SL) DST is available at reference laboratory.	Partial panel of SL drugs can be tested at the reference level using reliable standardized	Partial panel of SL drugs (at least FQs and AMK) can be tested using reliable standardized	Full panel of SL drugs can be tested using reliable standardized assay at the reference	Full panel of SL drugs can be tested using reliable standardized assay in the reference	Full panel of SL drugs can be tested using reliable standardized assay in the reference

Question number	Questions	Stages					
		0	1	2	3	4	5
	tuberculosis (Hr-TB)? Is reference testing for resistance to the full panel of second line (SL) anti-TB agents available on site or by referral throughout the network? Note: Full panel includes all the drugs used in the country to treat TB for which there are reliable laboratory tests.		assays. Panel must include FQs and AMK if the short MDR-TB regimen is used.	detection assay at the reference laboratory and DST for FQs (and AMK if the short MDR-TB regimen is used) is available on site or by referral in <30% of the districts (molecular or phenotypic methods) for patients with RR or MDR-TB.	laboratory; and DST for FQs (and AMK if the short MDR-TB regimen is used) is available on site or by referral in <50% of the districts (molecular and phenotypic methods) for patients with RR or MDR-TB.	laboratory; and DST for FQs (and AMK if the short MDR-TB regimen is used) is available on site or by referral in <80% of the districts (molecular and phenotypic methods) for patients with RR or MDR-TB and those with Hr-TB.	laboratory; and DST for FQs (and AMK if the short MDR-TB regimen is used) is available on site or by referral in all districts (molecular and phenotypic methods) for patients with RR or MDR-TB and those with Hr-TB.
4.3.3	Does the algorithm include the DST needed to address the DRTB burden in the country? Priority groups for DST include all smear microscopy positive at month 2, relapses cases, failure, DRTB contacts.	No, the algorithm does not address any of these DRTB high risk groups	The algorithm addresses only one criteria of these high-risk group	The algorithm addresses two high risk groups (DR-TB contact and relapses cases) of these high-risk group and partially implemented in public sector	The algorithm addresses all criteria of these high-riskgroupbut partially implemented in public sector	The algorithm addresses all criteria of these high-riskgroupbut fully implemented in public sector	The algorithm addresses all criteria of these high-riskgroupbut fully implemented in public and private sector

Capacity 5. Biosafety

Question number	Questions	Stages					
		0	1	2	3	4	5
Component 5.1. Facilities							
5.1.1	Are TB laboratory-specific building requirements consistently applied to all laboratory facilities? TB-specific requirements should address specifications for ventilation, separate rooms for certain testing, biosafety level, materials, electrical supply, water supply, etc.	There are no building requirements specific for TB laboratories.	National requirements for TB laboratories exist but they are not consistently applied.	National requirements for TB laboratories exist and are consistently applied to all new buildings in the public OR private sector.	National requirements for TB laboratories exist and are mandatory for new facilities in the private and public sector.	All new and existing TB laboratories facilities are aligned with national building requirements.	All new and existing TB laboratory facilities are aligned to national building norms and are regularly checked.
5.1.2	Are TB laboratory facilities regularly maintained and is there an uninterrupted availability of general utilities (water, energy, communication lines)?	No	TB laboratories are sporadically maintained, and some general utilities are available at some tiers.	TB laboratories are periodically maintained, and all utilities are available at some tiers.	TB laboratories are periodically maintained, and all utilities are available at all tiers with backup systems for at least electricity at some levels.	Ongoing preventive maintenance at some tiers and backup systems for at least electricity at all levels.	Ongoing preventive maintenance at all tiers and backup systems for all utilities are available, regularly tested and replaced when necessary.

Component 5.2. Biosafety and biosecurity manual							
5.2.1	Does the biosafety and biosecurity manual cover key requirements for the safe handling of TB samples (specimens, isolates, strains) based on bio-risk assessment? The requirements may be addressed as part of the national laboratory biosafety and biosecurity manual or in a separate TB laboratory biosafety and biosecurity manual.	There is no biosafety manual.	There is a national laboratory biosafety and biosecurity manual but M. tb is not explicitly addressed.	The manual explicitly addresses M. tb but covers only 1-2 key requirements. Includes risk assessment mainly in the perspective of safeguarding the laboratory staff (biosafety).	The manual addresses all elements, for both staff safety (biosafety) and the protection of the environment (biosecurity).	Stage 3 and documented risk assessments conducted at facility level.	Stage 4 and the manual is regularly reviewed and updated.
5.2.2	Is the national laboratory biosafety and biosecurity manual implemented and incorporated into standard operating (SOP) procedures that contain adequate information on TB laboratory biosafety?	There is no laboratory biosafety and biosecurity	There is a manual that is out of date with no current SOPs OR there	There is an up- to-date manual in place with no current TB SOPs OR some	There is an up- to-date manual in place, but TB biosafety and biosecurity are	Stage 3 plus TB biosafety and biosecurity are fully incorporated	All of the previous stages and the manual is regularly

Question number	Questions	Stages					
		0	1	2	3	4	5
		manual and no SOPs.	are some out of date SOPs in place with no manual. The manual or SOPs are available in the laboratory but are not implemented.	current TB SOPs are in place with no manual. The manual or SOPs are available in the laboratory and are partially implemented.	not fully incorporated into current SOPs. The manual and SOPs are available in the laboratory and are fully implemented.	into current SOPs.	reviewed and updated.
Component 5.3. Biosafety systems							
5.3.1	Are designated safety officers available in all facilities? (part-time or full time) Note: The safety officer functions may be provided be district or regional laboratory advisor who regularly visits (at least quarterly) the laboratory to conduct safety assessments, safety training and consultations. The advisor must be trained in TB laboratory biosafety and certified as competent.	No designated safety officer at any facilities.	Some facilities at some tiers of the public sector have a designated safety officer.	All facilities at some tiers of the public sector have a designated safety officer.	All facilities at all tiers of the public sector have a designated safety officer.	All facilities of the public sector and some private sector facilities have a qualified and designated safety officer who receives regular (e.g., annual) refresher trainings.	All facilities in the public and private sector have a qualified and designated safety officer that receive regular refresher trainings.
5.3.2	Is safety equipment needed for safely working with TB specimens and isolates	No	Some safety equipment	All safety equipment	All safety equipment	All safety equipment	All safety equipment is

	available and used (e.g., PPE)?		available.	according to the national guidelines is available and properly used by some laboratory workers.	according to national guidelines is available and properly used by all laboratory workers at some levels in the public sector.	according to national guidelines is available and properly used by all laboratory workers at all levels in the public sector and some levels in the private sector.	available and properly used by all laboratory workers at all levels and regularly monitored and replaced when expired.
5.3.3	Are certified biosafety cabinets (BSCs) available according to the facility biosafety level (BSL) wherever needed?	Certified BSCs are needed but are not available in the country.	BSCs are available according to BSL only at some tiers or in some facilities.	Certified BSCs are available according to BSL at all facilities in need in the public sector but are not regularly serviced.	All of the before and including some private labs and BSCs are regularly serviced at some tiers but not by a certified body.	BSCs are regularly serviced and certified at all relevant tiers by a certified body.	At all relevant tiers of the laboratory network in the public and private sector and these are regularly serviced and certified

Question number	Questions	Stages					
		0	1	2	3	4	5
							according to a national or institutional maintenance plan.
5.3.4	Have all TB laboratory staff received health screening including assessing of signs and symptoms of TB in the past 1 year and have they received training in the risks of laboratory-acquired infection and on the signs and symptoms of TB in the past 1 year?	Screening of laboratory staff for TB is not conducted. Laboratory staff are not provided training in the signs and symptoms of TB or risk of laboratory - acquired infection.	Infrequent screening of laboratory staff for TB is conducted on an ad hoc basis. Laboratory staff at some levels of the diagnostic network are provided training in the signs and symptoms of TB or risk of laboratory-acquired infection.	TB laboratory staff at some levels of the diagnostic network are provided annual training in and screening for TB signs and symptoms and risk of laboratory-acquired infection, but the results are not documented in personnel files. Additional medical evaluations and testing are provided for those with signs and symptoms of TB. TB treatment is provided as needed.	All TB laboratory staff at all levels of the diagnostic network are provided annual training in and screening for TB signs and symptoms and risk of laboratory-acquired infection and the results are documented in personnel files. Additional medical evaluations and testing are provided for those with signs and symptoms of TB. TB treatment is provided as needed.	Stage 3 and possible instances of laboratory acquired TB infection are investigated and corrective actions taken.	Stage 4 and the screening program is regularly reviewed and update.

Component 5.4. Waste management							
5.4.1	Are standardized procedures for collecting, storing and disposal of identified categories of waste available and implemented according to the national standards?	No procedures or national standards exist.	National standards or standardized procedures for collecting, storing and disposal of identified categories of waste have	National standards or standardized procedures for collecting, storing and disposal of identified categories of waste have been	National standards or standardized procedures for collecting, storing and disposal of identified categories of waste have been	Stage 3 and conformance to waste management is partially monitored in accordance with level-specific biosafety and	Stage 4 and waste management conformance is fully monitored in accordance with level-specific biosafety and biosecurity requirements in all facilities of the

Question number	Questions	Stages					
		0	1	2	3	4	5
			been developed, but not implemented.	implemented in some facilities at some tiers of the TB diagnostic network.	implemented in all facilities at all tiers of the TB diagnostic network.	biosecurity requirements.	TB diagnostic network.
5.4.2	Do laboratories have access to methods and equipment (e.g., autoclaves or incinerators) for safely disposing of infectious waste?	No access to autoclaves nor incinerators.	Some laboratories have access to autoclaves and/or incinerators.	All laboratories have access to autoclaves, and some have access to incinerators.	All laboratories have access to both autoclaves and incinerators, but they are not used for the disposal of all eligible waste.	All laboratories have access to autoclaves and incinerators, and they are used for the disposal of all eligible waste in all public sector and some private sector laboratories.	All laboratories have access to autoclaves and incinerators, and they are used for the disposal of all eligible waste in all public sector and private sector laboratories.

Capacity 6. Equipment and supplies

Question number	Questions	Stages					
		0	1	2	3	4	5
Component 6.1. Supply chain management							
6.1.1	Are standardized quality-assured reagents used at all levels of the TB diagnostic network?	No	Standardized reagents are available for some but not but tests in the tier-specific TB testing package.	Standardized reagents are available for all tests in the tier-specific TB testing package but are not used at all levels in the TB diagnostic network.	Standardized testing reagents are used at all levels in the TB diagnostic network, with regular monitoring and updating.	Stage 3 and SOPs are available for reporting complaints on quality of laboratory supplies and for corrective actions. Reagents are quality assured by lot verification testing.	All laboratories in the TB diagnostic network operate using state-of-the art standardized quality-assured testing reagents that can be procured locally or regionally. Contract management capacity for reagents and supply is demonstrated in central laboratories.

6.1.2	Are there regulatory procedures in place for the control of in vitro diagnostics (IVD)?	No	Regulatory procedures are being developed.	Regulatory procedures are in place and a list of authorized IVDs is available.	The list of authorized IVDs is routinely updated. Post market surveillance is organized for some IVDs including those for TB.	The list of authorized IVDs and the regulatory procedures are routinely updated. In country post market surveillance include IVDs for TB.	Post-market control is done for all IVDs used in the country
6.1.3	Is there a procurement and distribution system allowing for the continuous supply of testing reagents in the country for public-sector laboratories and private or academic laboratories that are in, or linked to the national TB diagnostic network?	No	System is in place for some supplies for some districts or tiers, but with regular stock outs.	System is in place for all supplies for some districts or tiers, but with regular stock outs in	System is in place for all supplies and for all districts or tiers, with occasional stock outs	System is in place for all supplies and for all districts or tiers with no stock outs in routine situation.	The national procurement system ensures the continuous distribution of all needed supplies with a universal coverage. The

Question number	Questions	Stages					
		0	1	2	3	4	5
				routine situations.	during routine situations.		system is regularly quality controlled.
6.1.4	Is there a system to monitor and forecast supply consumption in the country? Note: This system should address the country or regional level monitoring and forecasting needed to ensure that all laboratories in the diagnostic network have the supplies they need for testing without any delays in testing due to stockouts.	No	Individual facilities monitor supply consumption (e.g., use stock cards) of some supplies, but the data are not compiled and used at the district or higher levels to forecast supply needs.	Individual facilities monitor supply consumption of some supplies, and the data are compiled and used at the district or higher levels to forecast supply needs. There are occasional stock outs.	Individual facilities monitor supply consumption of all supplies, and the data are compiled and used at the district or higher levels to forecast supply needs. There are no stock outs.	Real time supply consumption monitoring and forecasting systems are in place for procurement, storage and distribution of some supplies.	Real time supply consumption monitoring and forecasting systems are in place for procurement, storage and distribution of all supplies and system is regularly monitored.

Component 6.2. Equipment management							
6.2.1	Does the country have a standardized list of laboratory equipment?	No	There is a list of equipment for routine testing, but it is not fully aligned with tier- specific requirements.	There is a list of equipment for routine testing, aligned with tier-specific testing requirements, and the national reference laboratory is compliant with the list.	There is standardized list of equipment for routine testing, aligned with testing requirements for all tiers of the laboratory network.	There is standardized list of equipment for routine testing, aligned with testing requirements for all tiers of the laboratory network. The list is enforced in all laboratories in the TB diagnostic network and is regularly reviewed and updated.	There is standardized list of equipment for routine testing for all tiers of the laboratory network which is enforced and regularly. Contract management capacity for equipment is demonstrated in central laboratories.
6.2.2	Is there a procedure for validation of equipment?	No	There is pre-service validation of some pieces of equipment at	There is pre-service validation of all pieces of equipment at	There is pre-service validation of some pieces of	There is pre-service validation of all pieces of equipment at all	There is pre-service and ongoing validation of all pieces of equipment at all

Question number	Questions	Stages					
		0	1	2	3	4	5
			the national level.	the national level.	equipment at all levels.	levels of the TB diagnostic network. Operational validation (in service) is done for some instruments at some levels.	levels of the TB diagnostic network.
6.2.3	Is there a maintenance plan (that covers spare parts, storage, and disposal) for all laboratory equipment at all levels? National guidelines for maintenance should be available. The maintenance plan and allocated budgets may be at the national, regional, or facility level.	No	A maintenance or service plan is in place only for essential or sophisticated equipment.	A maintenance plan is in place for all equipment at the national level and some sub-national levels.	A maintenance plan is in place for all equipment at all levels in the public sector. Contracts and engineers are available at national and regional levels for some equipment.	As before and including some private laboratories. Contracts and engineers are available for all equipment in some districts.	Companies are evaluated and contracts are reviewed, renewed, or replaced. Coverage of all laboratories of the TB diagnostic network. Engineers are available for all equipment in all laboratories.
6.2.4	Are diagnostic platforms used for TB and other diseases (e.g., Xpert testing for TB and for HIV), including planning, procurement, use and maintenance?	No	There are no guidelines on integration, and it is conducted only in a limited number of facilities.	There are guidelines which advocate integration of services, and it is implemented in some facilities.	Stage 2 plus shared planning and budgeting in some location at the national levels.	Stage 3 with shared planning and budgeting in all public sector facilities	Use of all relevant diagnostic platforms is integrated across TB and other diseases, with joint planning and budgeting.

Capacity 7. Workforce

Question number	Questions	Stages					
		0	1	2	3	4	5
Component 7.1. Education and training							
7.1.1	Is practical training on TB testing part of the pre-service curriculum and does it include training on TB biosafety, biosecurity and quality practices?	No	Practical training on TB testing is only organized outside the training institute. Some pre-service educational curricula include quality or biosafety or biosecurity management	Practical training on TB testing is organized inside the training institute but consist mainly of observation/ demonstration. All pre-service educational curricula include quality, biosafety and biosecurity management.	Practical training on TB testing is organized inside the training institute and consists mainly of hands-on practical trainingonclassic techniques. Pre-service training includes practical training in TB-specific aspects quality, biosafety and biosecurity management	Hands on practical training on TB testing Is organized inside the training institutes on both classic and modern techniques. All pre-service practical training in TB-specific aspects quality, biosafety and biosecurity management includes competency testing.	Hands on practical trainings in all TB methods used in the laboratories are regularly reviewed and updated with input from the end users (lab managers).

7.1.2	Is there a training program for laboratory management in place?	No	Sporadically, courses on aspects of laboratory management (i.e., leadership course) are available.	Regular courses on aspects of laboratory management are available for upper-level laboratory managers.	A training program for laboratory management at all levels, either separately or as a specialized track in a broader program, is functional.	All of the previous and the program(s) is(are) available up to Master (MSc or MBA) programs.	All of the previous and the programs are regularly reviewed and updated.
7.1.3	Are there continuous education training programs in place?	No	There are continuous education trainings organized by the program, local partners or international	There are continuous ad hoc or unofficial education trainings organized by the government or training institutes.	There is an official national program and annual plan for continuous education, which is partially functional.	All of the previous and the program is regularly reviewed and updated. There is an official national program	All of the previous and personal development plans for laboratory workers are based on this

Question number	Questions	Stages					
		0	1	2	3	4	5
			partners on an ad hoc basis.			plan for continuous education, which is fully functional.	program which is updated annually.
7.1.4	Is the licensing of laboratory workers based on education, continuous education and competency?	There is no licensing mechanism in place.	One-time licensing is automatically issued with registration or graduation for some categories of laboratory workers.	Stage 1 for all categories of workers.	Stage 2 and there is a regular re- licensing system in place.	There is a re-licensing mechanism in place based on qualification, continuous education and national standard of competency.	All of the previous and the content of the re-licensing requirements are regularly reviewed and updated.
Component 7.2. Staffing							
7.2.1	Is there a national staffing plan for the TB diagnostic network that is based on workload forecasting that takes into account any anticipated changes in the TB laboratory testing algorithm?	No	There is a national staffing plan, but it is not based on workload forecasting.	A workload forecasting - based staffing plan is being developed.	A workload forecasting based staffing plan is being implemented at some tiers.	There is an implemented staffing plan for all tiers based on workload forecasting.	There is an implemented staffing plan for all tiers based on workload forecasting with procedures for surge capacity.

7.2.2	Are numbers of different categories of TB laboratory workers sufficient to cover the workload needs at all levels? Note: The workload need is expressed as 'full-time equivalents. In laboratories, this need may be filled by several workers who each spend part-time rotations doing TB testing.	There are no numbers or figures available to quantify the availability or shortage of staff.	Shortages based on positions available exist for all categories of TB laboratory workers. Needs based on workloads are not defined.	All positions available are not filled for some categories of TB laboratory workers or in some districts or at some tiers. Needs based on workload are defined at some facilities or at some tiers.	All available positions are filled but shortages exist based on the workload-based staffing norms.	Positions available are based on workload-based norms and are all filled within a reasonable time period.	There is a sufficient number of all categories of laboratory workers based on current and anticipated workload and assist during surge capacity needs.
Component 7.3. Human resources development strategies and plans							
7.3.1	Does the national TB laboratory strategic plan or national TB strategic plan address key issues of the laboratory workforce including staffing, salaries, retention, career	There is no strategy (either stand alone or as an integral part of	The strategy addresses <3 key issues.	The strategy addresses 3-6 key issues including staffing, salaries,	Stage 3 and the strategy addresses 7-10 key issues with clear targets. Some HR	The strategy addresses all issues. All HR strategies exist	The national strategy addresses all key issues with clear targets

Question number	Questions	Stages					
		0	1	2	3	4	5
	development, etc. and is it implemented? (See background for a list of key issues)	a larger health strategy) for the development of the laboratory workforce.		and career development.	strategies are implemented at some facilities.	are implemented at some facilities.	that are revised based on monitoring and evaluation. All HR strategies are implemented at all facilities.
Component 7.4. Competency-based job descriptions							
7.4.1	Are competency-based job descriptions available for all positions in the laboratory and are competency assessments routinely conducted and documented?	No job descriptions at all.	Non-standardized job descriptions available for some positions.	Non-standardized job descriptions are available for all positions.	Standardized and competency-based job descriptions are available for some positions and are non-standardized for some other positions. Assessments of staff competency are not routinely conducted, OR results are not documented in personnel files.	Standardized and competency-based job descriptions are available for all positions, including support staff positions. Assessments of staff competency are conducted annually, and results documented in personnel files.	All of the before and regular review and updating.

Capacity 8. Diagnostic data management

Question number	Questions	Stages					
		0	1	2	3	4	5
Component 8.1. Data collection forms							
8.1.1	Are test request forms standardized for all testing and being used at all levels throughout the country? Is quality control of data entry performed? Are the data on the request forms collected and analyzed (e.g., are all required fields completed; are Xpert tests being ordered according to the national algorithm)?	Standardized test forms are not available or are not fully aligned with the testing.	Request forms are standardized for some tests only at national level.	Request forms are standardized for some tests only at national level and some lower levels OR in some parts of the county.	Request forms are standardized for ALL tests at national level and some lower levels OR in some parts of the country.	Stage 3 and the request forms are fully used at all levels. Data on test request forms are captured by laboratory, verified (i.e., quality controlled) and used in the testing process.	Stage 4 and request forms are regularly reviewed. Data on test request forms are captured in logbooks/online in real-time/LIMS and regularly reviewed and analyzed.
8.1.2	Are standardized forms used for collecting and reporting data on the performance of the diagnostic network (e.g., test statistics or key performance indicators)?	No	Forms are standardized for some tests or data elements only at national level.	Forms are standardized for some tests or data elements only at national level and some lower levels OR in some parts of the county.	Forms are standardized for ALL tests and data elements at national level and some lower levels OR in some parts of the country.	Stage 3 and the forms are fully used at all levels.	Stage 4 and forms are regularly reviewed, and data analyzed and used for decision making.

Component 8.2. Reporting							
8.2.1	Are reporting forms for all TB tests standardized and according to best practice, and include information on interpretation of results? Are they being used at all levels throughout the country?	No	Reporting is not standardized for any tests and reports do not include all essential data.	Reporting is standardized for some tests and reports do not include all essential data.	Reporting is standardized with all essential data for all tests at national level and some lower levels OR in some parts of the country in the public sector.	Stage 3 at all levels in all facilities in the TB diagnostic network. The reporting form contains information on the interpretation of results for some tests.	Standardized reporting forms are used in all facilities in the TB diagnostic network. The reporting form contains information on the interpretation of results for all tests.
8.2.2	Is there an electronic system supporting the reporting of diagnostic data to clinicians for patient management (e.g., LIMS, eTB manager, electronic medical records)?	No	Electronic reporting is functional in reference laboratories only.	Stage 1 and functional at regional levels laboratories.	Stage 2 and functional at some lower levels.	Stage 3 and functional to all referring clinicians at all levels in the public sector and some private sector facilities.	Electronic reporting is fully functional to all referring clinicians at all levels in the TB diagnostic network.
8.2.3	Is there an electronic system (e.g., LIMS) that enables	No	Electronic reporting for	Stage 1 and functional at	Stage 2 and functional at some	Stage 3 and functional at all levels in the TB	Stage 4 plus data are routinely

Question number	Questions	Stages					
		0	1	2	3	4	5
	reporting of laboratory test data (e.g., test statistics or key performance indicators) to local and national programs? Dolocal and national programs give feedback to reporting laboratories? Do local and national programs analyze and use data routinely for decision- making and program improvement, including network management and equipment maintenance, supply chain, quality assurance?		programme purposes is functional in reference laboratories only.	regional levels laboratories.	lower levels or in some parts of the country and analyzed for a limited range of purposes.	diagnostic network. Data are analyzed routinely for multiple purposes.	analyzed and used for a full range of purposes.
Component 8.3. Data connectivity and remote monitoring							
8.3.1	Have data connectivity solutions been implemented in the TB diagnostic network?	No	Policies, procedures and SOPs for connectivity and remote monitoring have been developed, approved and disseminated.	Diagnostics connectivity solutions have been implemented in some laboratories in the TB diagnostic network.	Diagnostic connectivity solutions have been implemented in most laboratories in the TB diagnostic network and remote monitoring initiated.	Diagnostic connectivity solutions have been implemented in most laboratories in the TB diagnostic network and remote monitoring is routinely conducted.	Diagnostic connectivity solutions are fully functional. Data collected by remote monitoring are routinely analyzed and used for a full range of purposes.
Component 8.4. Data analysis and sharing							

8.4.1	Is there a fully functional laboratory data unit with adequate numbers of trained personnel, hardware and software that receives laboratory data from all levels, analyzes the data and generates reports? The central unit that collects and analyzes TB laboratory data may be part of a public health laboratory data unit at the MoH or part of the NTP data unit.	No unit	There is a unit but no staff.	Stage 1 but not fully equipped or trained.	There is a unit with staff, which is equipped but not fully operational.	Stage 3 and fully operational.	Laboratory data unit is able to generate reports on a regular basis.
8.4.2	Are statistical data reported, analyzed, used for decision making purposes and shared	No	Data aggregated on an informal and irregular basis.	Only the national laboratory can report aggregate data to the MoH.	Data are aggregated at some laboratories	Data are aggregated from all levels. Procedures are in place for data sharing.	National data reports are written, distributed and shared with other

Question number	Questions	Stages					
		0	1	2	3	4	5
	within MoH and other government agencies?				but not reported to national level.	Reports are sent to the national unit and data are collated and analyzed nationally.	sectors within the government.
Component 8.5. Surveillance and epidemiology							
8.5.1	Is there an up to date, implemented national plan for surveillance of TB and DR-TB, which defines the role of the laboratory?	No plan for TB laboratory surveillance exists.	National plan for surveillance of TB and DR-TB explicitly describing the role of laboratory has been designed but not approved.	National plan for surveillance of TB and DR-TB has been approved. A policy to require laboratory reporting of data on TB or DR-TB cases to the local or national TB control program has been approved.	National plan is being implemented. Designated sentinel sites are conducting surveillance of TB and DR-TB.	All of before. Designated sentinel sites have conducted surveillance of TB and DR-TB for at least 1 year. Data are made available to pertinent clinical organizations to guide local treatment decisions.	Designated sentinel sites have conducted surveillance of TB and DR-TB for 5 years with a system for continuous improvement.

8.5.2	Are laboratory-based surveillance procedures in place and implemented for TB and DR-TB? Are TB and DR-TB surveillance data reported to the epidemiology unit and used as per procedure?	No	A TB prevalence survey OR a Drug Resistance Survey has been conducted.	Stage 1 plus laboratory-based surveillance for TB and DR-TB is conducted in sentinel sites representing at least 30% of the country. Laboratory TB and DR-TB surveillance data are inconsistently reported to the epidemiology unit. There is no approved procedure for data reporting.	Stage 3 plus laboratory-based surveillance for TB and DR-TB is conducted in sentinel sites representing at least 80% of the country. OR A system is in place for ongoing laboratory-based surveillance for TB and DR-TB in >30% of the high-prevalence districts in the country. TB and DR-TB surveillance data are regularly reported to the epidemiology unit as per (approved) procedure.	A system is in place for ongoing laboratory-based surveillance for TB and DR-TB throughout the country (including public and private facilities). Stage 3 and TB and DR-TB surveillance reports are regularly generated by the epidemiologyunit.	Stage 4 with evidence that data have been used to update or draft national diagnostic and treatment guidelines

Question number	Questions	Stages					
		0	1	2	3	4	5
Component 8.6. Security and confidentiality of information							
8.6.1	Are there policies and procedures governing the security of laboratory data and confidentiality of patient data, whether paper based or electronic?	No	Security of laboratory data is managed in an informal and inconsistent way.	Policies or procedures for laboratory data security and patient data confidentiality are drafted but not approved.	Stage 2 and policies or procedures are approved but implemented at national level only, not at lower levels.	Stage 3 and policies and procedures are implemented in most laboratories at all levels of the TB laboratory network.	Stage 4 and policies are fully implemented in all facilities at all levels of the TB diagnostic network, and procedures are regularly reviewed.
8.6.2	Are there SOPs and policies in place to support the back up and retrieval of data?	No	Back up and retrieval of laboratory data is managed in an informal and inconsistent manner.	Policies for laboratory data back up and retrieval are drafted but not approved.	Stage 2 and policies and procedures are approved but implemented at national only, not lower levels.	Stage 3 and policies and procedures are implemented in most laboratories at all levels of the TB laboratory network.	Stage 4 and policies and procedures are fully implemented in all facilities at all levels of the TB diagnostic network, and procedures are regularly reviewed.

Capacity 9. Quality in the diagnostic network

Question number	Questions	Stages					
		0	1	2	3	4	5
Component 9.1. Documents and document control							
9.1.1	Do all of the documents and procedures required to ensure the quality of the TB diagnostic network and testing exist and are they accessible at all testing sites (e.g., National TB Diagnostic Algorithm, test requisition forms, recording and reporting forms, quality indicator reporting forms, corrective action forms, SOPs, job aids, etc.)?	Nationally approved documents are not available.	Nationally approved documents are available for some aspects of the TB diagnostic network but are not widely available. A system is in place in some laboratories that records that each user has read and understood the relevant quality documents.	Nationally approved documents are available for aspects of the TB diagnostic network and are accessible at most public sector testing sites. A document control system is implemented in some laboratories of the TB diagnostic network.	Nationally approved documents are available for all aspects of the TB diagnostic network and are accessible at most public and private sector testing sites. A document control system is implemented in most laboratories of the TB diagnostic network.	Nationally approved documents for aspects of the TB diagnostic network are accessible at all testing sites. A document control system is implemented in all laboratories.	Stage 4 plus regular review and updating of documents.

9.1.2	Do national standard operating procedures (SOPs) exist for all TB diagnostic technologies and procedures within the network and are they accessible at all testing sites?	Nationally approved or locally approved SOPs are not available.	Nationally approved SOPs or job aids are available for some TB diagnostic procedures but are not widely accessible. OR Locally approved SOPs are available for all TB diagnostic procedures performed in the laboratory.	Nationally approved SOPs are available for most TB diagnostic procedures and are accessible at most laboratories in the TB diagnostic network.	Nationally approved SOPs are available for all TB diagnostic procedures and are accessible at most laboratories in the TB diagnostic network.	Nationally approved SOPs for all TB diagnostic technologies are accessible at all testing sites in the TB diagnostic network.	All of the before and the SOPs have been revised at least once.
Component 9.2. Quality assurance							
9.2.1	Are quality indicators and performance measures monitored and evaluated for all TB tests?	No	Quality indicators and performance measures are not routinely	Quality indicators and performance measures are routinely monitored for	Quality indicators and performance measures are routinely monitored and	Stage 3 with corrective actions routinely taken for non-conformities	Stage 4 for all laboratories in the TB diagnostic network. Includes regular

Question number	Questions	Stages					
		0	1	2	3	4	5
			monitored for any TB test.	some TB tests at some tiers, but infrequently analyzed.	evaluated for all TB tests at all tiers of the TB diagnostic network. Results are reported to the supervisory laboratory.	identified by the quality indicators and performance measures in most laboratories in the TB diagnostic network.	review of quality indicators and monitoring systems.
9.2.2	Do all laboratories have internal quality controls in place for all TB tests?	No	Internal quality controls are included for some TB tests in some laboratories in the TB diagnostic network.	Locally produced internal quality controls are included for all TB tests in some laboratories in the TB diagnostic network.	Standardized internal quality controls are included for all TB test in most laboratories in the TB diagnostic network.	Internal quality control procedures are standardized throughout the network for all TB tests and used in all laboratories in the TB diagnostic network.	Internal quality control procedures are standardized throughout the network for all TB tests and reviewed to detect and correct trends. Includes all public and private sector labs.

9.2.3	Are there national EQA programs in place for all TB diagnostic tests at the different tiers?	No	There is a draft EQA program, but it has not been approved or implemented. OR There is a partially implemented EQA program without documented feedback to laboratories.	An EQA program for some TB tests at some tiers is in place with feedback of results in the public sector. Some laboratories in the TB diagnostic network participate in the EQA program.	An EQA program is implemented for some TB tests at all tiers in the public sector is in place with feedback of results. Most laboratories in the TB diagnostic network participate in the EQA program.	An EQA program for all TB tests is in place at all tiers of the TB diagnostic network with feedback of results and action for improvement.	No testing is permitted that does not have an EQA component for all laboratories in the TB diagnostic network.
9.2.4	Do reference laboratories participate in international EQA (internationally certified/or accredited EQA-ISO 17043) programs where available?	No	Yes, but not for all EQA programs available.	Yes, for all EQA programs available.	Yes, for all EQA programs available and with action plans for improvement after each round.	Stage 3 and with compliant results for some of the programs for at least the last 3 years.	Stage 4 and with compliant results for all programs for at least the last 3 years.

Question number	Questions	Stages					
		0	1	2	3	4	5
9.2.5	Is there a formal system of supportive supervision within the TB diagnostic network? - provide corrective and supportive feedback on performance to the laboratory worker. - provide updates on technical guidelines etc. - identify opportunities for improvement and on-site training. - review of quality indicators, results of PT, and corrective actions.	No	System of supervision defined but not routinely implemented. Ad hoc supervisions are organized in case of problems.	<3 selected supervision elements routinely implemented only from the reference laboratory to the rest of the network.	<3 selected supervision elements routinely implemented from the higher intermediate reference laboratory (IRL) to lower tier laboratories (district or sub-district).	Routine supervision for all elements is in place supporting most laboratories in the TB diagnostic network.	Routine supervision for all elements in place throughout the network and covers all laboratories in the TB diagnostic network.
Component 9.3. Quality management system							
9.3.1	Is the position of quality or quality assurance officer filled in in each laboratory? (part-time or full-time) **Note:** The functions of a quality officer may be provided by a quality officer from another laboratory (e.g., the supervisory laboratory) or by a district or regional laboratory advisor who regularly visits (at least quarterly) the laboratory to conduct quality assessments, quality training and consultations. The advisor must be trained in TB laboratory quality assurance and certified as competent.	No	Only reference laboratories have a designated quality officer. The quality officer has received training in the principles and practices for ensuring quality in the TB laboratory.	Stage 1 plus the quality officer has clearly defined role and responsibilities documented in a job description. The quality officer leads regular meetings (monthly or quarterly) to address quality issues.	Stage 2 plus some facilities at some tiers of the TB diagnostic network have a designated quality officer with clearly defined role and responsibilities documented in a job description.	All facilities of the TB diagnostic network have a qualified, trained and designated quality officer.	Stage 4 plus the quality officer receives regular refresher trainings.

9.3.2	Are quality management activities implemented in all laboratories providing TB testing?	No	Not according to a structured approach.	Only in reference laboratories using a structured approach with QMS implementation tools (e.g., GLI, LQSI, LQMS, SLIPTA, SLMTA, mentoring).	In national reference laboratories and most intermediate reference laboratories and some lower-level laboratories using a structured approach with QMS implementation tools (e.g., GLI, LQSI, LQMS, SLIPTA, SLMTA, mentoring).	In all laboratories at the national and intermediate levels and most laboratories at the peripheral level.	In all laboratories in the TB diagnostic network.

Question number	Questions	Stages					
		0	1	2	3	4	5
Component 9.4. Certification and accreditation							
9.4.1	Are there national certification standards for laboratories?	No	There are approved national certification standards for some TB tests. A laboratory certification body exists in country.	There are national certification standards that are mandatory for some laboratories.	There are national certification standards that are mandatory for all laboratories conducting TB testing in the public sector.	All of the previous and including some private sector and enforced.	All of the previous and fully aligned with ISO standards
9.4.2	Are there mandatory accreditation standards for laboratories and are they implemented?	No	There are national accreditation standards. A national or international accreditation body exists in country.	There are national accreditation standards that are implemented for laboratories at the national level.	There are national accreditation standards that are implemented for laboratories at national and reference levels in the public sector.	All of the before and enforced, and including some private sector labs	All of the before and including all public and private sector labs at national and reference level, and fully aligned with ISO standards

Capacity 10. TB-HIV

Question number	Questions	Stages					
		0	1	2	3	4	5
Component 10.1. Political, legal, regulatory, and financial framework							
10.1.1	Is there a national policy for tuberculosis preventive therapy for HIV-positive individuals?	There is no national TB policy, guideline, or plan.	There is a national policy, guideline or plan but not approved and aligned with national TB and HIV policies and plans.	The national policy, guideline or plan is approved and aligns with the national TB and HIV policies and plans.	All of the before and up to date and partially implemented.	Fully implemented and there are formalized procedures to link HIV+ persons found for whom TB has been ruled out to tuberculosis preventive therapy.	Implemented and aligned with overall health strategic plan. Revised at least once.
10.1.2	Is there a national policy which enables?	No	Only limited diagnostics (e.g.,	TB laboratory tests are	TB laboratory tests are	TB laboratory tests are	All TB diagnostic

	- 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?		smear microscopy or HIV rapid tests) are provided free of charge in parts of the public sector only.	available free of charge or reimbursed in public sector for HIV+ patients. or HIV laboratory tests are available free of charge or reimbursed in public sector for TB patients.	available free of charge or reimbursed in public sector for HIV+ patients. AND HIV laboratory tests are available free of charge or reimbursed in public sector for TB patients.	available free of charge or reimbursed for HIV+ patients in the public sector and some private sector facilities. AND HIV laboratory tests are available free of charge or reimbursed for TB patients in the public sector and some private	testing is free or reimbursed for all HIV+ patients being evaluated for TB in the public or private sector. AND All HIV diagnostic is free or reimbursed for all TB patients in the public or private sector.

						sector facilities.	
10.1.3	Does the Ministry of Health (MoH) or other responsible ministry have dedicated organizational unit in charge of coordination between the TB diagnostic network and the HIV/AIDS diagnostic network? The organizational unit may be a part of a unit that coordinates TB and HIV programs.	No. Only disease-specific units exist.	There are several entities involved in coordination of the TB and HIV diagnostic networks.	Dedicated entity but not at senior management level within the MoH. There is an official mandate, defined TOR and setting of targets.	Stage 2 plus coordination mechanisms with TB and HIV programs and public health-related committees. There are regular	Stage 3 plus the entity is a directorate or a department, representing laboratory services at top management level of the MoH with the private sector	All of the before, with inter-ministerial coordination.

Question number	Questions	Stages					
		0	1	2	3	4	5
					(e.g., quarterly) meetings.	included in oversight.	
Component 10.2 Structure and organization of the diagnostic network							
10.2.1	Does the TB diagnostic network collaborate with the HIV diagnostic network regarding laboratory and diagnostic services (e.g., shared diagnostic platforms, referrals for testing, etc.)?	No	There is limited collaboration between TB and HIV diagnostic networks mostly at the NRL level or program level.	Formal collaboration occurs on an ad hoc basis at various levels in the tiered laboratory networks.	Formal collaboration and coordination mechanisms between TB and HIV diagnostic networks take place at least annually.	Coordination mechanisms of TB and HIV diagnostic networks occur at least once a year. A national level unit coordinates collaboration between TB and HIV diagnostic networks.	Formal collaboration between TB and HIV diagnostic networks and regular coordination meetings held. Review and analysis of collaboration on regular basis.
Component 10.3. Coverage							
10.3.3	Are procedures in place to ensure efficient linkage of PLHIV who have signs and symptoms of TB to appropriate TB diagnostic	No	No formalized procedure; linkage is on an informal and irregular basis.	Formalized procedure is in place for some facilities at some tiers of	Formalized procedure is in place for all facilities at all tiers in the	Stage 3 with all public sector and some private sector facilities.	Stage 4 with all public and private sector facilities, with assessment

	services?			the network.	public sector.		of impact and review of procedures .
Component 10.4. Diagnostic algorithm							
10.4.1	Does the national TB diagnostic algorithm include appropriate referral for HIV testing?	A national TB diagnostic algorithm is not available or does not adequately address HIV testing on-site or by referral.	The national diagnostic algorithm for TB addresses HIV testing but is not current or complete or is only implemented in some facilities.	The national TB diagnostic algorithm addresses HIV testing and is available and implemented at all facilities in the public sector but is not current or complete.	The national TB diagnostic algorithm adequately addresses HIV testing and is current, available, and implemented, but not at all public facilities.	Stage 3 and is available and implemented at all public facilities and some private facilities.	Stage 4 and is available and implemented available at all public and private facilities and regularly reviewed and updated.
10.4.4	Is there access to the LF-LAM for priority HIV+ patients in all districts	The use of the LF- LAM for the diagnosis of TB in priority HIV+ patients is not described in	The use of the LF- LAM for the diagnosis of TB in HIV+ inpatients in accord with the	The use of the LF-LAM for the diagnosis of TB in HIV+ inpatients and	All of the before in 10-49% of the districts.	All of the before in ≥50 % of the districts.	On site testing or referral services for the LF-LAM is available in all

		national TB policy	current WHO recommendations	outpatients is described in the national TB policy			districts for all priority patients.

Question number	Questions	Stages					
		0	1	2	3	4	5
		or the national TB diagnostic algorithm or is not in accord with the current WHO recommendations.	is described in the national TB policy and national TB diagnostic algorithm, but there currently is no laboratory on site testing or referral services for the LF-LAM in any of the districts.	and national TB diagnostic algorithm. Onsite testing or referral services for the LF-LAM is available for priority HIV+ patients in <10% of the districts.			
Component 10.5. Workforce							

10.5.1	Are staff in TB diagnostic laboratories and TB clinics trained in the HIV diagnostic algorithm and procedures for obtaining HIV testing on-site or by referral? Are staff in HIV testing laboratories and HIV clinics trained in the TB diagnostic algorithm and procedures for obtaining TB testing on-site or by referral including training on which test to order, test requisition forms, specimen collection, packaging and specimen referral? Are health care workers provided with standardized sensitization content (e.g., algorithm diagrams, brochures, training materials, customer handbook)?	No	Some training provided to some laboratorians, clinicians, and providers in the public sector in some districts but is not current or complete. Sensitization content is available atsome facilities but not current or complete.	Training is provided to all laboratorians and some clinicians and providers in the public sector but is not current or complete. Sensitization content is available at all facilities in the public sector, but not current or complete.	Current and complete training is provided to all lab staff, clinicians, and providers in the public sector in some districts. Up-to-date sensitization content is available, but not at all public facilities.	Stage 4 with training provided to all laboratorians, clinicians and providers in the public sector and some private sector. Up-to- date sensitization content is available at all public facilities and some private labs.	All laboratorians, health care workers, and program staff are trained in the application of the algorithm, which is regularly reviewed and updated. Up-to-date sensitization content is available at all public and private facilities and regularly reviewed and updated.

Component 10.6. Diagnostic data management							
10.6.1	Does the standard TB test requisition form include fields for HIV status? Are data entered in those fields on all TB test request forms? Are the data on the completeness of entry and HIV status collected and analyzed?	Standardized TB test request forms are not available or do not contain fields for HIV status.	TB test request forms containing HIV status fields are standardized but only available at the national level.	Standardized TB test request forms containing HIV status fields are available at the national level and some lower levels OR in some parts of the county.	Standardized TB test request forms containing HIV status fields are available at all levels and all parts of the country.	Standardized TB test request forms containing HIV status fields are used at all levels. HIV status fields are routinely completed. Data on request forms are captured and	Stage 4 and request forms are regularly reviewed. Data on test request are captured in logbooks/online in real-time/LIMS and regularly

Question number	Questions	Stages					
		0	1	2	3	4	5
						used in the testing process.	reviewed and analyzed.
10.6.2	Do the standard data collection forms adequately capture the relevant TB and HIV test statistics and performance indicators? Are the following performance indicators collected: - Number and proportion of newly diagnosed TB patients with known HIV status? - Number and proportion of newly diagnosed TB patients referred for HIV testing or tested on site if HIV status unknown? - Number and proportion of HIV+ persons with signs and symptoms of TB who were	No	Forms are standardized for some tests or data elements only at the national level.	Forms are standardized for some tests or data elements only at national level and some lower levels OR in some parts of the county.	Forms are standardized for ALL tests and data elements at the national level and some lower levels OR in some parts of the country. Data for 2 or 3 of the listed performance indicators are collected and reported.	Stage 3 and the forms are fully used at all levels. Data for >4 of the listed performance indicators are collected and analyzed.	Stage 4 and forms are regularly reviewed, and data analyzed and used for decision making.

	tested for TB or referred for TB testing? - Number and proportion of newly diagnosed HIV+ persons referred for HIV counseling? - Number and proportion of HIV+ patients eligible for IPT according to national policy that were referred for IPT?						
10.6.3	Are TB, HIV, and TB-HIV statistical data reported, analyzed, used for decision making purposes and shared within MoH and other government agencies and between the NTP and National AIDS Control Program (NACP)? Do the local and national TB and AIDS control programs analyze and use the collected data routinely for	No	Data aggregated on an informal and irregular basis.	Only the national laboratory can report aggregate data to the MoH. Aggregate data are shared between the NTP and NACP.	Data are aggregated at some laboratories but not reported to the national level. Data are analyzed for a limited range of purposes.	Data are aggregated from all levels. Procedures are in place for data sharing. Reports are sent to the national unit and data are collated and analyzed nationally. Data are analyzed	National data reports are written, distributed, and shared with other sectors within the government. Data are routinely analyzed and used for a full

	decision-making and program improvement including improvements in coordination					routinely for multiple purposes.	range of purposes .

Question number	Questions	Stages					
		0	1	2	3	4	5
	between the TB and AIDS control programs?						
10.6.4	Is there an up to date, implemented national plan for surveillance of HIV-associated TB, which includes defining the roles of the NTP, NACP, and TB and HIV diagnostic networks?	No plan for TB- HIV surveillance exists.	National plan for surveillance of TB- HIV explicitly describing the role of the NTP, NACP and laboratory networks has been designed but not approved.	National plan for surveillance of TB-HIV has been approved. The roles of the NTP, NACP and laboratory networks have been clearly defined.	National plan is being implemented. Designated sentinel sites are conducting surveillance of TB-HIV.	All of the before. Designated sentinel sites have conducted surveillance of TB- HIV for at least 1 year. Data are made available to pertinent clinical organizations to guide local treatment decisions. A national surveillance system is being developed and implemented.	Designated sentinel sites have conducted surveillance of TB-HIV for 5 years with a system for continuous improvement. A national surveillance system has been implemented and is routinely collecting data.

Annex 4. Site Visit Summaries

CENTRAL ZONE AND LAKE ZONE

Assessors: Mr. Peter Torokaa, Team Lead; Dr. Nicholas Mnyambwa, Consultant; Mr. Prosper Ngoi; Mr. Dominic Fwiling'afu; Dr. Leobrate Mleoh

Central Zone facilities visited

Dodoma Regional Referral Hospital

Findings

- There was no evidence of refresher trainings for the past one year.
- The facility has GeneXpert that is connected to GxAlert and properly functioning.
- The laboratory performs solid culture and refers specimens to the Central Tuberculosis (TB) Reference Laboratory (CTRL) for drug susceptibility testing (DST).
- The line probe assay (LPA) machine was not functioning for more than six months and needed repair. The facility has reported the problem to the CRTL/National TB Program (NTP) and is waiting for the repair.
- The facility does not fill supervisory and monitoring roles to the lower facilities it serves.
- The laboratory does not receive feedback from the CTRL for referral specimens. The feedback is being sent directly to the referring facilities.

Singida Regional Referral Hospital Findings

- Singida Regional Referral Hospital (RRH) has GeneXpert that is connected to GxAlert and is functioning well.
- The hospital receives patients instead of specimens from referring facilities (with no Xpert) for rifampicin resistance testing, a practice that has cost implications to the patients and increased risks for transmission of the pathogen.
- Specimen packaging and referrals are being done by the TB clinic, and the laboratory unit is not involved. Both triple packages and referral logbooks were found at the TB clinic, but none at the laboratory.
- Specimens are sometimes referred directly to the CTRL, skipping the zonal laboratory (Dodoma RRH).

Sokoine Health Centre (peripheral), public facility

Findings

- The facility has no X-ray services.
- The facility does have a pediatric clinic, but there is no supportive environment for children.
- No refresher trainings were conducted for the past one year.
- Specimens and reagents are being stored in the same fridge, which is violation of

biosafety regulations. There are not enough freezers for proper storage.

Tumaini Health Centre (peripheral), private facility Findings

- The facility has no care and treatment clinic; hence, it refers HIV patients to other facilities, primarily Singida RRH.
- The facility has no GeneXpert; patients are being referred to Singida RRH for rifampicin resistance testing.
- The biosafety officer was not trained.
- The facility has no X-ray services.

Lake Zone facilities visited

Sekou Toure Regional Referral Hospital Findings

- No refresher training was conducted for the past one year.
- There was a delay getting results for DST from zonal laboratory (Dodoma RRH) and CTRL.
- The facility was not fulfilling supervisory role to lower health facilities as required.
- Meetings involving key TB stakeholders (laboratory, HIV, TB) were not consistently conducted.

Bugando Medical Centre, zonal laboratory Findings

- The facility has GeneXpert that is connected to GxAlert and is functioning well.
- There was no evidence of refresher trainings conducted in the past one year.
- The site performs solid culture and refers specimens for DST to the CTRL.
- Two biosafety cabinets (BSCs) needed repair.
- The facility does not perform a supervisory role as required.
- The facility does not receive feedback from the CTRL for referral specimens.
- The facility does not track specimens sent to the CTRL for DST.
- Some key indicators (e.g., HIV status) are not present in the current customized requisition forms.

Central Zone and Lake Zone Recommendations

- Conduct regular refresher trainings and supportive supervision for improved performance of the network.
- Strengthen quality assurance of laboratory supplies and maintenance of equipment (microscopy, GeneXpert, LPA machine, etc.).
- Ensure that diagnostic algorithms and other sensitization materials are available and distributed in all clinics of each facility.
- Ensure that the CTRL provides feedback for referral specimens to both laboratories intermediate/zone laboratories and the referring facility.
- Provide training for all biosafety officers.

- Increase the capacity for laboratory supplies at all levels to prevent stockouts.
- Develop a maintenance plan for laboratory infrastructure and equipment.
- Develop regular monitoring and evaluation (M&E) plan; monitoring should be done on a quarterly basis.
- Review the specimen referral mechanism, with the aim to improve it.
- Coordinate and maintain triple package inventory control and specimen referrals under the laboratory unit, not the TB clinic.
- Ensure that council health management teams (CHMTs) provide training on various guidelines to other facilities in their jurisdiction.
- Ensure that care and treatment clinics, TB, and laboratory regularly meet to discuss matters and challenges of TB, HIV, and pediatric TB services.
- Expedite the use of Ultra cartridges for implementation and rollout.
- Roll out TB lipoarabinomannan (LAM) for special groups testing, as per World Health Organization (WHO) recommendations.
- Clearly define and enforce roles and responsibilities of each tier in TB and HIV diagnostic network.
- Chest X-ray has been recently promoted and recommended by WHO as a useful tool for pulmonary TB screening and triaging algorithms. The National Tuberculosis and Leprosy Program (NTLP) should consider including it in a policy.

NORTHERN ZONE

Assessors: Davis Rumisha, Consultant; Onna Panga, Ministry of Health (MOH); Herbert Mutunzi, Consultant; Raymond Shirima, CTRL

Site Name	Town/City	Site Type	TB Tests Done
Mombo Health Centre	Korogwe	Shepheard laboratory	Microscopy, Xpert
Kibongoto Infectious Disease Hospital	Moshi	Zonal intermediate reference laboratory	Microscopy, X-ray, Xpert, first-line (FL)/second-line (SL) LPA, FL/SL DST
Arusha RRH	Arusha	RRH	Xpert Mycobacterium tuberculosis (MTB)/ rifampicin (RIF), X-ray, smear microscopy
Mirerani Health Centre	Arusha	Mining health center	Microscopy
Shree Hindu Charitable Hospital	Arusha	Private hospital	Microscopy, X-ray
Selian Lutheran Hospital	Arusha	Faith-based organization hospital	Microscopy, X-ray
Meru District Hospital	Meru	District hospital	Microscopy, Xpert, X-ray

Tanga Region, Mambo Health Center

Findings

- In the strive toward 100 percent capability, training for persons who come to contact with sputum is mandatory. Staff in Mambo reported to have had no refresher training for the past three years.
- Data use at the point of collection improves accuracy and completeness and adds value to the data. Data analysis and usage at the point of collection were limited. Staff are collecting data for posting to relevant authorities. Data are often only used for estimation of needs.
- Staff rarely monitor their performance indicators. Data on the key indicators are incomplete and mostly not available.
- Competence assessments have not been conducted in the past three years.
- Specimen referral poses a challenge in terms of packing material and training of all involved.

Kilim njaro Findings

- The facility is well staffed, better resourced, and accredited in microscopy and Xpert MTB/RIF.
- There is poor attention to pediatric TB diagnosis, and only one person is trained and capable of performing gastric lavage and sputum induction.
- TB specimen collection in children is limited, and specimens received from outside the facility are usually poorly packed.
- There were reports of reagents and specimen packing containers stockouts.
- Some supervisory functions in the zone, which are the mandate of Kibong'oto, are also conducted by the CTRL.

Arusha Region Findings

- Arusha RRH, Meru District Hospital, Shree Hindu Charitable Hospital, and Seliani Lutheran Hospital all experienced specimen packaging materials and Xpert MTB/RIF cartridge stockouts.
- All facilities experienced challenges on infrastructure, including lack of spatial data (e.g., maps showing location of satellite facilities or telephone numbers and names of supervised facilities).
- For all facilities except Arusha Regional Referral Laboratory, laboratory safety and biosecurity indicators were poor.
- All facilities maintain electronic patient information management systems, but unfortunately TB and HIV are not included.

Manyara Findings

- Linking the patient to treatment was not always assured because there are no formalized procedures.
- Recording and reporting of TB and HIV data was poor, and often the data entry was not complete. Data were not used for decision-making, as evidenced by lack of local analysis or aggregation of the data.
- The facility experienced stockouts of specimen packaging materials and GeneXpert cartridges.

Northern Zone Recommendations

- Urgently, we call for consorted efforts to review the specimen transport system and restructure it to allow for check and balances to ensure safety and viability of specimens in a timely manner and digital means of tracking specimens and results.
- Training and retraining of all who come in contact with specimens, especially the transportation crew, and provision of uninterrupted packing material, refrigeration atmospheres for specimens on transit, and safe storage of specimens is crucial.
- Immediate training of all health care workers (HCWs) responsible for diagnosis and treatment of TB, especially the laboratorians, is essential to ensure equitable access to quality testing and treatment. Many of these staff have not undergone pediatric specimen collection training or completed a competence assessment.

- The NTP should optimize the application of digital technology to address issues such as training, specimen transport and tracking, communication, patient data management, etc.
- The NTP should also urgently review the program position on the use of newer approaches like lateral flow (LF)-LAM, GeneXpert Ultra, and digital X-ray with artificial intelligence to optimize case finding and treatment.
- Engagement of the private sector is growing but needs more push to maintain a sustained role in TB control. Currently, some are charging for services (e.g., X-ray), and some have decided just to refer.
- The program scored poorly on biosafety and biosecurity capacities; urgent attention is needed on this important missing link. Most of the HCWs in TB did not receive screening for TB for the past many years, and we recommend immediate attention to this problem.

EASTERN ZONE

Assessors: Zablon Nkika, Consultant; Salum Ali, MOH; Edger Luhaga, MOH; Fredrick Kangave, Consultant; Samwel Mulungu, United States Agency for International Development (USAID)-funded Infectious Disease Detection and Surveillance (IDDS) project; Zubeda Salum, Pemba Health Laboratory

Site Name	Town/City	Site Type	TB Tests Done
Mnazi Mmoja RRH	Urban Unguja	Regional referral	Xpert Ultra, smear microscopy
Al Rahma Hospital	Urban Unguja	Private hospital	Smear microscopy
Kivunge District Hospital	North Unguja	District hospital	Xpert Ultra, smear microscopy
Chake District Hospital	Southwest Pemba	District hospital	Xpert Ultra, smear microscopy
Abdallah Mzee RRH	Southwest Pemba	Regional referral	Smear microscopy
Pemba Public Health Laboratory	Chake Chake	TB zonal referral	Solid TB culture, smear microscopy
Morogoro RRH	Morogoro	Regional referral	MTB/RIF cartridge, smear microscopy
Saba Saba Health Center	Morogoro	Health center	Sputum collection
Turian Designated District Hospital	Morogoro	District hospital	MTB/RIF cartridge, smear microscopy

TB Specimen Referral System Findings

- Two parallel systems exist in Zanzibar for TB and HIV specimen referrals—one in which TB specimens are being transported to diagnostic centers along with HIV viral load and dried blood spot specimens, and the second in which specimens are being transported by health care providers to testing laboratories. This is different from Tanzania mainland, where the specimen referral system fully integrates TB specimens.
- Weak specimen referral system: TB walk-in patients were observed in private laboratories (e.g. at Alhamad and Regency Hospital laboratories). These clients were referred from peripheral/nearby facilities that are not diagnostic centers. This contradicts the purpose of an integrated specimen referral system that is aimed at increasing access while ensuring efficiency, especially in peripheral facilities.
- In Tanzania mainland, for example, specimens for culture or DST are referred to designated referral laboratories by the National Postal Services through Expedite Mail Services. This is different from Zanzibar, where specimens that require additional testing at Pemba Health Laboratory are transported by a district TB coordinator. Lack of

documentation, service disruption when the district coordinator goes on leave, and unsustainability are part of challenges that currently exist due to the lack of a solid specimen referral system.

- A reverse TB network was also observed in Zanzibar between Abdalla Mzee RRH laboratory and Chake Chake District Hospital laboratory, in which all TB specimens for GeneXpert were being referred to Chake Chake.

Recommendations

- There is an urgent need to create a Zanzibar Integrated HIV, Hepatitis, TB, and Leprosy Program (ZIHHTLP) that will address HIV and TB specimen referral challenges. Leveraging lessons learned from the Tanzania mainland in terms of creating an integrated specimen system will be crucial.
- It is also important to build a robust system for the poor and marginal groups to access TB health services (i.e., to address the root cause of patients' referrals from peripheral facilities to private laboratories). The NTLP, the MOH, and the CTRL must ensure that only specimens are referred and not patients, because this is biased against clients with low income. For example, some interviewed clients shared that the lack of fare to travel to referred clinics limits their ability to get diagnostic services and consequently treatment services.
- To improve the system and to improve turnaround times, geographic information system mapping of GeneXpert machines should be conducted.
- A high-level specimen referral strategic plan for TB needs to be developed that clearly stipulates the roles of each tier in the TB diagnostic network. Consequently, capacity needs to be built for each tier to align with its role in the specimen referral system.

Equipment Findings

- Unlike Tanzania mainland facilities, Zanzibar has adopted the use of more sensitive diagnostic tools.
- Throughout the visited facilities (Zanzibar), there was evidence that Ultra cartridge is in use and the algorithm was being used. However, there was no evidence that showed that verification was done.
- Power supply and electricity fluctuations were a challenge that led to a high error rate during TB testing.

Recommendations

- Continue the adoption of more sensitive new diagnostics, as per WHO evidence-based recommendations, such as LF-LAM, to enhance case identification and improve results standards.
- Consider adoption of Truenat technology for peripheral facilities with unstable power supply.

- Build capacity of the laboratory team to carry out new platforms, verification, and documentation of any verification done.
- Create a list of all TB health service technology (equipment), along with verification information and maintenance status that is regularly updated and owned at the facility level.
- Campaign for integration of comprehensive plans and budgets for equipment maintenance and verification in council-level, regional-level, and district-level budgets.

Biosafety Findings

- Each facility had a working BSC that was certified, with the exception of Turiani designated district hospital (DDH) and Chake Chake District Hospital laboratory.
- National biosafety manual is not in place.
- Good ventilation was observed in all facilities, which minimizes the risk of infections.
- All visited facilities had personal protective equipment, such as masks, respirators, gloves, and gowns.
- All visited facilities had a TB infection prevention and control (IPC) focal person and IPC guidelines. However, there was no evidence that staff were trained on TB IPC.
- There is a gap in staff risk assessment. For example, among visited clinics, it was evident that HCWs who work in the TB section are not screened for TB on an annual basis.
- BSCs were serviced and certified; however, all BSC services and certification were overdue, except for Zanzibar.

Recommendations

- Establish zonal biosafety workshops that bring together all TB IPC focal persons and other TB points of contact in key facilities that aim to empower them with core components of the IPC program and a review of IPC guidelines, including any updates that exist.
- Develop an equipment maintenance master list so that the CTRL and National Health Laboratory Quality Assurance and Training Centre use it as reminder for quick follow-up of all BSCs that will be due for services.
- Build capacity of the zonal biomedical engineers so that they can service and certify BSCs regularly.
- MOH/CTRL/NTLP to accelerate national biosafety manual development and dissemination.
- Conduct a risk assessment to identify risk levels of all diagnostic centers for TB (e.g., whether they are well ventilated and whether they align with the WHO IPC guidelines).
- Sensitize HCWs on the need for and importance of TB screening, so that TB screening and

risk assessment ownership at the staff level will ensure that it done regularly.

Supplies

Procurement of TB commodities is coordinated by the MOH/Pharmaceutical Services Unit, which is mandated to coordinate all pharmaceutical services, including the supply chain of health services. The procedure for procurement and supply chain management is well-stated in the NTLP policy. Procurement of TB commodities is funded by Global Fund through NTLP coordination, and the Medical Stores Department (MSD) is responsible—through a special unit that is dedicated to deal with public health programs—for storing and distributing TB commodities through zonal MSDs. There are funds available from the U.S. President's Emergency Plan for AIDS Relief, as well as the Global Fund, for the procurement of cartridges.

Findings

- New staff have been recruited under the MOHCGGEC and the Global Fund to strengthen the supply chain management system.
- There is availability of a logistics management system to manage TB and leprosy commodities.
- Frequent stockouts remain a major challenge, and they are mainly caused by delays in processing of import permits and port clearance procedures.
- There is a low budget for TB commodities procurement, especially during clearance.
- Physical inventory is not conducted regularly.

Recommendations

- Port clearance regulations need to be revised to avoid delays during clearance of commodities by leveraging experts from Procurement and Supply Management and MOH. Delays during clearance were the main reason for reagent stockouts both in mainland Tanzania and Zanzibar.
- The NTLP must ensure sufficient allocation of funds in the Government Procurement Services Agency account, so that clearance will be done in advance to address the delay at the clearance phase.
- There is a need to implement facility-level an electronic logistic management system (MOH/Pharmaceutical Services Unit/NTLP).
- There needs to be a liaison with the MSD to ensure constant availability of essential diagnostic equipment, reagents, and emergency contingency supplies.

Quality Management Systems

External Quality Assessment Scheme

In all visited laboratories, several gaps were observed in their external quality assessment (EQA) schemes.

Findings

- All visited sites showed evidence that they are enrolled in an EQA; however, inconsistent EQA program participation, delays, and a lack of feedback reports from EQA providers were prominent. This compromises the quality of results due to delay of corrective action.
- A partial EQA scheme exists, especially for TB microscopy laboratories.
- There is non-functional EQA for culture and DST laboratory in Zanzibar and the mainland.

Recommendations

- Build the capacity of the CTRL and Pemba Health Laboratory by collaboration with the National Health Laboratory Quality Assurance and Training Centre to prepare and distribute panels, with prioritization given for TB microscopy laboratories.
- Strengthen external assessments and effective feedback of results. There is a need to strengthen the EQA scheme feedback system such that it reaches all facilities in a timely manner and corrective actions are triggered in real time.
- Ensure that the CTRL coordinates targeted mentorship for all facilities that fail to address identified gaps.

Laboratory Information Systems

Laboratory information systems (LIS) (i.e., Electronic TB and Leprosy Register [ETL] and TB-LIS) are available at the CTRL and Pemba Health Laboratory; all the other facilities visited used the Government of Tanzania—Hospital Management Information System (SabaSaba, Turian, and Morogoro Hospital laboratory). In addition, in the CTRL, information technology staff and data units are active, but the following findings were observed.

Findings

- All facilities visited in Eastern Zone and Zanzibar had a standardized system for reporting laboratory statistics indicators for TB tests. Due to Strengthening Laboratory Management Towards Accreditation/Stepwise Laboratory Improvement Process Towards Accreditation program enrollment, all visited facilities in Zanzibar, including TB diagnostic centers, had standardized forms for documenting laboratory statistics indicators.
- Although data collection systems are strong, there is weak data analysis, interpretation, dissemination, and use.
- Parallel reporting systems were noted, which is a burden to health workers. For example, the

ETL and LIS are not interfaced, which causes duplicate efforts and data entry errors.

- Inconsistent use of ETL in all visited facilities and a lack of connectivity were observed in Pemba Health Laboratory, Zanzibar.
- All information technology/data staff are new and require capacity building.
- There is a gap between the CTRL data unit and stakeholders. For example, the data unit does not generate key reports—such as turnaround time, contamination rates, rifampicin resistance, and number of specimens tested—that aim at improving TB implementation at the respective facilities.
- TB-LIS monthly, quarterly, and yearly reports generation were only observed in the Tanzania mainland.
- In private laboratories visited, the TB test was not integrated in LIS even though they had active LIS-MedTech, which can track specimens even during the referral process. It was reported that because TB is free of charge and their laboratories are meant for business that is why TB test was not included in their LIS system.

Recommendations

- Create a strong capacity-building guide and onboarding program for TB data human resource.
- Move beyond data collection to data interpretation, use, and dissemination. For example, by creating avenues and a committee responsible for discussing data trends that comprises physicians, nurses, and data managers on a monthly/quarterly basis. This will ensure that key TB performance indicators are actively used to improve service provision and clients' satisfaction (e.g., monthly turnaround times, quarterly infection rates, review meetings that trigger action plans).
- Establish a connection between GxAlert and existing systems such as ETL and TB-LIS to avoid duplication of efforts and duplicate errors in the system. Specifically, TB-LIS and ETL must also be interfaced.
- Encourage the MOHCGEC/CTRL to ensure that TB tests are included in all existing LIS, including in private hospital laboratories.
- Scale up the Afya Care system that was reported to exist in a few sites. Integration of TB tests into the Afya Care system, coupled with a scale-up plan for all facilities, has the potential to improve turnaround times.
- Ensure that the NTLP/ZIHHTLP allocates a budget that ensures data connectivity at all facilities with the ETL.
- Strengthen the relationship between private and public hospital laboratories. The starting point could be through supportive supervision.

National-level Policy Guidelines and Practices Adherence

Findings

- Incomplete filling of test request forms was observed at all facilities, but this issue was more acute in some facilities than others. For example, at Chake Chake District Hospital, most request forms were partially filled with the most critical information missing (e.g., laboratory tests were not ordered).
- In all visited facilities, it was also observed that the specimen management/documentation procedure was not in place, which compromises the quality of results, therefore resulting in poor patient management. For example, all forms did not have information on when the specimens were tested.
- Although the TB strategic plan and guidelines exist at a national level, there was no awareness of their existence or adherence to best practices listed in the guidelines at all the visited facilities. For example, some district hospitals were referring specimens to health centers. In all visited facilities, national TB guidelines and the strategic plan need to be disseminated from the national level to all facilities through virtual meetings and supervision.
- Despite the availability of key performance indicators (KPIs)/quality indicators, TB tests were not monitored in all visited facilities except in CTRL.

Recommendations

- ZIHHTLP needs to have a supervision plan in place at least quarterly. All facilities with wrong/improper/incomplete feeling of test request forms for TB should target mentorship coupled with post-mentorship monitoring.
- A system for documenting previous assessment findings and recommendations should be created; a computerized central database with visibility at facilities and the district level will be key in monitoring progress and ensuring that assessors are leveraging previous lessons learned and build on the work that is already established.
- Standard operating procedures (SOPs) for specimen management, job aids, and bench work should be prepared and disseminated to all diagnostic centers.
- National TB guidelines and tools should be developed and disseminated; there is a need to ensure that best practices as listed in the national TB strategic plan are shared and disseminated in private and public health facilities. An effective way of doing this could be by ensuring that there is a known web page or leveraging social platforms to link all TB focal persons with key national TB guidelines and new updates in a real-time manner.
- There is also a need to sensitize different levels of the service provision staff on importance of documentation of clients' records and how it affects patient management.
- Standardized laboratory indicators should be developed by the CTRL, along with regular supervision and mentorship in all TB diagnostic centers.
- A Strengthening Laboratory Management Towards Accreditation/Stepwise Laboratory

Improvement Process Towards Accreditation program should be mandatory in all TB diagnostic centers.

KAGERA REGION (LAKE ZONE)

Assessors: Sode Matiku, Consultant; Siril Kullaya, USAID-IDDS; Peter Mashosho, President's Office, Regional Administration and Local Government Tanzania; and Ester Shija, MOH

Facilities Visited

SN.	Name of the Facility	Ownership	District
1.	Zamzam Health Centre	Public	Bukoba MC
2.	Nyakahanga DDH	Public	Karagwe DC
3.	Kayanga Health Centre	Public	Karagwe DC
4.	St. Theresa Health Centre	Private	Bukoba MC

Zamzam Health Centre Findings

- There is a 16-module GeneXpert machine with an average of 120 specimens per month for the last quarter.
- A TB diagnostics algorithm is present, and specimens are ordered according to the algorithm.
- The laboratory has no defined or written terms of reference or an agreed-upon mandate to provide public health services and clinical diagnosis services.
- There was no evidence of a competency assessment for staff.
- X-ray services for TB screening were not available for free or by direct costs.
- The position of a safety officer was not available.
- There are no SOPs for reporting poor quality of laboratory supplies or for corrective actions.
- There are no records of specimens rejected by the laboratory.
- There was a shortage of triple packaging materials.
- There was no evidence of monitoring KPIs.

St. Therese Health Centre Findings

- The facility is an example of private-sector involvement in TB activities.
- Specimens are referred to Zam Zam Health Centre for GeneXpert testing.
- An algorithm is present, and specimens are ordered according to the algorithm.
- There was a delay of receiving results sent for Xpert MTB/RIF testing from Zamzam Health Centre.
- There was no documentation on referred specimens.
- There was shortage of triple package materials.
- There were no SOPs for specimen collection, labeling, packaging, and transporting to the referral laboratory.
- There were no SOPs for reporting poor quality of laboratory supplies or for corrective actions.

- There was no evidence of monitoring KPIs.
- The laboratory has no defined or written terms of reference or an agreed-upon mandate to provide public health services and clinical diagnosis services.
- These was no evidence of competency assessment for staff.
- There was a shortage of sputum containers.
- There were stockouts of acid-fast bacilli testing reagents and consumables.

Nyakahanga DDH Findings

- GeneXpert and smear microscopy testing were available at the facility. GeneXpert (4 module) utilization was around 90 specimens per month.
- There was no data backup in place.
- There was no training on data management conducted for laboratory staff.
- There was no budget set for TB issues by the facility.
- There was no contingency plan for TB testing.
- There was no verification testing for reagents.
- There were no supervisory reports seen.
- There was no document control procedure seen.
- KPIs are monitored (e.g., relapses, multidrug-resistant TB).
- There were stockouts of X-ray consumables.
- There were shortages of triple package materials.
- There were stockouts of radiology and imaging supplies.

Kayanga Health Centre Findings

- The laboratory has no defined or written terms of reference or an agreed-upon mandate to provide public health services and clinical diagnosis services.
- There was a delay of results at Kayanga Health Centre, after receiving results from the testing laboratory.
- There was no evidence of a competency assessment for staff.
- There were no SOPs for reporting poor quality of laboratory supplies or for corrective actions.
- Supervisor/laboratory manager has not received training for laboratory management.
- There was no evidence of monitoring KPIs.
- There was a stockout of chemistry tests.
- There were no SOPs for specimen receipt and accessioning.
- There were no rejection forms and logs.

General Lake Zone Findings

- At the time of the visit, there was no evidence documented on their registers to indicate that they are preparing and performing internal quality control to all sites visited.
- At the time of visit, it was observed that it was only Nyakahanga DDH had evidence of performing EQA, and other sites visited (Kayanga Health Centre, St. Therese Health Centre, Zam Zam Health Centre) had no evidence documented to verify.
- There was no evidence documented to verify lot-to-lot verification of reagents or whether there was a change of batch number for all sites.
- There were no SOPs for reporting poor quality of laboratory supplies or for corrective actions.
- There were no SOPs for specimen collection, labeling, packaging, and transporting to the referral laboratory.
- There was no evidence to verify that supervision or on-the-job training was performed internally or externally.
- There were no contingency plans for any of the sites visited.
- Competence assessments were not available at any of the sites.
- There was no evidence documented for M&E performed at any of the sites.
- There were delays of results for DST from Bugando Testing Laboratory.
- There was no clear system for specimen rejection.

General Lake Zone Recommendations

- Regional health management teams (RHMTs) and CHMTs, in collaboration with the visited sites, are to establish a system of rejection of specimens through rejection forms and registers for quick reference on rejected specimens, reasons for rejection, and corrective actions made.
- Competency assessments for the laboratory staff performing TB testing should be conducted in the respective sites visited.
- Quality assurance on the whole cascade of TB testing should be conducted, which includes lot-to-lot reagent verification, SOPs for reporting poor quality of laboratory supplies, and SOPs for corrective actions.
- RHMTs and CHMTs, in collaboration with the visited sites, should set the KPIs (e.g., transit time, turnaround time, number of results returned among the referred TB specimens) for regional, council, and facility M&E.
- RHMTs, CHMTs, and facilities, in collaboration with the NTLP, are to procure or improvise triple packaging materials for specimen transportation.
- There is a need to build capacity on quality issues for accuracy results because it seems facilities were not aware that internal quality control should be documented in registers.
- There is a need to build capacity on quality issues for accuracy results, because it seems facilities were not aware that EQA and laboratory testing are mandated and not an "interest."

- Laboratories should perform lot-to-lot verification of reagents or if there is a change of batch number for all sites.
- SOPs for reporting poor quality of laboratory supplies and for corrective actions should be developed.
- Laboratory managers are to record supervision and on-the-job training performed by RHMT/CHMT (including regional TB and leprosy coordinators [RTLCs] and district TB and leprosy coordinators [DTLCs]) and keep records.
- Contingency plans should be developed for all sites.
- Competence assessments should be performed and records of them kept.
- M&E should be performed and documented.

Specific Recommendations

- DTLC, medical officer in charge, and laboratory managers to follow up on availability of triple package at Nyakahanga DDH and St. Therese.
- DHMT to follow up on availability of radiology and imaging supplies at Nyakahanga DDH.
- DTLC and health facility in-charge to follow up on sputum containers at St. Therese.
- Health facility in-charge and laboratory manager to ensure that acid-fast bacilli testing reagents and consumables are available at St. Therese.
- RTLC and DTLC to follow up on the delay of results sent for Xpert MTB/RIF testing from Zamzam Health Centre to St. Therese.
- Orient KPIs for Kayanga Health Centre and St. Therese, to accurately monitor.
- DTLC to follow up on delay of results at Kayanga Hub to understand the reason and resolve the problem.
- RTLC and DTLC to follow up on delayed results sent for Xpert MTB/RIF testing from Zamzam Health Centre for St. Therese and resolve any issues.
- RTLC to follow up and resolve issues regarding the delay of results from Bugando Testing Laboratory to health facilities.
- St. Therese to document all referral specimen and results received from Zam Zam Health Centre.

SOUTHERN HIGHLANDS LAKE ZONE

Assessors: Dr. Sode Matiku, Consultant; Dr. Siril Kullaya, USAID-IDDS; Mr. Salim Bossy, CTRL; and Mr. Bresyson Malewo, CTRL

Facilities Visited

SN.	Name of the Facility	Ownership	District
1.	Mbeya Zonal Referral Hospital	Public	Mbeya MC
2.	Mbeya Regional Hospital	Public	Mbeya MC
3.	Ruanda Health Centre	Public	Mbeya MC
4.	Amenye Dispensary	Private	Mbeya MC

Mbeya Zonal Referral Hospital Findings

- There were stockouts of reagents for culture and FL/SL-LPA.
- There were no data for rejected specimens.
- There were challenges with specimen referral (i.e., delay of results, lack of triple packaging in referring sites, and delay of results for DST sent to CTRL).
- There was no dedicated staff for data management.
- There was no training on data management for laboratory staff.
- There was no refresher training for TB diagnostics.
- There were no TB diagnostics algorithms.
- There was an inability to get sputum specimens from children.

Mbeya Regional Hospital

Findings

- There was no functional link of clients with an abnormal chest X-ray.
- There is a lack of training on X-ray interpretation.
- There was no dedicated staff for laboratory data.
- There is a challenge of incompleteness of data from specimen referring facilities.
- There was no training on sputum collection in children; and pediatric TB trainings were not conducted separately.
- Diagnosis and enrollment of children is mainly based on clinical criteria.

Ruanda Health Centre Findings

- This GeneXpert facility is a specimen referral hub; however, it faces challenges, including poor quality of specimens received, stockout of packaging materials, and delay of results or feedback from the zonal laboratory.
- Staff working in the TB clinic are not supported with a transport allowance to follow up on results for cultures at the zonal referral laboratory.

- The facility displayed an old TB diagnostic algorithm.
- Suspected TB patients are referred to the laboratory instead of collecting specimens at the clinic and referring the specimens to the laboratory.
- The TB services (e.g., screening, contact tracing) are decentralized to the community level using HCWs who are equipped with appropriate messages/brochures. However, there are frequent stockouts of these information, education, and communication materials.
- TB and HIV specimen referrals were not well integrated (e.g., different staff are used).
- Staffs are not conversant in GeneXpert use (i.e., data archiving and GeneXpert maintenance).

Amenye Dispensary Findings

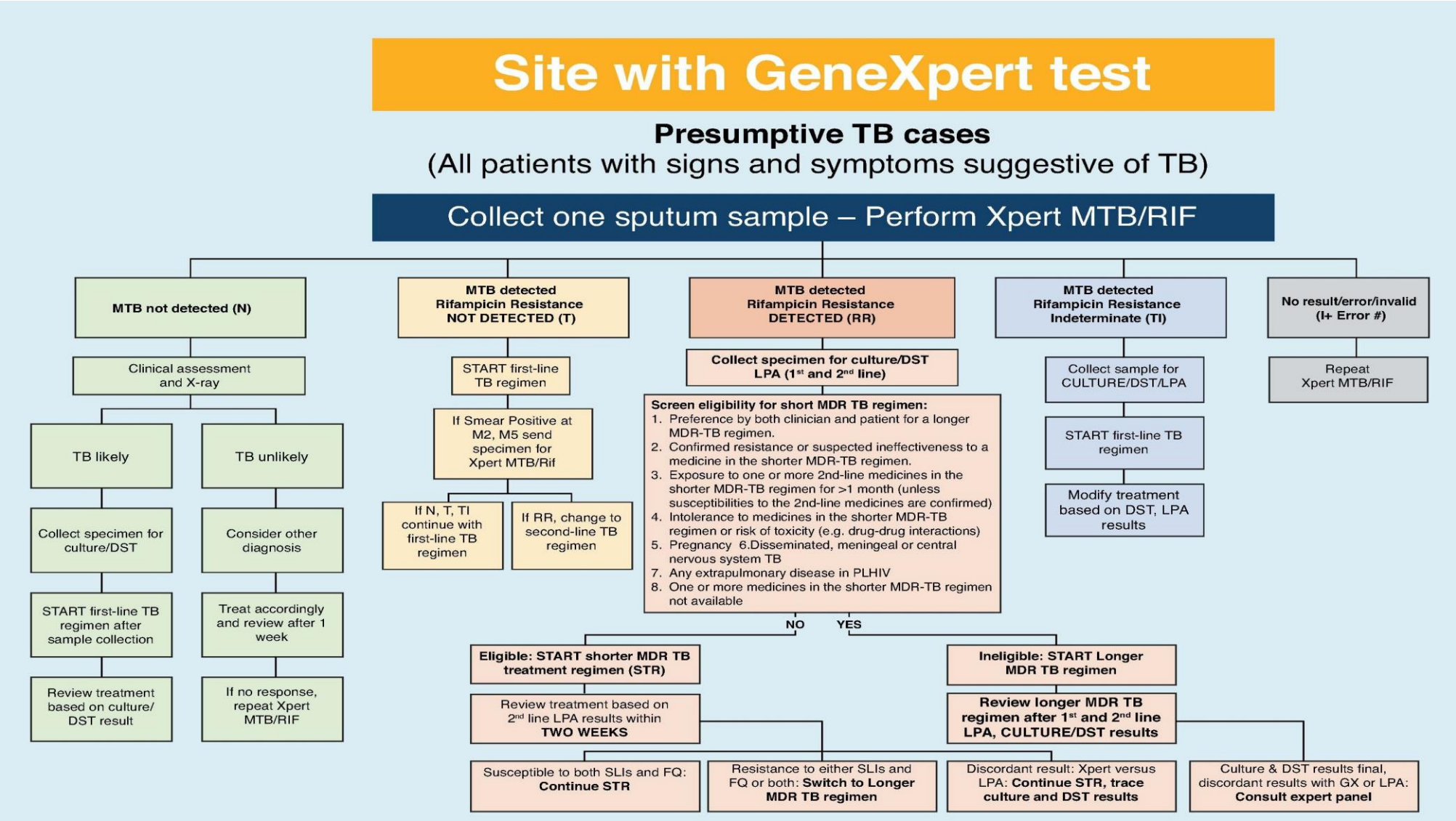
- This facility does not conduct TB diagnostics tests. All presumptive clients are referred to Mbeya RRH for GeneXpert testing.
- There is no TB or HIV clinic onsite. The facility is within five km of Mbeya RRH; all presumptive clients are referred there for diagnosis and care.
- There is close collaboration, and the facility is incentivized to work with the government on TB interventions.

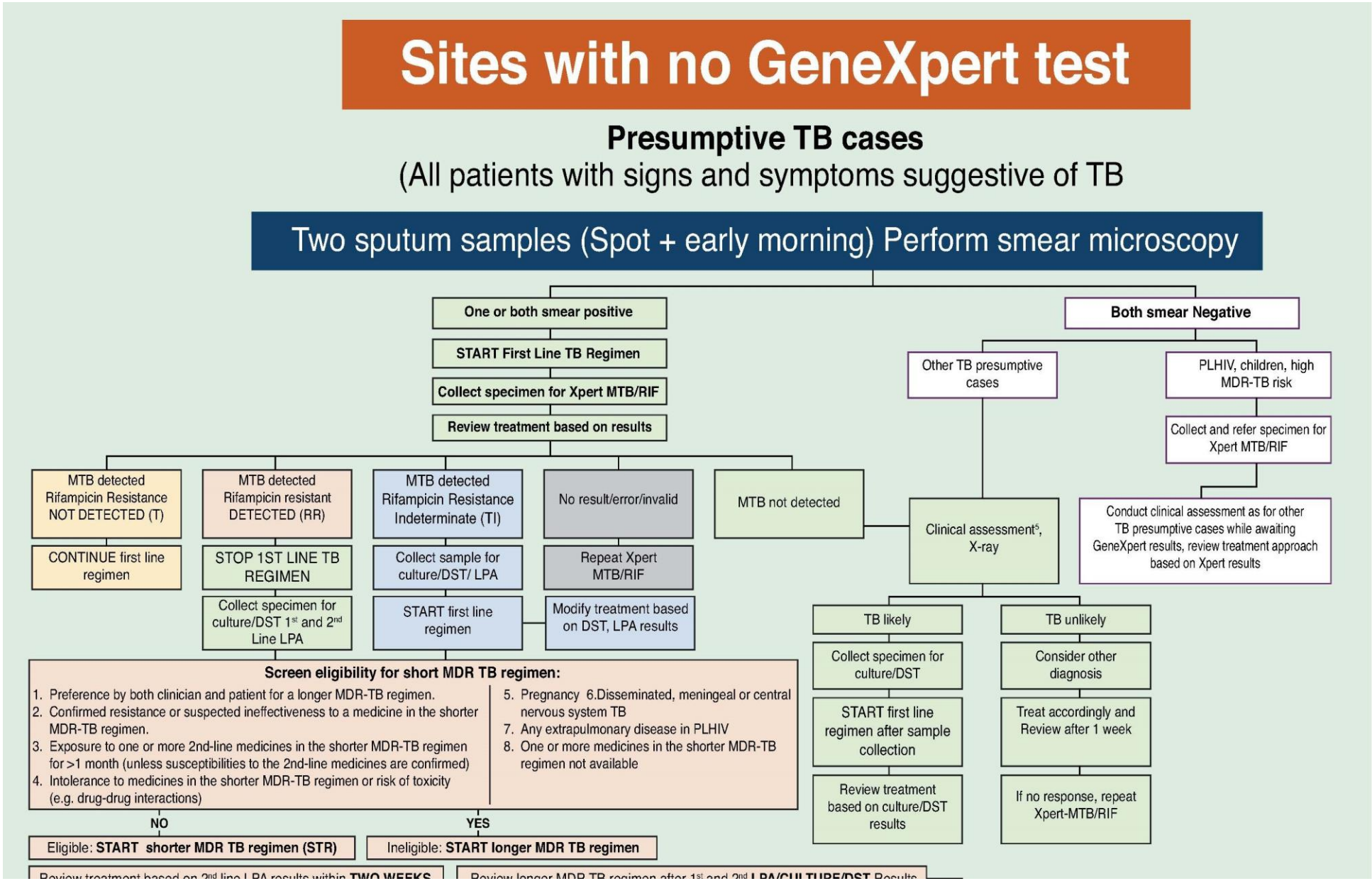
Southern Highlands Lake Zone Recommendations

- CTRL and NTLP to work on quantification and forecasting of TB diagnostic reagents and supplies, including triple packaging materials, as well as fast tracking the clearance process of the imported TB consignment in close collaboration with the MSD and the Government Procurement Services Agency.
- CTRL and NTLP to build capacity of zonal, regional, and peripheral TB focal persons on data management, documentation, and all other quality management system indicators.
- CTRL and zonal laboratories to enhance use of ETL for timely results submission and tracking of specimens.
- Ensure data management is documented in the job description of laboratory staff.
- Support regional and zonal laboratories to ensure that human resources are available for laboratory data management.
- CTRL and NTLP to plan and conduct refresher trainings on data management, algorithms, and other TB diagnostics-related trainings (e.g., GeneXpert maintenance and data archiving).
- CTRL to ensure timely dissemination and use of the current TB diagnostic algorithms in the lower-level facilities.
- CTRL and NTLP to mobilize resources to train and equip facilities to perform sputum induction in children.

- Establish collaboration between zonal and regional levels so that X-ray experts at zonal-level hospitals can provide technical assistance in the interpretation of X-ray findings at the regional levels.
- Ensure the availability and use of SOPs on specimen collection, packaging, referral, and documentation at all levels.
- Enhance the integration and coordination of TB and HIV specimen referrals at all levels and ensure that TB specimens are collected onsite (i.e., refer specimens and not patients).

Annex 5. Diagnostic Algorithms




Sites with no GeneXpert test
Presumptive TB cases
(All patients with signs and symptoms suggestive of TB
Two sputum samples (Spot + early morning) Perform smear microscopy
One or both smear positive
START First Line TB Regimen
Collect specimen for Xpert MTB/RIF
Review treatment based on results
Both smear Negative
Other TB presumptive cases
PLHIV, children, high MDR-TB risk
Collect and refer specimen for Xpert MTB/RIF
MTB detected Rifampicin Resistance NOT DETECTED (T)
MTB detected Rifampicin resistant DETECTED (RR)
MTB detected Rifampicin Resistance Indeterminate (TI)
No result/error/invalid
MTB not detected
CONTINUE first line regimen
STOP 1ST LINE TB REGIMEN
Collect sample for culture/DST/ LPA
Repeat Xpert MTB/RIF
Collect specimen for culture/DST 1st and 2nd Line LPA
START first line regimen
Modify treatment based on DST, LPA results
Clinical assessment5, X-ray
Conduct clinical assessment as for other TB presumptive cases while awaiting GeneXpert results, review treatment approach based on Xpert results
TB likely
TB unlikely
Collect specimen for culture/DST
START first line regimen after sample collection
Review treatment based on culture/DST results
Consider other diagnosis
Treat accordingly and Review after 1 week
If no response, repeat Xpert-MTB/RIF
Screen eligibility for short MDR TB regimen:
1. Preference by both clinician and patient for a longer MDR-TB regimen.
2. Confirmed resistance or suspected ineffectiveness to a medicine in the shorter MDR-TB regimen.
3. Exposure to one or more 2nd-line medicines in the shorter MDR-TB regimen for >1 month (unless susceptibilities to the 2nd-line medicines are confirmed)
4. Intolerance to medicines in the shorter MDR-TB regimen or risk of toxicity (e.g. drug-drug interactions)
5. Pregnancy 6.Disseminated, meningeal or central nervous system TB
7. Any extrapulmonary disease in PLHIV
8. One or more medicines in the shorter MDR-TB regimen not available
NO
YES
Eligible: START shorter MDR TB regimen (STR)
Ineligible: START longer MDR TB regimen