TB Diagnostic Network Assessment – Intro

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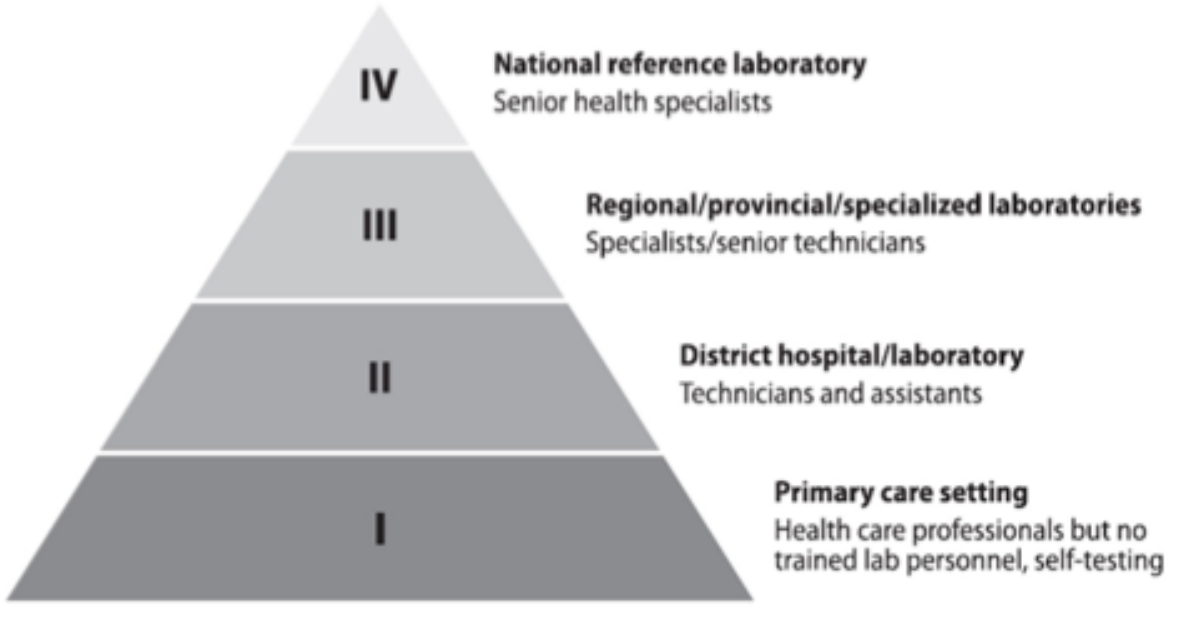
TB Diagnostic Process

Healthcare pyramid



TB Diagnostic Network Assessment

Purpose:

Comprehensively evaluate a country's TB diagnostic network 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

Key Objectives:

- Evaluate the diagnostic network, current practices and algorithm
- Identify challenges that prevent the overall diagnostic network from performing efficiently and effectively
- Propose evidence-based short- and medium-term interventions to improve access, capacity and quality of the TB diagnostic network, and increase detection of TB and MDR-TB

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TB Diagnostic Network Assessment (cont.)

Methodology:

- Use of an assessment tool with semi-quantitative scoring for the country to identify the stage of various aspects of the diagnostic network and to describe current capabilities and identify key areas for improvement.
- Verification of the self-assessed staging using a set of standardized tools and checklists and including site visits to a selection of sites.
    - Conducted by an experienced group of international laboratory, diagnostic network and TB program experts with support from in-country lab and TB experts.

Outcomes:

- Evidence-based and results-oriented recommendations to inform the development of a TB diagnostic network operational plan that serves as the roadmap for the MoH, NTP, NRL, sub-national level program, donors, and technical partners.

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TB Diagnostic Network Assessment tool

What the tool is:	What the tool is not:
✓ Will 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	✕ A way to impose new algorithms, policies, recommendations to countries blindly
✓ Structured to use semi-quantitative scoring to identify the "capability" stage of various aspects of the network	✕ A way to find fault or blame within a country's network or program
✓ A means to help identify areas for improvement	✕ A scorecard to compare networks among different programs
✓ Usable to monitor performance of national TB diagnostic networks and systems over time	✕ A way to provide a list of non-specific recommendations
✓ Country-led and owned	✕ A means to conduct routine supervision at various levels or assess individual facility-level services

ATOR

Core Capacities and Components

Capacities	Components
1. Political, legal, regulatory & financial framework	Legislation & policies; National policies & plans; Governance; Financing
2. Structure & organization of the diagnostic network	Network structure; Coordination & management
3. Coverage	Diagnostic network coverage; Sample referral system; Rapid response & preparedness
4. Diagnostic algorithm & laboratory-clinical interface	Algorithms; TB diagnosis; Drug-resistant TB; Linkages; Surveillance
5. Biosafety	Facilities; Biosafety manual; Biosafety systems; Specimen storage; Waste management
6. Equipment and supplies	Supply chain management; Equipment
7. Workforce	Education & training; Staffing; Human resources development strategy
8. Diagnostics data management	Data collection; data analysis & sharing; reporting; surveillance / epidemiology
9. Quality of the diagnostic network	Quality assurance; Quality management systems; Certification and accreditation
10. TB/HIV	Capability of the diagnostic network to provide laboratory services to address TB/HIV

Questions and Attributes

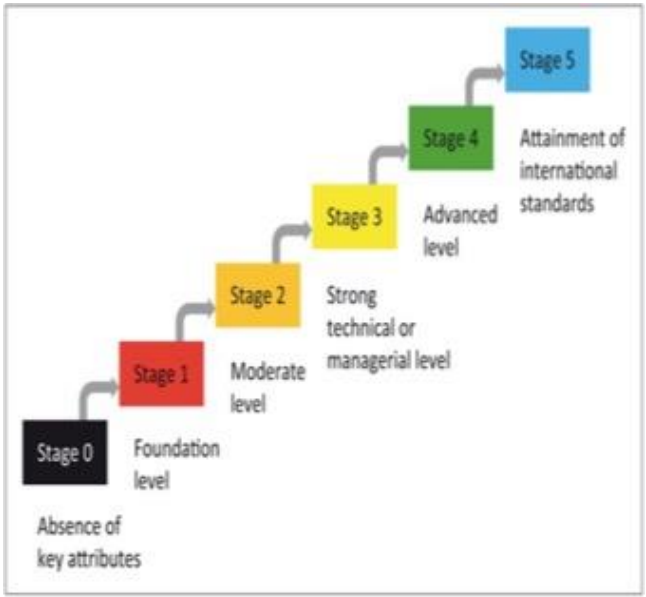
Questions are used to assess to what degree each component meets the network standard and predefined attributes of each question are used to define six stages of capability

Core Capacity 4. Diagnostic Algorithm: Component 4.1. Algorithm					
Question 4.1.1: Is a national TB diagnostic algorithm available that is responsive to the epidemic, patient-centered, and based on international best practices?					
Stages and defining attributes					
0	**1**	**2**	**3**	**4**	**5**
No	National diagnostic algorithms for TB are available at some laboratories but not current or complete.	National diagnostic algorithms and SOPs are available at all facilities in the public sector, but not current or complete.	Current national diagnostic algorithm available, but not at all public facilities.	Current national diagnostic algorithm available at all public facilities and some private labs.	Current national diagnostic algorithms available at all public and private facilities and regularly updated.

Stages and Capability Level

Key Objectives:

- Stages or capability levels range from ‘completely absent’ to ‘fully compliant with international standards
- Target level/stage for each component may vary by the needs of the program



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Stage Verification questions and checklists

Verification visits with laboratory and programme staff at the national, intermediate and peripheral levels are conducted to assess staging using standardized checklists

3. Coverage

			Description of situation (stage)						
Question nr.	Components	Questions	0	1	2	3	4	5	Stage
2	Relates to the overview of the facilities throughout the country. The information can be used for planning and for integrating rationally all available capacity into the network.	Is there a current map or list of laboratories that fall under the national TB diagnostic network? Is there a map of TB diagnostic tests (microscopy, Xpert MTB/RIF, culture, DST, etc.) and instruments within the existing diagnostic network (including utilization levels)?	No	A map or list of exists of some laboratories in the public sector.	A map or list of exists of all laboratories in the public sector.	A map or list of exists of all laboratories in the public sector and some laboratories in the private, private-not-for-profit, military and academia with incomplete GPS mapping.	A map or list of exists of all laboratories with incomplete GPS mapping.	All laboratories offering TB lab services in the country are inventoried and GPS-mapped.	

Scorecard question Number	Question	Yes/ Partial/ No	Comment
3-2	Is there a current map or list of laboratories and facilities that are included in the TB diagnostic network?		
3-2	Does the map or list include private sector laboratories and facilities?		
3-2	Is a GPS-based map of the locations of the laboratories and facilities available?		
3-2	Does the NRL or RRL have up-to-date information on the TB diagnostic network in its jurisdiction and on its performance, including all technologies?		
3-2	Is a map available of TB diagnostic tests (microscopy, Xpert MTB/RIF, culture, DST, etc.) and instruments within the diagnostic network (including utilization levels) encompassing the laboratory?		

Capability Stage

Core Capacity 4. Diagnostic Algorithm								
No.	Questions	Stage						
Component 4.1. Algorithm		0	1	2	3	4	5
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?						✓
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?			✓			

Capability Percentage

- Measures the overall progress towards reaching stage 5 (or 100% capability). Calculated for each core capacity
- [(Total number of points for all questions within a core capacity) / (total number of questions x 5)] x 100

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 1	3
		Question 2	4
		Question 3	5
		Question 4	2
		Question 5	1
	Detection of TB:	Question 1	3
	Detection of DR-TB	Question 1	3
		Question 2	1
		Total	22

The capability percentage is: [22/(8x5)]x100 = 55%

TB-Net Tool

National TB Diagnostic Network Assessment Tool

The purpose of this tool is to assess the functionality of a national TB diagnostic network and system from the perspective of their capacity to meet the needs of the country's National TB Strategic Plan for achieving global TB goals as outlined in the End TB Strategy. The development of this tool was based on the ASLM/APHL National Laboratory Network Assessment (LABNET) scorecard [Ondoa et al, 2017], developed by APHL, KIT and AIGHD, and the National TB diagnostic network standards and assessment tools developed and piloted by USAID, the Global Laboratory Initiative (GLI) and partners based on an earlier GLI assessment tool focusing on TB microscopy laboratory networks.

This diagnostic network assessment tool assesses the extent to which TB Diagnostic Network Standards have been met. 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. Standardized questions are used to assess to what degree each component meets the diagnostic network standard. Answers to the questions identify stages of maturity of the diagnosic network which provides a semi-quantitative measure of the stepwise progression towards complete fulfillment of each component of a core capacity. Full details on use of the assessment tool are provided in the National TB Diagnostic Network Assessment Manual. To see the Network Quick Guide, double-click the icon here.

Network Quick Guide

The assessment tool includes nine worksheets, each corresponding to a core capacity. The worksheets describe the components, questions, and stages and provides spaces for assigning a stage for each question and providing comments. Background information for each question can be assessed through the hyperlink in the 'References' column (typing 'F5' and 'Enter' returns the reader to the original question). To aid in the verification process, a suggested approach to verification is provided for each question.

Note that 'private sector laboratories' refer to laboratories in the private sector that participate in, or collaborate with, the national TB diagnostic network.

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

TB Diagnostic Network Standard	Capacities and Components
The country has a fully endorsed political, legal and regulatory framework in place which supports the achievement of the National TB Strategic Plan (NSP) and that organizes and controls all public and private diagnostic services to support the NSP, with sufficient	1. Political, legal, regulatory and financial framework

Introduction | 1.Policy | 2.Structure | 3.Coverage | 4.Algorithm | 5.Biosafety | 6. Equipment&Supplies | 7.Workforce | 8. Data management | 9.Quality | 10. TB-HIV | 11. Aggregated Data analys | 12.Percentage core capacities | Background

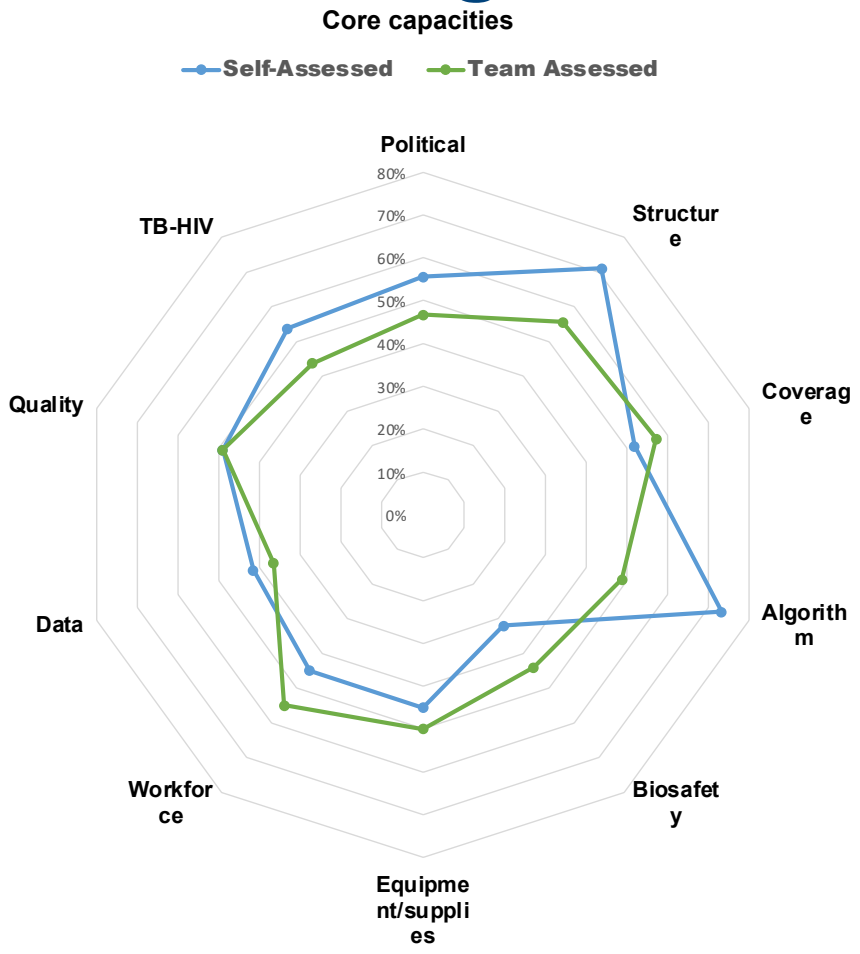
TB-Net Tool (cont.)

A	B	C	D	E	F	G	H	I	J	K	L	M	N
1. Political, legal, regulatory and financial framework													
		Description of stage											
Question nr.	Questions	0	1	2	3	4	5	Stage	Evidence	Source of verification	Reference		
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 - 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.			Review copies of the policies, plans, regulation or legislation	1.1		
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 systems, use standard operating procedures and appropriate quality assurance processes, and have adequate biosafety and sufficient human resources?	There is no national TB laboratory policy, guideline, or plan	There is a national TB laboratory policy, guideline or plan but 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 a TB laboratory network.	All of before and up to date and partially implemented. The plan prioritizes the development of an efficient TB laboratory network.	Fully implemented. The plan prioritizes the development of a comprehensive TB laboratory network that encompasses both private-sector and public-sector laboratories.	Implemented and aligned with overall health strategic plan. Revised at least once.			Review copies of the endorsed current national laboratory policy, TB NSP with accompanying strategic and operational plans whenever applicable. ? Verify knowledge of and implementation at intermediate and peripheral levels	1.2		
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 implementation of the 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.*,	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	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, prioritising some or all of the core capabilities, based on the NLSP, and all indicators and annual targets are being routinely monitored.			Review of operational plan or relevant sections of the NLSP. ? Verify knowledge of and implementation at intermediate and peripheral levels.	1.3		
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	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.			Review copy of the current licensing procedure, lists of licensed laboratories, and licenses of visited laboratories.	1.4		
1.2.4	Do laboratories inform the local and national programme of cases of TB detected in their laboratory?	No	Infrequently and on an *ad hoc* basis.	Informing the local or national TB programme	Regular informing of the TB programme at all tiers	Informing the TB programme occurs at all	Stage 4 with all tiers in the public and private			Review copy of policy.			

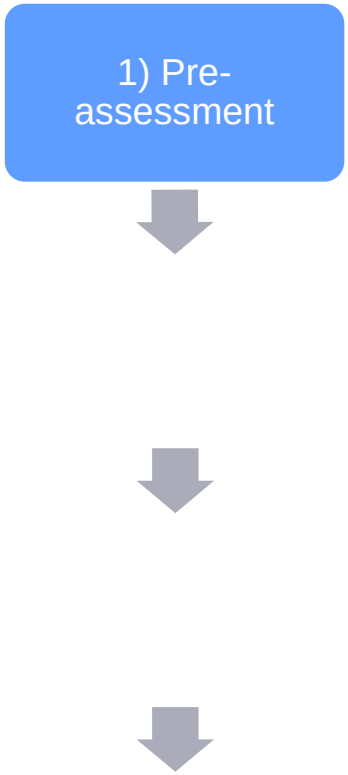
Introduction | 1.Policy | 2.Structure | 3.Coverage | 4.Algorithm | 5.Biosafety | 6. Equipment&Supplies | 7.Workforce | 8. Data management | 9.Quality | 10. TB-HIV | 11. Aggregated Data analys | 12.Percentage core capacities | Background

Core capacities final scoring

Core Capacity	Capability	
	SELF	TEAM
1. Political, legal, regulatory, and financial framework	56%	47%
2. Structure and organization of the diagnostic network	71%	56%
3. Coverage	52%	57%
4. Diagnostic algorithm	73%	49%
5. Biosafety	32%	44%
6. Equipment and Supplies	45%	50%
7. Workforce	45%	55%
8. Diagnostic data management	42%	37%
9. Quality of the diagnostic network	49%	49%
10. TB-HIV	54%	44%



4 PROCESSES



Data collection and NETWORK analysis (remote work)

- National and sub-national data on diagnostic and laboratory variables are collected before the assessment to support the in-country site level review and score verification process.

- As part of a pre-assessment data collection plan, documents, reports and data from the National TB Control Program including the National Strategic Plan, the most recent annual report, and other recording and reporting forms are reviewed. Data and other information was provided by the country.

4

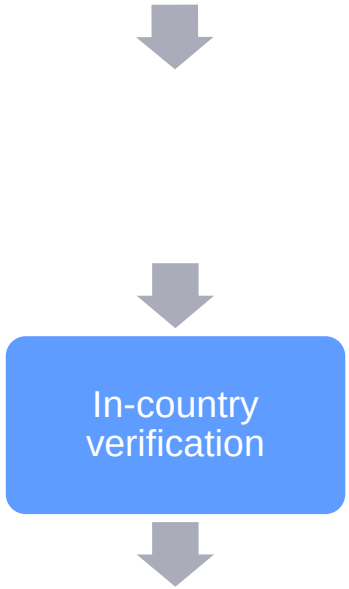
PROCESSES

Self-assessment of the TB diagnostic/lab network core capacities by the country using the TB-Net Tool (remote work)

- The country will “self assess” their capacity in key diagnostic network/laboratory components areas by assigning a stage using the pre-defined criteria in the TB-Net Tool for each core capacity
- Scores are assigned by the MoH team to each of the 10 core capacities of the Tool

4

PROCESSES



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 national program

- The Tool contains a list of points to verify for the corresponding questions during the verification visits.

Stages for other questions are assessed during 'verification' visits to national, intermediate and peripheral laboratories, and during interviews with national, intermediate and peripheral program staff

- The Tool contains a list of points to verify for the corresponding questions during the verification visits.
- A standard list of questions to guide the verification process for each core capacity and component is in the Tool.

4

PROCESSES

Develop recommendations

- Review findings from the pre-assessment data analysis, self-assessment, verification visits, stakeholder interviews and supplemental checklists
- Identify challenges that prevent the overall TB diagnostic network from performing efficiently and effectively
- Propose evidence-based interventions to improve the overall ability of the TB diagnostic network to meet the goals and targets of the NSP

Critical next steps include the TB program reviewing the external assessment findings and recommendations and developing a costed workplan with clearly defined and prioritized activities, responsibilities, deliverables and timeline

Challenges

During planning (6 to 8 weeks):

- Ensure and maintain joint involvement of the NTP, NTRL, USAID IP in-country with competing priorities
- Massive logistic planning
- Need to have external assessors (right ones to cover core capacities)

During implementation (3 to 4 weeks):

- Last minute withdrawal of External assessors
- Management of the observers during the field visits and workshop

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Key takeaway

i. Tailored SOW to be developed

ii. All 4 processes will be jointly planned and implemented with the MoH

iii. Main findings and issues are objectively identified and verifiable

- responses from TB-Net tool will be recorded in a data collection and analysis software (Survey CTO)
- verification team will review both the analyzed data and supportive documents before assigning a consensus score to each component of the 10 Diagnostic Network Core capacities
- Specific recommendations will be formulated

iv. Verification of the self assessment

- Conducted by External Expert & experienced in-country TB consultants with the involvement of:
  - Local key stakeholders (WHO, CDC, PR), other TB partners and IP
  - NTP and NTRL staff (central and regional levels) as observers strongly encouraged

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Key takeaway

v. Included in the Pre-assessment data collection and analysis (if required by the country):

- Lab Spatial Analysis
  - To assess the population coverage and accessibility of the diagnostic network (WRD instruments)
    - identify gaps and propose country specific recommendations/scenarios for network optimization, expansion and improvement
  - To assess WRD capacity effectively available (if multiplexing at the site level: HIV, COVID, HCV, and other non-TB tests performed)
  - MDR-TB component added to the LSA
    - Identification of optimal areas and facilities for new DR-TB capacity placement based on defined NTP targets, including NSP recommendations and priorities
  - To assess specimen referral linkages
    - Propose re-design if applicable to ensure efficiency and optimization of the SRS
    - Develop detailed routing planning for specimen referral

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