National TB Diagnostic Network Assessment

Manual for Assessors Revised

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About this manual

The manual provides practical guidance and tools to plan and implement an assessment of a country’s TB diagnostic network. This document includes:

* an overview of the TB diagnostic cascade, the assessment tool and assessment process
* advice on organizing an assessment team and scheduling activities
* checklists and questionnaires to assess the overall maturity of the network.

The TB-Net Tool is designed to be suitable for use in any country, however, it may be necessary to slightly modify or customize the TB-Net Tool for some countries to meet the local context of a country’s health system.

Target audience

This guide is intended to inform Ministry of Health officials, national TB programs and laboratory staff, donors, implementing partners, international agencies and organizations interested in assessing TB diagnostic networks in low- and middle-income countries.

List of acronyms

|  |  |
| --- | --- |
| AFB | acid-fast bacilli |
| APHL | Association of Public Health Laboratories |
| ASLM | African Society of Laboratory Medicine |
| BSL | biosafety level |
| CQI | continuous quality improvement |
| DR-TB | drug-resistant tuberculosis |
| DST | drug-susceptibility testing |
| EQA | external quality assessment |
| FLD | first-line anti-TB drugs |
| FQ | fluoroquinolone (e.g., levofloxacin or moxifloxacin) |
| GDF | Global Drug Facility |
| GHSA | Global Health Security Agenda |
| GIS | geographic information system |
| GLI | Global Laboratory Initiative |
| HIV | Human Immunodeficiency Virus |
| HR | human resources |
| IDSR | Integrated Disease Surveillance and Response |
| IHR | International Health Regulation |
| LABNET | national laboratory network assessment scorecard |
| LED FM | light emitting diode-based fluorescence microscopy |
| LPA | line-probe assay |
| LIMS | laboratory information management system |
| MDR-TB | multidrug-resistant tuberculosis |
| MoH | Ministry of Health |
| MTB | *Mycobacterium tuberculosis* complex bacteria |
| NRL | national reference Laboratory |
| NSP | national strategic plan for tuberculosis elimination |
| NTP | National TB Program |
| PLHIV | people living with HIV |
| PPE | personal protective equipment |
| QA | quality assessment |
| QC | quality control |
| QMS | quality management system |
| RR-TB | rifampicin-resistant tuberculosis |
| SLID | second-line injectable anti-TB drug (i.e., kanamycin, capreomycin or amikacin) |
| SL-LPA | second-line line-probe assay |
| SOP | standard operating procedure |
| SRL | supranational reference laboratory |
| TB | tuberculosis |
| ToR | terms of reference |
| USAID | United States Agency for International Development |
| WHO | World Health Organization |
| WRD | WHO-recommended rapid TB diagnostic |

Definitions

**Diagnostic services**. **Clinical diagnostic services** or functions may include symptom screening, radiology, specimen collection and referral of specimens to a testing site. Clinical diagnostic services may be provided at a health facility or at the community level by community health workers. **Laboratory diagnostic services** or functions include specimen receipt, laboratory testing and reporting of results. In some settings patients are referred to a laboratory, and the laboratory is responsible for specimen collection.

**External assessment team.** A team of national and international TB laboratory, diagnostic network and program experts that conducts the assessment. External refers to persons who are not directly associated with the TB program or diagnostic network being evaluated.

**External assessment team focal person.** A member of the external assessment team that serves as the primary point of contact to facilitate communications between the external assessment team and the MoH and NTP.

**MoH and NTP focal person**. A member of the MoH or NTP that serves as the primary point of contact to facilitate communications between the MoH, NTP, in-country workgroups and the external assessment team.

**Private sector facility**: Private sector facilities (laboratories, health facilities, hospitals, private practitioners) are broadly defined to include all facilities that are not funded or controlled by the national or state TB program or Ministry of Health and that are not included in the NTP/NTRL systems for reporting, supervision, monitoring and evaluation of TB services. These facilities may include private for-profit and private not-for-profit facilities, commercial laboratories, academic laboratories and hospital laboratories.

**Self-assessment.** An assessment of a country’s own TB diagnostic network by the MOH, NTP or designated individuals associated with the TB program using the TB diagnostic network assessment tool.

**Supplemental checklists.** Topic-specific checklists that supplement the main assessment tool verification questions to ensure that enough detail on specific diagnostic network components (e.g., specimen referral) is gathered to address the overall objectives and scope of work of the assessment.

**TB diagnostic cascade** starts with a person experiencing symptoms and deciding to seek care or a health care worker identifying a person to be evaluated for TB and continues through the ordering of an appropriate test, timely referral of a specimen to the laboratory, accurate and quality-assured laboratory testing, return of the test results, initiation of appropriate treatment, and monitoring of the response to therapy.

**TB diagnostic network** is a collaborative group including all (public, private, non-governmental) laboratories and health facilities within a country, whose mission is to address individual patient care and public health needs from the peripheral to the national level.

**TB diagnostic network assessment tool.** A tool based on network standards, core capacities, components, and capability stages. Standardized checklists, questions, and pre-determined attributes of each stage of each component are used to assess the degree to which the network meets the diagnostic network standard.

* **Network standards** are used to define the practices, methods, systems and requirements that are essential for a comprehensive, well-functioning TB laboratory network.
* **Core capacities** are capabilities required of a TB diagnostic network to provide the laboratory services needed to detect and identify TB, link patients to care, monitor patients on therapy, and conduct surveillance of TB disease. Each core capacity corresponds to one of the diagnostic network standards.
* **Components** are key capabilities and essential functions of the TB diagnostic network that must be fulfilled to meet the diagnostic network standard.
* The **capability stage** assigned to a component reflects the degree to which that component meets the diagnostic network standard. The stages are quantified using a semi-quantitative, six-step staging system from stage 0 (completely absent) to stage 5 (fully compliant with international standards).

**Verification visits**. Site visits with laboratory and program staff at the national, intermediate and peripheral levels to verify the stages assigned in the self-assessment done by the national program. Verification visits are not visits to evaluate the performance or competencies of individual laboratories.

1. Introduction

WHO’s global strategy for TB prevention, care and control for 2015–2035[[1]](#footnote-2) (the End TB Strategy) calls for the early diagnosis of TB and universal drug-susceptibility testing (DST). The End TB Strategy highlights the critical role of laboratories and emphasizes that meeting the targets of the End TB Strategy will require that WHO-recommended rapid TB diagnostics (WRDs) are available to all persons with signs or symptoms of TB; all bacteriologically confirmed TB patients receive DST at least for rifampicin; and all patients with rifampicin-resistant TB (RR-TB) receive DST at least for fluoroquinolones (FQs) and second-line injectable drugs (SLIDs). WHO recommends that national TB programs prioritize the development of a network of TB laboratories that use modern diagnostics, have efficient referral systems, use standard operating procedures (SOPs) and appropriate quality assessment (QA) processes, and have adequate biosafety and sufficient human resources4,[[2]](#footnote-3). These priorities should be comprehensively addressed in national strategic plans and adequately funded.

The TB diagnostic process (Figure 1) starts with the person experiencing symptoms and deciding to seek care (i.e., passive case finding) or a health care worker identifying a person to be evaluated for TB (i.e., active case finding). The process continues with the ordering of an appropriate test by a health care worker, timely and safe referral of the specimen under appropriate transit conditions to the laboratory, accurate and quality-assured testing by the laboratory, return and receipt of the test results by the health care worker, initiation of appropriate treatment, monitoring of response to therapy and post treatment follow-up for potential relapse cases). Attrition from or delays in any of the steps can reduce the clinical and public health impact of the laboratory test.



**Figure 1**. The TB diagnostic process

A recent study[[3]](#footnote-4) of the TB diagnostic cascade in India revealed that in 2013, only 39% of the estimated 2.7 million new TB patients complete the entire patient pathway to achieve a sustained cure. Significant losses along the patient pathway include 1) only 72% of estimated TB patients reach a TB diagnostic center, 2) of these only 84% are diagnosed with TB, 3) of these 87% are registered for treatment, and 4) of these only 74% achieve a sustained cure (Figure 1). Strengthening the entire diagnostic network and patient pathway can produce reductions in the time from the moment when the patient seeks care to a clinician making a patient care decision, reduce loss to follow up, and increase access to quality assured laboratory services for all patients.

Similar results were observed in a study in South Africa[[4]](#footnote-5), which reported losses of 5% during access to laboratory services, 13% during diagnosis, 12% during registration and treatment initiation and 17% during treatment.

A comprehensive, high-quality TB diagnostic network is essential to diagnose TB accurately and rapidly; to link bacteriologically confirmed TB patients to appropriate and timely treatment; and to monitor patients on therapy. Laboratory services are a key component of a well-functioning diagnostic network. However, a laboratory test is just one part of the diagnostic process. The diagnostic network must engage all health care facilities and workers in the diagnostic process and must have efficient linkages between steps in the diagnostic process. As such, a comprehensive evaluation of a diagnostic network must use an assessment tool, such as the TB Diagnostic Network Assessment Tool described in this manual, that addresses the entire diagnostic network, not just one component such as laboratory testing. A network assessment tool is quite different than the tools used to assess the quality of individual laboratories such as the WHO Laboratory Assessment Tool[[5]](#footnote-6). A network assessment tool should not be used to assess individual laboratories.

The TB diagnostic network is a shared responsibility between a TB program and all levels of TB or general laboratories within the network. The network encompasses all points where community members seek care – both within the public and private sectors and among formal and informal providers.

In addition to the laboratory testing needed to diagnose TB, a variety of laboratory and clinical tests are needed to refine treatment regimens and monitor therapy. For example, all TB patients should receive an HIV test. To monitor potential adverse drug effects, patients may require baseline and follow-up testing such as hemoglobin and white blood cell counts; measurements of serum levels of urea, creatinine, electrolytes, liver enzymes; hearing and vision tests; and ECGs[[6]](#footnote-7). This testing is usually conducted in clinical or hospital laboratories and not in a TB diagnostic laboratory. Although it is important that TB clinicians and programs ensure access to such testing for TB patients, the assessment tool described in this manual focuses on the laboratories that provide services for the diagnosis of TB and does not address this ancillary testing or these laboratories.

# The TB Diagnostic Network Assessment Tool (TB-Net Tool)

The TB Diagnostic Network Assessment Tool (hereafter referred to as the ‘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 National Strategic Plan (NSP) for TB. The TB-Net Tool is designed to be suitable for use in any country, however, it may be necessary to customize the TB-Net Tool for some countries to meet the local context of a country’s health system.

## Diagnostic Network Standards, Core Capacities and Components

The foundation of a diagnostic network assessment is a set of standards that provides a qualitative measure of quality or attainment of a comprehensive diagnostic network. The standards used here are based on the national TB diagnostic network standards and assessment tools developed and piloted by the Global Laboratory Initiative (GLI) and partners[[7]](#footnote-8), which were based on an earlier GLI assessment tool focusing on TB microscopy laboratory networks[[8]](#footnote-9). 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.

The core capacities and components were adapted from the original nine LABNET[[9]](#footnote-10) core capacities which were developed for evaluating national laboratory networks in Africa with respect to achieving global health security. The standards, core capacities and components used in the assessment of the TB diagnostic network are shown in Table 1.

**Table 1.** Diagnostic Network Standards, Core Capacities and Components

|  |  |  |  |
| --- | --- | --- | --- |
|  | Standard | Core Capacity | Components |
| 1 | The country has a fully endorsed political, legal and regulatory framework in place which supports the achievement of the NSP and that organizes and controls all public and private diagnostic services to support the NSP, 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. | Political, legal, regulatory and financial framework | * Legislation and policies * National policies and plans * Governance * Financing and budgeting |
| 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. | Structure and organization of the diagnostic network | * Diagnostic Network * Coordination and management * Programmatic and operational research |
| 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 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 performed and ensures the timely linkage of diagnosed patients to appropriate care and treatment. | Coverage | * Diagnostic network coverage * Sample referral system * Linkages * Emergency preparedness |
| 4 | A national TB diagnostic algorithm(s) 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. | Diagnostic algorithm | * Algorithms * Detection of TB * Detection of drug-resistant TB |
| 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 samples and materials, both in routine as well as in emergency circumstances. | Biosafety | * Facilities * Biosafety and biosecurity manual * Biosafety systems * Waste management |
| 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. | Equipment and supplies | * Supply chain management * Equipment management |
| 7 | Adequate numbers of competent, well-trained and motivated technical and managerial staff are available at all levels of the diagnostic network. | Workforce | * Education and training * Staffing * Human resources development strategies and plans * Competency-based job descriptions |
| 8 | Inter-operable and inter-connected 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 sub-national level. A laboratory information management system (LIMS) provides up to date information about the status of the laboratories and is linked to the Health Management Information System of the country. | Diagnostics data management | * Data collection forms * Reporting * Diagnostics connectivity and remote monitoring * Data analysis and sharing * Surveillance and epidemiology * Security and confidentiality of information |
| 9 | High quality diagnostic services producing accurate and reliable results are available throughout the network. Continuous quality improvement targets all facilities within the network and includes quality indicator monitoring, external quality assessment, and regular on-site supervision. A system of national certification is in place for all public and private laboratories within the network and reference and referral level laboratories are accredited according to national or international standards. | Quality of the diagnostic network | * Documents and document control * Quality assurance * Quality management system * Certification and accreditation |
| 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+ persons should be screened for TB and linked to appropriate diagnostic testing. Coordination and communication between the National AIDS Control Program and 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, etc.). | TB/HIV | * Legislation and policies * Structure and organization of the network * Coverage * Diagnostic Algorithm * Workforce, * Diagnostic Data Management |

## Questions and Stages

The TB-Net Tool uses the same semi-quantitative scoring procedures as African Society of Laboratory Medicine (ASLM)/Association of Public Health Laboratories (APHL) National Laboratory Network Assessment (LABNET) scorecard[[10]](#footnote-11), developed by ASLM, APHL, the Royal Tropical Institute (KIT) and the Amsterdam Institute of Global Health and Development (AIGHD) to identify the ‘capability’ stage of various aspects of the diagnostic network to describe current capabilities and to help identify areas for improvement. The TB-Net Tool may also be used to monitor performance of national TB diagnostic systems and networks over time.

Within the TB-Net Tool, standardized “questions” are used to assess to what degree each component meets the diagnostic network standard and pre-defined attributes of each question are used to define six stages (0–5) of capability from ‘completely absent’ to ‘fully compliant with international standards’. The stages, based on a Capability Maturity Measurement Model (CMM)[[11]](#footnote-12), to provide a semi-quantitative measure of the stepwise progression towards complete fulfillment of each component of a core capacity. The stages of capability are defined as:

* *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. Listed attributes including 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 relevant background information are found in Annex 1 and are organized by core capacity and associated components used in the assessment. Each question is graded from 0 to 5 based on the pre-defined answers that are provided. There is no possibility for yes or no answers. All questions need to be evaluated in order to proceed to the final analyses.

## Determining the capability stage and progress towards achieving core capacities

A capability stage (Figure 2) is determined for every ‘question’ of a component by reviewing applicable documents (e.g., policies, guidelines, SOPs) and data; interviewing program, clinical or laboratory staff; or direct observation. Many questions can be evaluated by reviewing documents (e.g., the NSP) at the national level. Stages for other questions (e.g., Are SOPs followed at all levels of the diagnostic network?) are assessed during ‘verification’ visits to national (NRL), intermediate (IRL) and peripheral laboratories (PL) and during interviews with national, intermediate and peripheral program staff. The purpose, background information, and source of verification for each question are described in Annex 1. A checklist of standardized questions (Annex 6) is used during verification visits to focus the visit on assessing the network and to avoid the visit becoming an assessment of a laboratory’s performance.

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Core Capacity 4. Diagnostic Algorithm** | | | | | | | |
| **No.** | **Questions** | **Stage** | | | | | |
| **Component 4.1. Algorithm** | | **0** | **1** | **2** | **3** | **4** | **5** |
| **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? |  |  |  | **** |  |  |
| **4.1.2** | Does the TB laboratory testing 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? |  |  |  |  | **** |  |
| **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? |  |  |  |  |  | **** |
| **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? |  | **** |  |  |  |  |
| **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) |  |  | **** |  |  |  |

**Figure 2.** Determining a component’s capability stage

This qualitative analysis can provide a quick visual assessment of the status of the overall diagnostic network core capacities and identify areas that need intensified strengthening. To provide an assessment of the progress towards achieving a strong diagnostic network, progress towards reaching stage 5 (or 100% capability) is calculated for each core capacity. Figure 3 is an example of how to determine progress towards achieving 100% 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 3 points, question 2 contributes 4 points, etc.
* Add up the points for all of the questions within the core capacity. In the example, the total is 22 points
* Calculate the capability percentage as: [(Total number of points for all questions within a core capacity) / (total number of questions x 5)] x 100. In the example, the percentage is: [22/(8x5)]x100 = 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 samples and materials, both in routine as well as in emergency circumstances. | Algorithm: Question 4.1.1 | **3** |
| Question 4.1.2 | **4** |
| Question 4.1.3 | **5** |
| Question 4.1.4 | **2** |
| Question 4.1.5 | **1** |
| TB Detection: Question 4.2.1 | **3** |
| DR-TB Detection: Question 4.3.1 | **3** |
| Question 4.3.2 | **1** |
| Total | 22 |

**Figure 3.** Determining Progress Towards 100% Capability for a Core Capacity

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

The TB-Net Tool is provided in a PDF file that can easily be printed but also as Excel files. The questions are exactly the same in the PDF and Excel format. Worksheets 1 to 10 correspond to the 10 core capabilities; worksheet 11 is a calculation sheet providing a summary of the aggregated and individual core capability data analyses.

# The Assessment Process

Although they may vary, the key objectives of an assessment of a TB diagnostic network typically are to:

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

The assessment should be conducted by a team of TB laboratory, diagnostic network, and program experts. The team may be composed of national experts, international experts or both. The team of external experts (i.e., persons not associated with the TB program or diagnostic network being evaluated) may be assisted by internal program and laboratory experts (i.e., persons associated with the national program or laboratory network). The assessment team should include experts to cover the range of diagnostic network components to be evaluated. All efforts should be made to ensure that there are no conflicts of interest for any assessor.

A four-part process is used for the diagnostic network assessment:

* Pre-assessment data collection and analysis
* Self-assessment of the TB diagnostic network core capacities by the program using the TB-Net Tool
* Review of the self-assessment and verification of self-staging by an assessment team through document review, interviews, and ‘verification’ visits to national, regional (supervisory), and peripheral laboratories
  + The purpose of a verification visit is to interview laboratory and program staff at the national, intermediate and peripheral levels to verify the stages assigned in the self-assessment done by the national program. For example, staff would be asked to determine if SOPs are implemented at all levels of the laboratory network to determine the stage for that question. Importantly, verification visits are **not** visits to evaluate the performance or competencies of individual laboratories.
* Review of the findings of the assessment, identification of strengths and weaknesses and development of evidence-based interventions to improve the TB diagnostic network

## 1. Pre-assessment data collection and analysis

National and sub-national data on diagnostic and laboratory variables should be compiled and provided to the assessment team by the country program at least 4 weeks prior to the in-country assessment visit to allow sufficient time for compilation and analysis. These data should also be reviewed as part of the self-assessment process. The list of potential analyses, figures and tables is extensive. The National program and assessment team should tailor the list to the country and to the specific objectives of the network assessment. Data may not be available for some analyses and some analyses may not be relevant to the objectives of the assessment.

Usually, one member of the external assessment team with expertise in data analysis and statistics will analyze the data provided by the program and prepare a pre-assessment data report (a template is available). The report should be provided to the assessment team at least two weeks prior to the in-country visit. Data and analyses provided in the pre-assessment report should include:

• TB and DR-TB case notification data according to WHO-recommended categories[[12]](#footnote-13) (e.g., pulmonary TB, extrapulmonary TB, bacteriologically diagnosed TB, pediatric TB, adult TB, TBHIV, MDR-TB, etc.) at national and sub-national levels (at least to province, region, or state level) and with disaggregation by public and private sectors where available

• Number and type of staff at national TB reference laboratory (NRL) and intermediate reference laboratories (IRLs) and whether the positions were approved and filled or vacant as well as source of funding (e.g., federal or state government, Global Fund, PEPFAR, implementing partner, *etc.*)

• Key test statistics performance indicators[[13]](#footnote-14) by state and district for each TB test conducted in the TB Diagnostic Network (e.g., AFB-smear microscopy, Xpert MTB/RIF, Line-probe assays, TB-LAMP, LF-LAM culture, first-line DST, second-line DST, etc., Annex 2)

• Number and types of laboratories conducting the different diagnostic technologies by state and district

• Key performance indicators for the TB diagnostic process and for laboratory strengthening under the End TB Strategy[[14]](#footnote-15) (Annex 3)

NOTE: Annexes 2 and 3 are available in an Excel format which includes worksheets that will automatically generate charts as data are entered in the main data collection worksheet.

The pre-assessment phase should also include a review of key documents such as the national TB strategic plan, national TB laboratory strategic and operational plans, most recent annual report, technical and operational guidelines, and diagnostic algorithms. Annex 4 has a complete list of documents that will be needed for the assessment.

To facilitate verification visits to peripheral and regional laboratories, where possible, facility or site-specific data (e.g., testing statistics and key performance indicators for tests done, *etc*.) should be collected and key variables analyzed and compiled in a usable format and made available to the assessment team prior to the site visits (see Annex 5. Laboratory statistics and data collection forms).

## 2. Self-assessment staging of TB diagnostic network core capacities

The country should perform a self-assessment of their capacity in key diagnostic network areas by identifying their capability stage using the TB-Net Tool which has pre-defined criteria (components and questions) for each of the ten core capacities. The self-assessment should be performed by a small technical group including representatives of the national TB program (NTP), national TB reference laboratory (NRL) and intermediate reference laboratories (IRLs) as well as other national level laboratory, program and clinical experts. Technical assistance to guide the self-assessment may be needed in some cases. This may come from in-country technical partners, USG, WHO or a local or international technical consultant. The completed self-assessment should be provided to the external assessment team at least two weeks prior to the in-country visit.

## 3. Review of self-assessment and in-country verification by the assessment team

During the in-country visit, the assessment team reviews and verifies the country’s self-assessed stages for each component. Many components can be verified by reviewing documents (e.g., the NSP) provided by the NTP. Annex 4 contains a list of documents to review for the corresponding questions. Stages for other questions (e.g.*,* Are SOPS followed at all levels of the diagnostic network?) are assessed during ‘verification’ visits to NRL, IRLs and peripheral laboratories (PLs). Verification will also require interviews with national, intermediate and peripheral program and clinical staff (e.g., District TB Officers, District Heath Officers, MDR-TB focal persons, etc.).

A standard list of questions to guide the verification process for each core capacity and component is in Annex 6. The checklist is used during site visits with laboratory and program staff at the national, intermediate and peripheral levels to verify the self-assessment done by the national program. Not all TB-Net Tool questions are to be verified at all levels of the network**. Verifying the answers for all questions at all levels raises the possibility of the verification visits becoming site assessment visits — something to be avoided.** Stage-defining questions that are important to ask at peripheral laboratories are marked with an ‘**’** in the checklist in Annex 6. Verification will involve interviews with laboratory and program staff at each level.

Most questions will be answered with a ‘Yes’ (achieved), ‘No’ (not achieved), ‘Partial’ (partially achieved) or N/A (not applicable). Space is provided in the checklist for comments for the responses for each question. To aid in the assessment, a suggested approach to assessment is provided for each question.

|  |  |
| --- | --- |
| **Symbol** | **Approach** |
| **** | Review applicable documents, e.g., policies, SOPs, guidelines, and data |
| **?** | Ask staff members or clients for their views or level of understanding |
| **** | Objective observations or conclusion |

To ensure that the assessment team receives enough detail on specific diagnostic network components (e.g., specimen referral), the assessment may include a limited number of topic-specific checklists to supplement the verification questions. The topic-specific checklists to include will depend on the overall objectives and scope of work of the assessment. See Annex 7 for topic-specific checklists for specimen referral, diagnostic data management, clinical-laboratory interface, National TB Strategic Plan, culture and drug susceptibility testing, private sector, ancillary testing for treatment monitoring, and chest X-ray.

Checklists are available in an editable format and may be modified to meet the objectives of the assessment or to reflect the organization of TB services in the country.

In addition to verification visits, the assessment team should, as appropriate, interview national level stakeholders and agencies (e.g., technical partners, clinicians, patient advocates, program committee and private sector representatives) and collect data and information according to the main assessment tool and topic-specific checklists. These interviews should occur after teams return from field visits and are helpful to clarify information gathered from facilities and through laboratory and program staff.

Following the review and the verification visits, the external assessment team will compile findings and determine the capability stage for each question in the TB-Net Tool. The assignment of a stage to a question is intended to represent a consensus of the external assessment team, as opposed to the opinion of a single individual.

## 4. Review of overall findings and development of priority interventions

The external assessment team will develop a set of key findings, recommendations and priority interventions. The review should identify challenges that prevent the overall TB diagnostic network from performing efficiently and effectively and should propose evidence-based interventions to improve the overall ability of the TB diagnostic network to meet the goals and targets of the NSP. A mixed-methods approach usually is used which includes both qualitative and quantitative data. Findings from the site level and national level assessments, stakeholder interviews and supplemental checklists should be used to inform the team’s final findings and recommendations. On the final day of the in-country visit, the assessment team should meet with the in-country team, MoH, NTP and NTRL and provide a verbal debrief including highlights of findings and an overview of recommendations (Annex: Template for Debriefing).

The external assessment team shall prepare a report of the assessment (a template is available) and submit it and relevant documents to the MoH, NTP and NTRL.

A critical next step is for the TB program to review the external assessment team’s findings and recommendations and empower a national Laboratory Technical Work group or an ad hoc workgroup to address the findings and recommendations and develop a costed workplan with clearly defined and prioritized activities, responsibilities, deliverables and timeline.

1. Organizing and conducting an assessment

A timeline with key activities and a budget template are presented in Annexes 8 and 9.

## Step 1: Pre-visit activities

*Define the scope of work, assemble the assessment team, and identify focal persons*

* Once a decision is made to conduct a network assessment using the TB-Net Tool, the MoH or NTP should define the scope of the assessment, determine a time frame, identify funding, and identify a third-party or technical partner to assist. The MoH or NTP should also identify areas of special interest (e.g., specimen referral systems, diagnostic data management, clinic-laboratory interface, etc.) to be investigated.
* Assembling the team of external assessors (i.e., national and international experts not associated with the TB program or diagnostic network being evaluated) is an important step and may require assistance from an implementing partner or donor. Sufficient lead time should be incorporated into the schedule if international assessors are involved to accommodate the need for travel arrangements, visas, etc. Some considerations when choosing the assessment team:
  + There should be an adequate mix of skills and expertise among the assessors to cover the objectives of the assessment. It is valuable to include some assessors who have experience working in the country to understand the country context.
  + Plan well in advance and send out a ‘save the date’ to potential assessors, especially those with distinct or unique expertise, as schedules often fill quickly for well-qualified assessors.
  + Assessors must be available for a pre-defined amount of time before and after the assessment to read documents, become familiar with the TB-Net Tool, participate in planning calls or meetings, and draft and finalize parts of the assessment report.
  + Assessors must be available for the full duration of the in-country assessment. Exceptions can occur but should be known in advance and arrangements made to cover all of the assessor’s roles and responsibilities.
  + If required, members of the assessment team should sign a non-disclosure or other data agreement to keep all non-public data or information shared during the assessment confidential. Assessors should not use data or information from the assessment for their or their organization’s use outside of the specified objectives of the assessment.
* Travel and accommodation logistics must be arranged for assessment team members
* A focal person for the external assessment team should be appointed and preferably should be someone located in country to facilitate communications. A focal person for the MoH/NTP should also be appointed.
* The external assessment team focal person shall lead an initial meeting with the designated MoH/NTP focal person to review the purpose of the assessment, explain the assessment process and provide an overview of the TB-Net Tool. The external assessment team focal person shall provide the MoH/NTP focal person with the TB-Net Tool and manual 6–8 weeks prior to the planned assessment. The focal persons should develop and agree upon the scope of work, roles and responsibilities, and timeline.

*Compile documents and national and sub-national data*

* In-country individuals or an in-country TB Laboratory working group identified by the MoH focal person in collaboration with the NTP will compile the required documents (see Annex 4) and collect the requested national and sub-national data on diagnostic and laboratory variables for the pre-assessment evaluation by the external team. External technical assistance may be needed.
* The MoH/NTP focal person shall provide the required documents to the persons conducting the self-assessment and to the external assessment team focal person.
* The MoH/NTP focal person shall provide the requested national and sub-national data to the external assessment team focal point at least four weeks prior to the assessment.

*Self-assessment of the TB diagnostic network*

* In-country individuals or TB Laboratory working group will be identified by the MoH focal person in collaboration with the NTP to complete the self-assessment of the TB diagnostic network using the TB-Net Tool. External technical assistance may be needed. If an in-country working group is used, the group may include representation from:
  + - NTP laboratory network representatives may include:
* Laboratory Services Director
* Laboratory Quality Unit
* Biosafety and Biorisk Unit
* Procurement and Supply Management Unit
* Finance Unit
* Human Resource Unit
* Environment and Infection Control Unit
* Planning Unit
* Statistics Unit

o Private laboratory and clinical sectors

o Education sector

o Representation for the laboratory tiers as appropriate

* The MoH/NTP focal person shall provide the completed self-assessed TB-Net Tool to the external assessment team focal point at least two weeks prior to the assessment.

*Selection of sites and preparations for verification visits*

(Guidance on selecting sites is presented in Annex 10)

* The MoH/NTP team with assistance from the external assessment team will determine which regions of the country to include in the assessment. If there are multiple designated NTRLs in the country, each NTRL should be visited as well as region(s) supervised by that NTRL. The regions should encompass the variation in diagnostic networks throughout the country and include regions where access to diagnostic services is easy (e.g., an urban area with a well-developed diagnostic network), moderately difficult and difficult (e.g., a sparsely populated rural area with few diagnostic facilities or with transportation challenges). It is not necessary to conduct verification visits in all regions of the country.
* Note: the number of regions and facilities to be visited will, in large part, determine the number of site-assessment teams and external assessors needed (plan for one site-assessment team per region and two external assessors per site-assessment team) and the number of facilities to visit per region will determine the number of days needed for verification visits (assume 2 to 4 sites can be visited each day depending on the time needed for travel between sites). For many countries, 4 to 5 regions with 6 to 10 facilities per region will be sufficient.
* The MoH/NTP focal person will prepare a list of facilities and persons at each tier of the diagnostic network that are available to be visited in the regions to be assessed. The laboratories should be representative of the laboratory tier and not the ‘best performing’ laboratories. The facilities selected for a verification visit will be determined by the MoH/NTP team with support of the external assessment team focal point to ensure representativeness. Any laboratory or facility that processes TB specimens or is involved in the diagnostic network should be considered including those in the private sector and other sectors as relevant in the country (e.g., NGOs, military, police, prison, corporate, etc.).
* Sites should be selected that represent five levels of TB diagnostic services:
  + National TB Reference or Public Health Laboratory
  + Intermediate reference laboratory (IRL)
  + Most, if not all, IRLs will have the responsibility for supervising peripheral laboratories.
  + In some countries, there may be IRLs that do not have supervisory responsibilities but have the responsibility for conducting centralized or sophisticated testing (e.g., LPAs, high-throughput molecular DST, culture, phenotypic DST, etc.).
  + Peripheral laboratory (district or sub-district)
  + Typically, PLs conduct microscopy and/or Xpert testing.
  + Health center or facility
  + Typically, health centers are responsible for screening patients to identify those needing TB testing, ordering testing and either collecting and transporting specimens to testing laboratory or referring patients to a testing site. Health centers may also be responsible for treatment and care of TB patients. Health facilities may be co-located with TB laboratories.
  + Community level
  + Community health workers may screen patients to identify those needing TB testing and refer presumptive TB patients to a diagnostic center, or preferably, collect specimens and transport specimens to a testing laboratory.
* One approach is to selecting facilities to visit is to select randomly one or two districts in the region and conduct verification visits to the responsible intermediate laboratory and to two to four peripheral laboratories or health facilities in the district.
  + Usually, verification visits last 1–3 hours depending on the facility. Depending on travel requirements, an assessment team should be scheduled to conduct three to four verification visits or interviews in one workday. See Annex 10 for an example of a schedule.
  + Include at least one testing site in the assessed region from the private sector or non-governmental sector (e.g., from an NGO or implementing partner) even if they are not contained in the selected district(s).
* In addition to diagnostic facilities, interviews should be scheduled with the program (e.g., District TB Officer), District or Regional Laboratory Supervisor, community health workers and clinical staff (e.g., District Health Officer, MDR-TB Focal person, clinicians).
* For Districts or regions concerned with TB/HIV, visits to the District or Regional HIV Officer and HIV clinics should be scheduled.
* The MoH/NTP team will identify MoH and NTP staff and in-country personnel who will participate in the verification visits.
* The MoH/NTP focal person will inform the District or Regional Program staff, head of the facility to be visited, staff of the laboratory or person to be interviewed well in advance of the upcoming verification visit. The visit request letter should include:
  + Purpose of visit with short description of the assessment team and structure of the visit
  + Date, time and expected duration of the visit
  + Requested staff (e.g., Laboratory Manager, Quality and Safety Officers, Procurement manager) and lab managerial documents such as laboratory registers, sample job descriptions, safety manual, quality manual, budget, work plan, etc. to be available

**Note**: this is a verification visit and not a facility assessment and this should be emphasized in the visit request letter.

* The MoH/NTP focal person shall provide laboratory statistics reporting form (Annex 5) to each laboratory to be visited and request that the form be completed and returned to the NTP focal point such that it can be provided to the external assessment team prior to the verification visits.
* Travel and accommodation logistics must be arranged for assessment team members for the verification visits.

*Pre-visit activities for assessors*

* Assessors are expected to attend webinar-based orientation and training on the assessment process, TB-Net tool, staging process, verification process and verification checklists. Webinars will be recorded to allow assessors to view at their convenience.
* A webinar or teleconference will be held to orient assessors to the purpose and objectives of the mission, specific areas of interest to the NTP, logistics and duties and responsibilities. This will also be an opportunity for assessors to ask questions about the assessment process, TB-Net tool, and checklists.
* A member of the external assessment team with expertise in data analysis and statistics will analyze the national and sub-national data on diagnostic and laboratory variables data provided by the program and prepare a pre-assessment data report (Annex X: Template for Pre-assessment Data Report). The report should be provided to the assessment team at least two weeks prior to the in-country visit. Presenting the pre-assessment data report to the team as a webinar may be particularly useful.
* Assessors should review the national TB strategic plan, national TB Laboratory strategic plan, pre-assessment data report and the self-assessed TB-Net Tool.

## Step 2: In-country activities

NOTE: For a small program, 5 – 7 working days in-country may be sufficient. For a large program or country, 10 – 14 working days in-country may be required. Travel days and rest days should be incorporated into the overall itinerary as appropriate. See Annex 11 for an example of a schedule of activities and agenda for a two-week in-country assessment.

*Days 1–2: In-country pre-assessment Team Meeting*

The assessment team should arrive two to three days before the verification field visits to have an initial team meeting to discuss roles and responsibilities of each assessor and to perform an initial review of the self-assessed TB-Net Tool completed by the in-country team. One or two team members should be pre-assigned as leaders or co-leaders to guide the team and the overall process; ensure the reports are provided within the requested time-frame and serve as the direct link(s) to the in-country focal person and NTP for the team. A team member(s) should be assigned responsibility for leading the preparation of the final report. Suggested roles:

* *External Team* *Leader:* Provides introductory remarks; presents overview of TB diagnostic network and TB-Net Tool; leads the discussion; collates data from verification visits and supplemental checklists; presents overview of the process and verification visits leads debrief meeting; coordinates completion of the report
* *Site-assessment Team* *Leader:* Leads the on-site assessment team, provides on-site introductory remarks; presents an overview of the TB-Net Tool, verification visit and assessment process; collates data from verification and supplemental checklists; provides an exit briefing for the site personnel
* *Data analysis leader:* Leads the pre-assessment data analysis, prepares the pre-assessment data report, and presents the pre-assessment data report to the assessment team on Day 1 of the in-country visit or as a webinar prior to the in-country visit
* *External assessment team (all external assessors)*:Provide input on the TB-Net Tool, examine available documents for verification; review country-prepared staging; review the verification checklist to ensure that issues raised in the review of the country-prepared staging are adequately addressed; conduct verification visits and interviews; review the findings of the verification visits; complete the TB-Net Tool (i.e., assign stages and describe stage-defining factors); develop and prioritize recommendations and interventions
* *Joint assessment team (external assessors plus members of the self-assessment team and internal experts)*: Prior to the verification visits, review the self-assessment and identify specific areas to address during the verification visits; review findings of verification visits; participate in the development of recommendations

Suggested activities:

* The in-country focal person shall ensure advance invitations are sent to the working group participants including representatives of the self-assessment team to attend the assessment discussions, and will arrange venue and logistics in advance (including tea breaks, water and lunch)
* MoH/NTP focal person and the external assessment team meet with MoH working group or in-country team
* The team leader gives a brief overview of the assessment agenda (as described here) and explains the purpose of the assessment. The purpose of the assessment is for countries to obtain data regarding their TB diagnostic network and its ability to support the NSP. The assessment report will highlight areas required for implementation or improvement within the diagnostic network.

**Note**: It is important for the team leader to emphasize that this activity is a systems and networks assessment and not a facility-based assessment. Site visits are part of the overall process to verify scores noted at the national level.

* External assessment team members should provide brief presentations to the participants covering:
  + An overview of the international standards for TB diagnostic networks
  + Brief review of the TB-Net Tool (do not include the country’s self-assessed stages), capacities, components, questions, staging process, and checklists of verification questions (Annex 6) (Note: all external assessors are expected to attend webinar-based training on the tool and checklists)
  + Thematic areas to address and topic-specific checklists (Annex 7) to be used
  + The assessment process, the specific agenda and logistics
* A designated member of the external assessment team will present the pre-assessment data report.
* The joint assessment team (external and internal assessors) will review the self-assessed TB-Net Tool to identify areas, questions and responses to be verified during the laboratory visits.

*Days 3–6: Verification visits and interviews*

**Note**: The time required for site visits will depend on the number of sites to visit and travel logistics (See Annex 10 for examples of site visit schedules). Also, for a large program or country, it may be necessary to have multiple assessment teams. Each team should have at least two external team members (one designated as the team leader) and an NTP liaison and be assigned to a specific region of the country for the verification visits. The NTP liaison would be responsible for ensuring that sites are prepared for the visits and interviews; facilitating communications between the team and sites; and addressing logistical issues. The teams should be comprised of individuals with expertise in the areas required for the verification visits. The assessment team may also include internal assessors and national experts.

* During the pre-assessment process, diagnostic facilities from each tier should have been selected for the verification process. Program (e.g., District TB Officer or Regional Laboratory Supervisor) and clinical staff to be interviewed will also have been identified. The MoH, in coordination with various stakeholders, will facilitate the visits to the selected facilities and program staff by the site-visit team (members of the external assessment team and in-country representatives).
* The assessment team will visit the selected laboratory, program and clinical staff within the diagnostic network for verification of the information provided in the self-assessed TB-Net Tool and tentative stages agreed upon during the pre-assessment meeting on days 1 and 2.
* The external assessment team shall use the checklists of verification questions and provided documents to verify the stages provided in the self-assessed TB-Net Tool at the site level. In the checklists, the verification questions have the same designation as the corresponding component and question in the TB-Net Tool. Verification checklists are tailored for the facilities or persons being interviewed (i.e., only a subset of the verification questions is asked of any one person or facility) and include:
* NTRL checklist
* Supervisory IRL checklist
* Non-supervisory IRL checklist
* Peripheral Laboratory checklist
* Health Facility checklist
* Community HCW checklist
* District TB Officer/District Health Officer checklist (TB Program checklist)
* District or Regional Laboratory Supervisor checklist
* TB/HIV checklist for the District or Region HIV Officer and HIV clinics
* Typically, each verification visit should last for 1–3 hours, depending on the facility. For example, 3 hours should be scheduled for a supervisory IRL, 2 hours for a peripheral laboratory and 1 hour for a health facility or community HCWs.
* In addition to verification checklists, additional checklists (Annex 7) may be used to investigate specific thematic areas or special areas of interest to the MoH/NTP such as specimen referral or diagnostic data management. Additional time will be need to be scheduled for completing the thematic checklists. Note that the questions in the additional checklists are not directly linked to a question of a component and may not be directly useful in assigning of stages to the components in the TB-Net Tool although they should be quite useful for developing recommendations.
* Prior to entering the facility, the team should be introduced to director or medical officer or manager of the facility via a brief courtesy meeting, facilitated by the MoH representative. The team lead will explain the purpose of the verification visit.
* It is important to emphasize the reason for the visit is to verify national systems and networks and it is not an assessment of the facility. The facility is not being scored. As far as possible, ensure the laboratory personnel are relaxed and the team should avoid interfering with laboratory testing and workload. This explanation should also be provided to the laboratory manager and personnel.
* Similarly, the visit is not a ‘supervision visit’; assessors should not be checking the quality of testing or other processes.
* When visiting a laboratory, the team will verify documents as well as address any questions or issues raised during the initial 2-day meeting of the assessment team. Avoid falling into a ‘site assessment’ trap vs verification of national information and avoid the use of jargon.
* If necessary, ensure there is a person who speaks the local language to translate or explain.
* Ask open-ended questions, e.g., how do you perform quality control on all of your tests? Avoid answering questions for the laboratory personnel. If he or she does not answer, try rephrasing the question for clarity.
* At the end of the visit the team leader should thank the personnel for their availability and time.
* At the end of the day, the assessment team should ensure that the electronic versions of the checklists are completed for each site visited or person interviewed. This may entail entering data from paper forms into the electronic versions. Assessment teams may also meet to debrief the day, discuss success of the process, identify challenges and review findings.
* During the verification process, the assessors should record observations and findings and draft recommendations to address challenges and shortcomings (see PowerPoint template for report back). This presentation may form the basis of a debriefing with region or district staff at the end of a visit to a region.

*Days 8— 12: post-verification visit activities*

* A designated external assessor(s) should collate all of the checklists into a master file (Annex X). In the master file, summary statistics (e.g., the number of ‘yes’ ‘no’ and ‘partial’ answers) will be automatically calculated for each verification question.
* Each site-assessment team should prepare a summary of the verification visits and interviews conducted in their assigned region that describes the sites visited, key findings and recommendations. The summaries should be reviewed by all team members and considered as part of the process for developing the overall findings and recommendations for the TB diagnostic network assessment. A PowerPoint template and an MS Word template are available for the summaries. It is recommended that the PowerPoint template be used to facilitate generating the debriefing presentations.
* The joint assessment team should hold consultations with 1) stakeholders including representatives of private sector laboratories and clinics, implementing and funding partners, and patent representatives, 2) clinicians, nurses and treatment focal persons and 3) representatives of the MoH, NTP, and other government programs,e.g., National AIDS Control Program. The consultations may involve the entire team or a subset of assessors.
* The external assessment team should review the TB-Net Tool and use a consensus-driven approach to determine stages based on the findings of verification visits, interviews, document review, consultations and group discussions. One approach to do this is to assign two or three external assessors to each core capacity to conduct an in-depth analysis including a review of site visit feedback and summary statistics of the and propose stages and draft justifications for the assigned stages (e.g., only 10 of 20 sites visited followed the national diagnostic algorithm). The proposed stages would be presented to the entire team and consensus reached on the ‘final’ team score.
* The external assessment team should devote two days to work on the report and recommendations while in country. One approach is to assign two or three external assessors to conduct an in-depth analysis of each thematic area and propose key findings and recommendations. The proposed findings and recommendations are then presented to the entire external assessment team (see PowerPoint template). The external team should agree on and prioritize the recommendations for each thematic area. Note that the analysis focuses on the national picture. The verification visits are not designed to generate sufficient data to allow stratifying the analyses by tier or type of laboratory, although generalizations may be possible (e.g., all supervisory laboratories lack sufficient funds to conduct supervisory visits).
* The external assessment team should use a consensus-driven approach to generate a list of 3 to 6 key recommendations and interventions. These ‘key messages’ should represent the most important findings and recommendations to communicate to senior management and decision makers.
* A draft of the key findings and recommendations and the debriefing presentations should be shared with the NTP and NTRL for their review and comments. PowerPoint templates for the debriefing presentations are available.
  + The debriefing should include 1) a brief overview of the assessment process and TB-Net Tool, 2) key messages (3-6 priority recommendations and interventions), 3) findings and recommendations for each core capacity, 4) next steps and 5) acknowledgements. The debriefing may be done as one presentation or split into two presentations.
  + The debriefing may also include a presentation of site-specific findings and recommendations. This presentation may be assembled from the feedback from each site-assessment team.
* On the final day of the mission, the assessment team should meet with the in-country team, MoH and NTP and provide a verbal debrief including highlights of findings and an overview of recommendations. The external team lead(s) has the primary responsibility for presenting the debriefing.
* The above meeting should allow time for discussion and the team should provide a positive and constructive environment.

## Step 3: Post-assessment activities

* The external assessment team, led by the Team Lead (s) will finalize the stages assigned for each component of the TB-Net Tool, complete qualitative and semi-quantitative summaries, and prepare a draft final report (a template is available). The draft report should be shared with the all external assessors, the NTP and NTRL for their review and comments. After this review, a final report should be produced and the report and relevant documents submitted to the National TB Program.

A critical aspect of a network assessment is the country follow-up. Countries should review the findings and recommendations of the assessment, empower a national Laboratory Technical Work group or an *ad hoc* workgroup to address the findings and recommendations and develop a costed workplan with clearly defined and prioritized activities, responsibilities, deliverables and timeline. Progress in implementing the workplan and improving the TB diagnostic network must be systematically monitored. A follow-up assessment may be done by internal assessors two or three years after the external assessment to assess progress. The country should engage technical assistance as needed.

Additional resources

**GLI Model TB Diagnostic Algorithms**. 2017. (<http://stoptb.org/wg/gli/assets/documents/GLI_algorithms.pdf>) This handbook provides model algorithms that graphically depict the most up-to-date WHO recommendations on use of TB diagnostics and provides guidance on the interpretation of test results and follow-up testing.

**GLI Quick Guide to TB Diagnostics Connectivity Solutions**. 2016. (http://www.stoptb.org/wg/gli/gat.asp) This guide provides an overview of diagnostics connectivity solutions, and what is required to establish one and use it effectively. It also contains a link to an online table comparing the functionalities of currently available software (<http://tinyurl.com/gliconnectivity>).

**GLI Practical Guide to TB Laboratory Strengthening**. 2017. (<http://stoptb.org/wg/gli/gat.asp>) This guide provides practical guidance on implementation of WHO recommendations and international best practices for TB laboratory strengthening.

**GLI Guide to TB Specimen Referral Systems and Integrated Networks**. 2017. (<http://www.stoptb.org/wg/gli/gat.asp>) This guide describes the various phases to create and strengthen specimen referral systems, essential components involved in referral, as well as other considerations for TB program and laboratory managers, Ministry of Health officials, and other stakeholders across disease programs.

**Laboratory Diagnosis of Tuberculosis by Sputum Microscopy- The GLI Handbook**. 2013. (<http://www.stoptb.org/wg/gli/gat.asp>) The handbook contains useful guidance on collecting sputum samples and conducting AFB-smear microscopy for the diagnosis of TB.

**WHO Definitions and Reporting Framework for Tuberculosis – 2013 revision.** 2013. [(http://apps.who.int/iris/bitstream/10665/79199/1/9789241505345\_eng.pdf?ua=1)](file:///C:\Users\Thomas\Desktop\FIND%202018\(http:\apps.who.int\iris\bitstream\10665\79199\1\9789241505345_eng.pdf%3fua=1)) This document revises previous WHO standard case definitions for TB and drug-resistant TB, the categories used to assign outcomes, and the standard reporting framework for TB.

**WHO Framework of indicators and targets for laboratory strengthening under the End TB Strategy**. 2016. (<http://www.who.int/tb/publications/labindicators/en/>) This Framework, developed by the WHO Global TB Programme and the GLI core group, describes 12 core indicators that measure countries’ capacity to detect TB accurately and rapidly using new diagnostics, provide universal DST, and ensure the quality of testing.

**WHO Tuberculosis Laboratory Biosafety Manual.** 2012. [(http://www.who.int/tb/publications/2012/tb\_biosafety/en/)](file:///C:\Users\Thomas\Desktop\FIND%202018\(http:\www.who.int\tb\publications\2012\tb_biosafety\en\)) This manual describes the minimum biosafety measures that should be implemented at the different levels of TB testing laboratories to reduce the risk of a testing site-acquired infection.

**GLI’s TB Microscopy Network Accreditation – An assessment tool.** 2013. (<http://www.stoptb.org/wg/gli/assets/documents/TBMicroscopy_Network_Accreditation_Web.pdf>) This manual describes standards and procedures for evaluating a TB microscopy network and served as one of the foundation documents for the TB Diagnostic Network Assessment Tool.

**Ondoa, P. *et al****.* A new matrix for scoring the functionality of national laboratory networks in Africa: introducing the LABNET scorecard. 2016. African Journal of Laboratory Medicine, 5. a498. <http://dx.doi.org/10.4102/ajlm.v5i3.498>

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2. *WHO Framework of indicators and targets for laboratory strengthening under the End TB Strategy*. 2016. <http://www.who.int/tb/publications/labindicators/en/> [↑](#footnote-ref-3)
3. Subbaraman R, Nathavitharana RR, Satyanarayana S, Pai M, Thomas BE, Chadha VK, et al. (2016) The Tuberculosis Cascade of Care in India’s Public Sector: A Systematic Review and Meta-analysis. PLoS Med 13(10): e1002149. https://doi.org/10.1371/journal.pmed.1002149 [↑](#footnote-ref-4)
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