USER GUIDE
Score-TB package

Building Quality-Assured Tuberculosis Testing and Management Capacity Utilizing SLIPTA Methodology

Version 1.5 – July 2020

PEPFAR

CDC Centers for Disease Control and Prevention

FIND Because diagnosis matters

ASLM African Society for Laboratory Medicine

gli global laboratory initiative advancing TB diagnosis

Contents

Acronyms & Abbreviations

ASLM	African Society for Laboratory Medicine
BSC	Biological Safety Cabinet
BSL	Biosafety Level
CDC	United States Centers for Disease Control and Prevention
DST	Drug Susceptibility Testing
EQA	External Quality Assessment
FIND	Foundation for Innovative New Diagnostics
GLI	Global Laboratory Initiative
GLI tool	Global Laboratory Initiative Stepwise Process Towards TB Laboratory Accreditation
ICMR	India Council for Medical Research
ISO	International Organization for Standardization
LF-LAM	Lateral Flow Urine Lipoarabinomannan Assay
LJ	Löwenstein-Jensen
LMIC	Low- and Middle-Income Countries
LPA	Line-probe Assay
LQSI tool	Laboratory Quality Stepwise Implementation tool
MTB	Mycobacterium tuberculosis
NA	Not Applicable
NTM	Nontuberculous Mycobacteria
NTP	National Tuberculosis Program
NTRL	National Tuberculosis Reference Laboratory
PT	Proficiency Testing
QMS	Quality Management System
RIF	Rifampicin
RCF	Relative Centrifugal Force
SR	Substrate Reagent
PPE	Personal Protective Equipment
QC	Quality Control
SLIPTA	Stepwise Laboratory (Quality) Improvement Process Towards Accreditation
SLMTA	Strengthening Laboratory Management Towards Accreditation
SOP	Standard Operating Procedure
TAT	Turnaround Time
TB	Tuberculosis
TB SLMTA	SLMTA adapted for TB laboratories
TB-LAMP	TB Loop-Mediated Isothermal Amplification
USAID	United States Agency for International Development
WHO	World Health Organization
ZN	Ziehl-Neelsen

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1. Guidance to readers

This user guide instructs assessors on how to use the Score-TB Package for tuberculosis (TB) laboratory assessment. Chapter 2 starts with an explanation of the structure and contents of the Score-TB Package. Chapter 3 proceeds with a brief explanation of how to schedule and perform assessments and how to use the individual TB Lab Quality Scorecards of the Score-TB Package. The chapter ends with instructions on how to report assessment findings.

Important: We assume that assessors are laboratory experts with experience in TB testing and in Laboratory Quality Management. Therefore, this user guide does not provide detailed information on specific TB tests. Instead, for each TB test, chapter 3 provides references to guidance and reference materials developed by partners (including the Global Laboratory Initiative (GLI), World Health Organization (WHO), and the United States Agency for International Development (USAID) Challenge TB project) that provide essential background information for assessors. Specific technical information is also provided in the scorecards themselves. It is assumed that assessors using the Score-TB Package are already certified and competent in conducting laboratory assessments and that they comply with the required assessor competency profile described in section 3.1.

Background

Despite the fact that laboratory results influence 70% of medical diagnoses, laboratory services in low- and middle-income countries (LMICs) have long been a neglected component of health care systems [1–7]. TB laboratories, which are an essential component in all stages of the TB care cascade, are no exception [8]. A key intervention to strengthen laboratory services is the implementation of a quality management system (QMS) [9–11]. A QMS is defined by the International Organization for Standardization (ISO) as the "management system to direct and control an organization with regard to quality" [12,13]. Hence it is the system ("the set of interrelated or interacting elements" [13]) aimed at implementing
and operationalizing quality management in an organization. Standardization of testing through implementation of a QMS has been shown to improve the quality of testing by reducing testing errors [14].

Several tools and initiatives to assist laboratories implement quality improvement activities have been developed. One of the most successful approaches to QMS improvement is the Strengthening Laboratory Management toward Accreditation (SLMTA) approach, first described by Yao et al. [15]. The SLMTA approach is often used in conjunction with the Stepwise Laboratory Improvement Process Towards Accreditation (SLIPTA) checklist [16]. The SLIPTA checklist was developed by the WHO Regional Office for Africa and partners in 2010 in recognition of the gap between the current state of laboratory quality and the requirements of the ISO 15189:2007 standard [17]. In 2015, the SLIPTA checklist was adapted to incorporate the requirements of the ISO 15189:2012 standard and became known as 'SLIPTA v2:2015' [18].

The Foundation for Innovative New Diagnostics (FIND) has reported on the development of a TB laboratory-specific approach called TB Strengthening Laboratory Management toward Accreditation (TB SLMTA) [19]. The program is based on the existing successful SLMTA approach and utilized a revised checklist (TB Harmonized Checklist) based on SLIPTA, but incorporating some elements from the GLI tool with a focus on the technical side of TB laboratory testing.

In 2019, an additional technical revision was made to the TB SLMTA Harmonized Checklist to include TB testing methods not included in previous revisions. The current major revision concerns the incorporation of the TB SLMTA Harmonized Checklist into the 'Score-TB Package', which also includes an electronic version of the checklist referred to as the 'e-tool'. The e-tool substantially increases user-friendliness and reduces the risk for errors by automating the calculation of assessment scores and presenting these in a reporting worksheet to visualize strengths and weaknesses of a laboratory's QMS (the SLIPTA score) and TB testing methods.

Target audience

The Score-TB Package is intended to inform Ministries of Health officials, health facility- and laboratory managers, donors, implementing partners, quality assurance personnel, program managers and supervisory staff at national, regional and facility level on requirements for delivering quality-assured laboratory testing for TB and ensuring effective use of laboratory resources as well as data for patient management and surveillance in LMIC.

2. Overview

The Score-TB Package consists of the following components:

1. The User Guide
2. The TB Lab Quality Scorecards, consisting of the following scorecards:
    1. General procedures
       This scorecard includes questions that are not related to one specific TB test but are relevant for a TB laboratory. This scorecard should always be completed for each assessment.
    2. Smear microscopy
       Contains question specific for smear microscopy (light microscopy and/or fluorescence microscopy), only applicable to laboratories that perform this test.
    3. TB culture for detection and identification of mycobacteria
       Contains questions specific for TB culture, only applicable to laboratories that perform this test.
    4. Phenotypic Drug Susceptibility Testing (DST)
       Contains questions specific for DST, only applicable to laboratories that perform this test.
    5. Xpert MTB/RIF
       Contains questions specific for Xpert MTB/RIF and Xpert MTB/RIF Ultra testing, only applicable to laboratories that perform this test.
    6. Lateral Flow Urine Lipoarabinomannan Assay (LF-LAM)
       Contains questions specific for the LF-LAM test, only applicable to laboratories that perform this test.
    7. Loop-Mediated Isothermal Amplification (TB-LAMP)
       Contains questions specific for the TB-LAMP test, only applicable to laboratories that perform this test.
    8. Line Probe Assay (LPA)
       Contains questions specific for LPA, only applicable to laboratories that perform this test.
    9. TrueNat
       Contains questions specific for the Truenat test, only applicable to laboratories that perform this test.

3. The SLIPTA checklist

In the hard copy version of the TB scorecards, references to SLIPTA checklist questions are given. In the e-tool, the TB scorecard questions are incorporated in the SLIPTA checklist, meaning that the scores on the TB scorecard questions are incorporated in the calculation of the SLIPTA score.

Additional resources:

1. WHO SLIPTA Checklist Version 2:2015

3. User Guide

This chapter explains how to schedule and perform assessments using the Score-TB Package and how to use the TB Lab Quality Scorecards, and how to calculate and report assessment findings. In addition, references to essential guidance and reference materials developed by partners are provided for each scorecard.

3.1 Required assessor competency profile

Assessments are objective measures to investigate compliance with standards and/or regulations. Assessments conducted using the Score-TB Package should yield detailed information on a TB laboratory's quality in general, and the correct conduct of specific TB diagnostic tests. It is therefore essential that assessors are competent and familiar with all the details of, and recommendations related to, the TB tests he/she is going to assess. Therefore, the assessments using the Score-TB package should **only be conducted by SLIPTA certified assessors** who, in addition, are:

- Familiar with TB laboratory practice
- Well versed in, and knowledgeable of, the details related to the specific TB tests included in the Score-TB Package.

3.2 Scheduling and performing assessments

Assessments are an effective means to: 1) determine if the TB laboratory is providing accurate and reliable results for TB; 2) determine if the TB laboratory and clinical sites are well-managed and laboratory results are being reported and used effectively for clinical management and surveillance; and 3) identify areas for improvement.

The scorecards can be used in several ways:

1. For the assessment of a TB laboratory, the TB Lab Quality Scorecards can be used with or without the SLIPTA checklist as will be further explained below.
2. Assessors may elect to conduct the assessment using paper-based scorecards with later entry of data into the e-tool for score calculation, analysis, and reporting, or they may enter data directly into the e-tool at the time of the assessment[1]. It is strongly recommended to use the e-tool for score calculation (see below).
3. Assessors may elect to perform the SLIPTA assessment first and then the TB assessment, or vice versa.
4. It is recommended that a minimum of two assessors perform the assessment, whereby one asks the questions and the second person records the answers.
5. The assessors should allow approximately 6 hours to complete the General Procedures-scorecard and approximately 1-2 hours to complete each test specific scorecard.
6. The assessor should allow approximately 1.5 days to complete the SLIPTA checklist.
7. Assessors should discuss accessing data with the laboratory prior to performing the assessment. Laboratories should also be requested to provide key quality documents (such as SOPs, quality manual, biosafety manual, etc.) and quantitative data in advance of the assessment for review by the lead assessor. If the laboratory is unable to provide documentation and data in advance, assessors should schedule additional time to review documentation on-site. Alternatively, an additional assessor can be tasked with document review, while the other assessor(s) assess the technical aspects of the laboratory.
8. Laboratories should be requested to provide key quality indicator data (see section 11 of each scorecard).

[1]Full instructions on use of the e-tool are provided within the e-tool itself. Information and data collected in the paper-based scorecards and e-tool are the same.

9. Assessors should note that when planning assessments of multiple laboratories, the length of the visits will vary based upon four main factors:

    I. Number of laboratories to be assessed.
    II. Size of the laboratories to be assessed.
    III. Test menu/diagnostic spectrum of the laboratories to be assessed.
    IV. Number of assessors on the assessment team.
    V. Logistics and transportation considerations.

During the assessment, assessors should:

- Explain at the start of the assessment the scope of the assessment, the assessment method, and ensure that staff are comfortable to contribute to the assessment by making them understand that this is not a personal competency assessment but, instead, an assessment of the laboratory processes, and that the assessment is not intended to lead to disciplinary measures against individuals but to improve the functioning of the laboratory as a whole.
- Aggregate data and/or review existing quality indicator data to determine the number of tests by method type, as well as the number of positive results, DST outcomes and number of negative or contaminated cultures (where applicable).
- Review laboratory and documents to triangulate findings and verify that policies, manuals, Standard Operating Procedures (SOPs) and other documentation are complete, current, accurate, and annually reviewed.
- Review records and other relevant documents to verify that TB policies are being followed.
- Observe laboratory operations to ensure:
    - aboratory testing follows written policies and procedures in pre-analytic, analytic and post-analytic phases of laboratory testing for TB.
    - laboratory procedures are appropriate for the testing performed.
    - deficiencies and non-conformities identified are adequately investigated and resolved within the established timeframe.
- Ask open-ended questions to clarify documentation seen and observations made. Ask questions like, “show me how…” or “tell me about…” It is often not necessary to ask all the checklist questions verbatim. An experienced assessor can often answer multiple checklist questions at the same time through open-ended questions.
- Follow a patient specimen through the laboratory from collection through registration, preparation, analyzing, result verification, reporting, printing, and post-analytic handling and storing samples to determine the strength of laboratory systems and operations.
- Check whether proficiency testing (PT) results are reviewed and corrective action taken as required.
- Evaluate the quality and efficiency of supporting work areas (e.g., sample collection, data registration and reception) and staff (messengers, drivers, cleaners and IT) and oversight committees such as the Hospital management and the National TB Program.
- Model proper safety practices and take necessary safety precautions during the assessment. E.g.: wear the proper Personal Protective Equipment (PPE) (gown, gloves, mask).

3.3 The SLIPTA checklist (Version 2:2015)

The TB Lab Quality Scorecards are designed to be used in conjunction with the SLIPTA checklist (Version 2:2015). The SLIPTA checklist was developed by WHO Regional Office for Africa, in collaboration with the African Society for Laboratory Medicine (ASLM), U.S. Centers for Disease Control and Prevention (CDC) and host countries. The objective of the checklist is to provide a framework for improving quality of (public) health laboratories in developing countries to achieve the requirements of the ISO 15189 standard. Since its inception in 2008, the SLIPTA checklist has undergone one revision in 2015. The current SLIPTA checklist (v2) can be downloaded from http://apps.who.int/iris/handle/10665/204423.

It is beyond the scope of this user guide to provide instructions on the use of the SLIPTA checklist. The SLIPTA checklist itself contains instructions for its use (see Part II of the SLIPTA checklist) and further instructions are provided in the SLIPTA Guide which can be downloaded at http://www.who.int/tb/laboratory/afro-slipta-checklist-guidance.pdf. Comprehensive training for SLIPTA auditors is provided by ASLM (http://www.aslm.org/what-we-do/slipta/).

3.4 The TB Lab Quality Scorecards

The TB Lab Quality Scorecards are available in hard-copy and electronic (e-tool) formats. The e-tool also contains a digital version of the SLIPTA checklist, whereby the TB Lab Quality Scorecards are merged with the SLIPTA checklist to enable calculation of one, overall, TB-SLIPTA score for the laboratory.

3.4.1 Use of the scorecards

It is strongly recommended to use the e-tool instead of the paper-based scorecards for score calculation because the e-tool enables automatic calculation of scores whereas with the paper-based scorecards this needs to be done manually, which is more prone to errors. Another advantage of using the e-tool is that it directly visualizes the scoring and the progress since the previous assessment, if applicable. The paper-based scorecards could be convenient for use during the assessment to note findings on the printed scorecards with transcription into the e-tool directly following the assessment. Note that, if observing TB testing in the Biosafety Level (BSL) 3 facility, paper-based scorecards should be used and the use of electronic devices be avoided for safety reasons.

The TB Lab Quality Scorecards can be used in two ways when using the e-tool:

1. One could assess the correct implementation and operation of specific TB tests, using the General Procedures-scorecard in combination with the respective scorecards for the tests as stand-alone scorecards. The e-tool will calculate a score for the scorecards that have been completed.
2. One could use the TB Lab Quality Scorecards as part of a comprehensive SLIPTA assessment to verify correct implementation of SLIPTA requirements, with a specific focus on TB testing. The e-tool will calculate scores for each scorecard but will also calculate one, overall, SLIPTA score.

In an assessment, the General procedures-scorecard should always be used. This scorecard contains questions to assess TB-specific laboratory processes unrelated to specific TB laboratory tests. Subsequently, depending on the test menu of the laboratory, the assessor(s) may use one or more technical scorecards to assess technical compliance of specific laboratory tests. For example:

- If a laboratory only performs smear microscopy, this laboratory should be assessed with the General procedures-scorecard and the Smear microscopy scorecard.
- If a laboratory performs smear microscopy, culture, DST and LF-LAM, this laboratory should be assessed with the General procedures-scorecard and the scorecards for smear microscopy, culture, DST and LF-LAM.

In the e-tool, on the ‘Set Audit Scope’-tab, the assessor can indicate which tests are performed. Based on the selection, the e-tool will provide a list of links to scorecards that should be used for the assessment.

3.4.2 Scoring

The TB Lab Quality Scorecards use the same scoring system as the SLIPTA checklist. Each scorecard question has been awarded a point value of 2, 3, or 5 points—based on relative importance and/or complexity. Responses to all questions are rated as, "yes", "partial", or "no". Questions answered with "yes" receive the corresponding point value (2, 3, or 5 points). For questions with sub questions or "tick lists", all sub questions must be answered with "yes" to receive the maximum number of points.

- Questions marked "partial" receive 1 point.
- Questions marked "no" receive 0 points.
- When marking "partial" or "no", notes should be written in the comments field to explain why the requirement was not fulfilled.
- When question consists of sub questions, the overall answer can only be "yes" if all sub questions are answered with "yes".

Where a checklist question does not apply, this should be indicated as "NA". In this case, the question does not count for the calculation of the overall score. The e-tool automatically omits questions answered with NA from the calculation of the overall score. It is therefore recommended to use the e-tool to calculate the scores. If the paper-based scorecards are used instead of the e-tool, the assessor should do this calculation manually. In this case, the assessor should calculate the sum of total possible points that can be scored with all questions answered with "NA" and subtract that from the total number of points that can be scored for the overall section. This prevents that laboratories for which certain questions are not applicable, are never able to reach the maximum score.

Example: During an assessment, question 11.2 of the General Procedures-scorecard: "Are aggregate reports shared periodically with clinicians/NTP/NTRL (as applicable)?" is answered with 'NA'. The total number of points that can be scored with this question is 2. The total number of points that can be scored in the General Procedures-scorecard is 72. But because this question is answered with 'NA', the two points for this question should be subtracted from the total number of points that can be scored in the General Procedures-scorecard, which, hence, becomes 70.

3.4.3 Information on the specific TB Lab Quality Scorecards

Below, detailed guidance is provided on completing each TB Lab Quality Scorecard, starting with the General Procedures-scorecard, followed by the test-specific scorecards. The scorecards (with or without SLIPTA) can also be used for internal and external audits.

Scorecard structure

All scorecards have the same structure, consisting of three parts:

- Score
- Part A: General information
- Part B: Technical information

Score summarizes the scores for the assessment. **This section should only be completed if the assessor uses the paper-based scorecards without the e-tool as the e-tool calculates the scores automatically.**

If completing this section, assessors should note the date of the current assessment and the date of the previous assessment, if any. The total points scored for each scorecard section should be transcribed to the place provided and the percentage for each section calculated (points of section divided by total points expressed as a percentage). Note that some questions may not be applicable which then affects the overall total of the checklist – assessors should replace the denominator and calculate score based on the percentage accordingly, as explained in paragraph 3.3.2. Once all the sections are completed, the total score and total percentage can be calculated. Stars are subsequently awarded based on the following thresholds:

- No stars: < 55%
- 1 star: 55% - 64%
- 2 stars: 65% - 74%
- 3 stars: 75% - 84%
- 4 stars: 85% - 94%
- 5 stars: ≥95%

If a previous assessment has been performed, assessors should review the scores and note whether the laboratory has improved since the last assessment. Improvements and progress (or lack thereof) towards meeting laboratory assessment objectives should be reviewed with laboratory management (see 3.4 Reporting the assessment).

Part A: General information is compulsory for all assessments. The section is used to collect general information about the TB laboratory and provides the assessor the context for performing the assessment. This section is most elaborate in the General Procedures-scorecard whereas it is only minor in the test-specific scorecards. The section is best completed by the facility manager (or equivalent) before the start of the assessment and verified at the start of the assessment at the laboratory.

Part B: Technical information, is the most elaborate part of the scorecards. In all scorecards, Part B starts with a section capturing quantitative data on specific aspects, such as equipment availability, functioning, servicing and maintenance, the number of tests performed, stratified in several categories, the reporting methodology used by the laboratory, etc. It is strongly recommended to ask the laboratory to complete the section itself prior to the assessment, after which the assessors verify correct completion of this section at the start of the assessment. This is recommended because the collection of quantitative data will require time that might not be available during the assessment.

The remainder of Part B consists of 'closed'/multiple-choice questions. The same outline is used for all scorecards, following the SLIPTA checklist. The questions in each section supplement the questions of the SLIPTA checklist and should be asked in conjunction with the questions from the SLIPTA checklist. The questions cover the following topics:

- Section 1: Documents & Records

  Questions cover documentation related to policies, processes, client instructions, and recording and reporting mechanisms specific for TB testing. Documents can be requested and reviewed prior to the assessment. The answers are best verified together with the Laboratory Manager and/or the person responsible for the document control system. Questions related to Section 2 are present in all scorecards.

- Section 2: Management Reviews

  Questions cover the reporting of laboratory findings and quality indicators at an aggregated level to decision makers such as NTP and NTRL. Documents such as yearly reports can be requested and reviewed prior to the assessment. The answers are best verified together with the Laboratory Manager. Questions related to Section 2 are only present in the General Procedures-scorecard.

- Section 3: Organization & Personnel

  Questions cover training of staff and staff following procedures as described in the relevant SOPs. Training records, competency assessment reports and duty rosters can be requested and reviewed beforehand and verified with the Laboratory Manager and/or HR Manager. Whether staff follows procedures should be observed at the bench and directly observed with the SOP. Randomly choose a few techniques to observe. Questions related to Section 3 are only present in the General Procedures-scorecard.

- Section 4: Client Management & Customer Service

  Questions cover instructions for sample collection of sputum samples as well as extra-pulmonary samples and feedback to clinicians after testing. Instruction documents such as the Customer Handbook can be requested and reviewed beforehand, feedback to clinicians can be discussed with the Laboratory Manager or microbiologist/ pathologist and proof should be requested. Questions related to section 4 are present in all scorecards.

- Section 5: Equipment

  Equipment questions cover the use of verified and validated methods[2], installation, location, and maintenance of equipment. These can be best discussed with the Equipment Officer (technical aspects) and the Quality Officer (verification and validation aspects). Randomly choose a few techniques to observe. Questions related to Section 5 are only present in the General Procedures-scorecard.

- Section 6: Evaluation and Audits

  Questions cover regular internal and external auditing of the TB laboratory (separately or as part of larger audits) and follow up of resulting recommendations and action plans. These can be best discussed with the Quality Officer. Documentation for follow up of actions should be reviewed. Questions related to Section 6 are only present in the General Procedures-scorecard.

- Section 7: Purchasing & Inventory

  Questions are related to the use of correct specifications and the correct storage of reagents and supplies. These can be best discussed with the Stock Officer. Visit the storage area and observe a few reagents and supplies critical to correct performance. Check storage conditions and expiration dates. Questions related to Section 7 are present in all scorecards.

[2]The main objective of validation and verification is to demonstrate that an examination procedure is fit-for-purpose (J Lab Precis Med 2017;2:58). Use of non-validated / non-verified examination procedures are not uncommon in the laboratory. When used without modification, a validated examination procedure shall be **verified**, whilst non-standard methods, home brew methods, validated methods which have been modified or are being used outside their intended scope shall be **validated**.

- Section 8: Process Control

  Process control is the most extensive section in all scorecards. Questions are related to the correct performance of the testing procedure, quality control, quality assurance and external quality[3]. Documents related to EQA scores can be requested and reviewed beforehand and discussed with the Laboratory Manager and/or Quality Officer. Execution of tests including quality controls should be observed at the bench and in the results recording ledger.

- Section 9: Information Management

  Questions cover the recording and reporting of individual test results. These can be best discussed and verified with the person responsible for report submission. The correct registration of results can be best checked for complex test result (for example DST or LPA) as transcription errors may be most prevalent. Questions related to Section 9 are only present in the General Procedures-scorecard.

- Section 10: Identification of Nonconformities, Corrective and Preventive Actions

  Questions are related to the identification and documentation of non-conformities, their analysis[10] and corrective actions. These questions can be best discussed with the Quality Officer. Documents describing non-conformities, their analysis and correction should be reviewed. Questions related to Section 10 are only present in the General Procedures-scorecard.

- Section 11: Occurrence/Incident Management & Process Improvement

  Questions are related to the collection and reporting of performance indicators. Documents can be requested and reviewed beforehand and are best discussed and verified with the Laboratory Manager and/or person responsible for data management. Questions related to Section 11 are present in all scorecards.

- Section 12: Facilities and Biosafety

  Questions cover the safe performance of testing and waste management. These can be best discussed with the Safety Officer and observed at the bench. Questions related to Section 10 are only present in the General Procedures-scorecard.

Not all scorecards contain questions for each section. For example: Section 2: Management Reviews, only contains questions in the General Procedures-scorecard. In the test-specific scorecards there are no questions related to management reviews.

[3]Quality Control: the activities undertaken during the testing procedure to ensure that results are reliable (in general: positive and negative controls).
Quality Assurance: the activities undertaken before testing to ensure that results are reliable (such as trained staff, high quality materials and equipment, presence of documents such as SOPs).
External Quality Assessment: proficiency testing, blinded retesting and/or inspection visits by an external entity to assess the reliability of laboratory test results.
[4]Root Cause Analysis aims at identifying the underlying problem causing the non-conformity. Established techniques are the Ishikawa Diagram (https://en.wikipedia.org/wiki/Ishikawa_diagram) and the Five Times Why method (https://en.wikipedia.org/wiki/Five_whys).

Information on completing the General Procedures-scorecard

Part A: General Information

This section is more elaborate in the General Procedures-scorecard compared to other scorecards. As explained above, this section captures the information to provide the context against which the assessment is conducted. The assessor will fill his/her name and affiliations and the name and details of the laboratory being assessed. To answer the question "Does the TB laboratory meet minimum space and infrastructure requirements?", the assessor may refer to the GLI Mycobacteriology Laboratory Manual, chapter 4, section 4.1[5].

Part B: Technical information

In the General Procedures-scorecard two questions have been included that capture quantitative/ descriptive data:

- Question GA is intended to get an overview of the available equipment and the state of maintenance/ calibration. Assessors should note whether the equipment is in working order, the functionality of equipment regularly checked; the equipment regularly serviced by a qualified service technician and whether the equipment is regularly maintained according to the manufacturer's recommendations. If molecular methods are being used, the assessor should review the SOP to determine the requirements and list these under "other equipment". Assessors may need to review the SOP or equipment "Book of Life" to determine specifics regarding maintenance, servicing etc. for specialized molecular systems.
- Question GB is meant to provide insight into the reporting process for the different laboratory tests.

The remainder of part B in the General Procedures-scorecard consists of closed/multiple choice questions. In the General Procedures-scorecard these questions are not specific to any laboratory tests. Instead, they are related to support process of the laboratory.

In the General Procedures-scorecard, questions are included in all twelve sections. Most questions are self-explicatory. However, if additional information is needed, the below resources can be consulted.

[5]GLI Mycobacteriology Laboratory Manual:
http://www.stoptb.org/wg/gli/assets/documents/gli_mycobacteriology_lab_manual_web.pdf

Resource	Description
General information	
GLI Mycobacteriology Laboratory Manual	A comprehensive laboratory manual that standardizes key laboratory procedures.
GLI Practical Guide to TB Laboratory Strengthening	Practical guidance on implementation of WHO recommendations and international best practices for TB laboratory strengthening.
GLI Model TB Diagnostic Algorithms	This handbook provides 4 model algorithms that graphically depict the most up-to-date WHO recommendations on use of TB diagnostics. The algorithms follow the principles of the End TB Strategy to provide universal access to rapid testing for *Mycobacterium tuberculosis* complex bacteria and DST, and include the use of Xpert MTB/RIF, line probe assays for 2nd line drugs, the LF-LAM assay and the TB-LAMP test, together with conventional tools including microscopy and phenotypic culture and DST.
WHO Definitions and reporting framework for tuberculosis	WHO standardized definitions and reporting structures for TB.
General information	
WHO Laboratory Quality Management System Handbook	Handbook for understanding the structure and requirements of a laboratory QMS based on international standards.
WHO Laboratory Quality Management System training toolkit	Training materials for understanding the structure and requirements of a laboratory QMS based on international standards.
WHO Laboratory Quality Stepwise Implementation (LQSI) tool	The LQSI tool provides a roadmap for stepwise implementation of a laboratory QMS based on international standards for (public) health laboratories.
ISO 15189 Quality Management System Implementation Look Before You Leap – Best Practice Guidance Document	This guidance document is designed to provide public TB laboratories with best practices when embarking on implementing a QMS and seeking ISO 15189 accreditation.
GLI Stepwise Process Towards TB Laboratory Accreditation ('GLI tool')	This tool provides a roadmap for stepwise implementation of a laboratory QMS based on international standards for TB laboratories.
GLI Standard Operating Procedures for the TB Laboratory	Templates of SOPs for the TB laboratory.
Specimen referral and transport	
GLI Guide to TB Specimen Referral Systems and Integrated Networks	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 programme and laboratory managers, Ministry of Health officials, and other stakeholders across disease programmes. In addition to describing transport mechanisms and equipment required to move specimens in a safe manner, this guide also provides information on logistics, results reporting, data management, monitoring and evaluation, and standard operating procedures that will facilitate and improve specimen referral systems

Resource	Description
Biosafety	
GLI Laboratory Safety Handbook	The Laboratory Safety handbook is a practical guide for laboratory staff. The Handbook uses simple text and clear illustrations to assist laboratory staff in understanding the important safety issues involved in performing culture and DST. The TB Laboratory Safety handbook should be used together with the WHO Tuberculosis Laboratory Biosafety Manual.
WHO TB Laboratory Biosafety Manual	This manual provides information and explanation on biosafety requirements for the TB laboratory context.
WHO Laboratory Biosafety Manual	This manual provides information and explanation on biosafety requirements for medical laboratories.
Other	
TBfacts.org	This website is a useful resource providing information on TB in general and for TB laboratory testing specifically.
GLI resource centers: • Guidance and tools • Training packages • SOPs	Provides many additional resources for TB laboratory practice.
Challenge TB tools, guidelines and manuals	Provides many additional resources for TB laboratory practice.
WHO publications on tuberculosis	Provides many additional resources related to TB detection, diagnosis, treatment, and care.

Information on completing the Smear Microscopy Scorecard

Part A: General Information

Part A of the Smear Microscopy Scorecard is limited to adding details about this assessment (incl. name and affiliation of the assessor and the laboratory being assessed, and information about the previous assessment, if any).

Part B: Technical information

Part B starts with a table to collect information on the number of smear microscopy tests for diagnosis and follow-up performed in the last year. Data should be stratified by the number of samples received and rejected, and the number of scanty positive, positive and negative results per quarter. It is recommended to ask the laboratory to complete this table in advance and verify the information during the assessment, as there will not be sufficient time available during the assessment for completion of this table.

- Section 1: Documents & Records
  Containing questions about documentation of smear microscopy-specific procedures.
- Section 4: Client Management & Customer Service
  Containing a question related to provision of information and instructions to clients on interpretation of smear microscopy results. A question focusing on correct collection of sputum samples is included in the General Procedures-scorecard.
- Section 7: Purchasing & Inventory
  Containing a question on storage of reagents needed for microscopy.
- Section 8: Process Control
  This section is most elaborate as it investigates technical details for correct execution of smear microscopy (useful resources are provided below).
- Section 11:
  Contains a question related to smear microscopy-specific quality indicators.

Most questions are self-explicatory and assessors complying with the assessor profile described in section 3.4 should be able to answer them. Below, several useful resources are listed that provide essential (technical) information about the smear microscopy procedure.

Resource	Description
Smear microscopy procedure	
Movie on Auramine staining	Demonstration of Auramine staining.
Movie on Ziehl Neelsen staining	Demonstration of Ziehl-Neelsen staining.
Handbook: Laboratory Diagnosis of TB by Sputum Microscopy	A practical guide to assist laboratory staff in understanding the important issues involved in conducting sputum smear microscopy.
GLI Mycobacteriology Laboratory Manual	Detailed information on sample preparation and staining, and smear examination (chapters 7, 8 and 9, respectively).
UNION Training Package on Acid-Fast Direct Smear Microscopy	Online training package on direct smear microscopy.
GLI Standard Operating Procedures for the TB Laboratory	Templates of SOPs for the TB laboratory, including SOP templates for smear microscopy.
Biosafety	
GLI Laboratory Safety Handbook	Includes information on biosafety specifically for smear microscopy.
WHO TB Laboratory Biosafety Manual	Includes information on biosafety specifically for smear microscopy.
Other	
TBfacts.org	This website is a useful resource providing information on TB in general and for TB laboratory testing specifically, including smear microscopy.

Information on completing the scorecard for TB culture for detection and identification of mycobacteria

Part A: General Information

Similar to other scorecards, part A of this scorecard is limited to adding details about this assessment (incl. name and affiliation of the assessor and the laboratory being assessed, and information about the previous assessment, if any).

Part B: Technical information

Part B starts with a table to collect information on the number of solid and liquid culture tests performed in the last year, stratified by outcome. It is recommended to ask the laboratory to complete this table in advance and verify the information during the assessment, as there will not be sufficient time available during the assessment for completion of this table.

The remainder of this scorecard contains questions related to:

- Section 1: Documents & Records
  Containing questions about documentation of culture-specific procedures.
- Section 4: Client Management & Customer Service
  Containing a question related to provision of information and instructions to clients on interpretation of culture results.
- Section 7: Purchasing & Inventory
  Containing a question on storage of reagents needed for solid and liquid culture and identification tests.
- Section 8: Process Control
  This section is most elaborate and investigates technical details for correct execution of TB culture. The section is divided into the following segments: quality control, decontamination, liquid culture procedure, solid culture procedure, and MTB identification procedure.
- Section 11:
  Contains a question related to culture-specific quality indicators.

Most questions are self-explicatory and assessors complying with the assessor profile described in section 3.4 should be able to answer them. Below, several useful resources are listed that provide essential (technical) information about the TB culture procedures.

Resource	Description
Culture procedures	
GLI Mycobacteriology Laboratory Manual	Provides detailed information on liquid and solid culture procedures (chapters 10 and 11, respectively).
GLI Training Package on Culture in Solid and Liquid Media	Zipped file (311 MB) with training materials.
GLI Standard Operating Procedures for the TB Laboratory	Templates of SOPs for the TB laboratory, including SOP templates for TB culture.
TBfacts.org	Information on TB culture.
Biosafety	
GLI Laboratory Safety Handbook	Includes information on biosafety specifically for TB culture.
WHO TB Laboratory Biosafety Manual	Includes information on biosafety specifically for TB culture.

Information on completing the scorecard for Phenotypic Drug Susceptibility Testing (DST)

Part A: General Information

Similar to other scorecards, part A of this scorecard is limited to adding details about this assessment (incl. name and affiliation of the assessor and the laboratory being assessed, and information about the previous assessment, if any).

Part B: Technical information

Part B of this scorecard starts with the collection of quantitative data on the number of tests performed last year, stratified by outcome. It is recommended to ask the laboratory to complete this table in advance and verify the information during the assessment, as there will be not be sufficient time available during the assessment for completion of this table.

The remainder of this scorecard contains questions related to:

- Section 1: Documents & Records
  Containing questions about documentation of DST-specific procedures.
- Section 4: Client Management & Customer Service
  Containing one question asking about provision of information on correct interpretation of DST results to laboratory clients.
- Section 7: Purchasing & Inventory
  Containing a question on storage of antibiotics and media needed for DST.
- Section 8: Process Control
  This section is most elaborate and investigates technical details for correct execution of DST, including quality control.
- Section 11:
  Contains a question related to DST-specific quality indicators.

Most questions are self-explicatory and assessors complying with the assessor profile described in section 3.4 should be able to answer them. Below, several useful resources are listed that provide essential (technical) information about the phenotypic DST procedure.

Resource	Description
DST procedures	
WHO Technical manual for drug susceptibility testing of medicines used in the treatment of tuberculosis	This technical manual focuses on the available DST methods for both first- and second-line anti-TB agents. Culture-based phenotypic DST methods for certain anti-TB medicines are reliable and reproducible, but these methods are time-consuming, require sophisticated laboratory infrastructure, qualified staff and strict quality control. Only indirect DST procedures for anti-TB medicines are included in this document. The methods described are LJ, 7H10 and 7H11 agar and MGIT.
GLI Mycobacteriology Laboratory Manual	Provides detailed information on DST using MGIT (chapter 12).
GLI Training Package on DST by Phenotypic and Molecular Methods	Zipped file (34 MB) with training materials on DST.
TB CARE I Complete Culture and DST Package	This package (140 MB) contains standardized training materials on culture and DST techniques.
GLI Standard Operating Procedures for the TB Laboratory	Templates of SOPs for the TB laboratory, including SOP templates for TB culture and DST.
TB-CARE I Standard Operating Procedures for Culture DST and Molecular Resistance Testing	This package of files contains new SOP templates on GeneXpert, MGIT960, DST Solid and LPA.
TBfacts.org	Information on TB DST.
Biosafety	
GLI Laboratory Safety Handbook	Includes information on biosafety specifically for TB culture and DST.
WHO TB Laboratory Biosafety Manual	Includes information on biosafety specifically for TB culture and DST.

Information on completing the Xpert MTB/RIF Scorecard

Part A: General Information

Similar to other scorecards, part A of this scorecard is limited to adding details about this assessment (incl. name and affiliation of the assessor and the laboratory being assessed, and information about the previous assessment, if any).

Part B: Technical information

Part B of the Xpert MTB/RIF Scorecard (including Xpert MTB/RIF Ultra) starts with the collection of quantitative data on the number of tests performed last year, stratified by outcome. The Score TB-Package adheres to the Xpert reporting system recommended by WHO[6] and updated by GLI[7]. It is recommended to ask the laboratory to complete this table in advance and verify the information during the assessment, as there will be not be sufficient time available during the assessment for completion of this table.
An additional question is included to collect information about the GeneXpert equipment availability, functionality, and maintenance.

The remainder of this scorecard contains questions related to:

- Section 1: Documents & Records
  Containing questions about documentation of GeneXpert-specific procedures.
- Section 4: Client Management & Customer Service
  Containing one question asking about provision of information on correct interpretation of GeneXpert results to laboratory clients.
- Section 7: Purchasing & Inventory
  Containing a question on storage of GeneXpert cartridges.
- Section 8: Process Control
  Containing questions on technical aspects of GeneXpert testing, including quality control.
- Section 11:
  Contains a question related to GeneXpert-specific quality indicators.

Most questions are self-explicatory and assessors complying with the assessor profile described in section 3.4 should be able to answer them. Below, several useful resources are listed that provide essential (technical) information about GeneXpert MTB/RIF and MTB/RIF Ultra testing.

[6]WHO Definitions and Reporting Framework for Tuberculosis – 2013 revision: https://www.who.int/tb/publications/definitions/en/
[7]GLI Planning for country transition to Xpert MTB/RIF Ultra Cartridges: http://www.stoptb.org/wg/gli/assets/documents/gli_ultra.pdf

Resource	Description
GeneXpert procedure	
Movie on GeneXpert testing procedure	Training video on conducting the GeneXpert MTB/RIF test.
GLI Training Package on DST by Phenotypic and Molecular Methods	Zipped file (34 MB) with training materials on DST.
Implementing a Quality Assurance System for Xpert MTB/RIF Testing	This practical guide, and accompanying short guide, provide useful information and tools to establishing and implementing a quality assurance (QA) system for the Xpert MTB/RIF test across the diagnostic network.
GeneXpert Training Materials with Guides (2015)	This is a full training package with guides to support the use of Xpert MTB/RIF (84Mb).
Standard Operating Procedures for Culture DST and Molecular Resistance Testing	This zipped package of files (1.8 MB) contains new standard operating procedures on GeneXpert, MGIT960, DST Solid and LPA.
TBfacts.org	Information on the GeneXpert for TB testing.
TBonline.info	Information on the GeneXpert for TB testing.
Biosafety	
GLI Laboratory Safety Handbook	Includes information on biosafety specifically for GeneXpert.
WHO TB Laboratory Biosafety Manual	Includes information on biosafety specifically for GeneXpert.
Other	
GLI Planning for country transition to Xpert MTB/RIF Ultra Cartridges	This guide provides practical guidance to develop an actionable implementation plan to smoothly transition to use of Xpert MTB/RIF Ultra cartridges, ensuring uninterrupted service and avoiding cartridge wastage.

Information on completing the Loop-Mediated Isothermal Amplification (TB-LAMP) scorecard

Part A: General Information

Similar to other scorecards, part A of this scorecard is limited to adding details about this assessment (incl. name and affiliation of the assessor and the laboratory being assessed, and information about the previous assessment, if any).

Part B: Technical information

Part B of the TB-LAMP scorecard starts with the collection of quantitative data on the number of tests performed last year, stratified by outcome. It is recommended to ask the laboratory to complete this table in advance and verify the information during the assessment, as there will be not be sufficient time available during the assessment for completion of this table. An additional question is included to collect information about the TB-LAMP equipment availability, functionality, and maintenance.

The remainder of this scorecard contains questions related to:

- Section 1: Documents & Records
  Containing questions about documentation of TB-LAMP-specific procedures.
- Section 4: Client Management & Customer Service
  Containing one question asking about provision of information on correct interpretation of TB-LAMP results to laboratory clients.
- Section 7: Purchasing & Inventory
  Containing a question on storage of TB-LAMP reagents.
- Section 8: Process Control
  Containing questions on technical aspects of TB-LAMP testing, including quality control, DNA extraction and MTBC detection.
- Section 11: Occurrence/Incidence Management & Process Improvement
  Contains a question related to TB-LAMP-specific quality indicators.

Most questions are self-explicatory and assessors complying with the assessor profile described in section 3.4 should be able to answer them. Below, several useful resources are listed that provide essential (technical) information about TB-LAMP testing.

Resource	Description
TB-LAMP procedure	
Movie on TB_LAMP	This short, animated video shows the background, the most important steps as well as the advantages of the TB-LAMP.
LAMP-tutorial	Short tutorial (movie) on the LAMP principle.
WHO Factsheet on TB-LAMP	Short description of the TB-LAMP assay and WHO recommendations.
TB-LAMP flyer	Information on the TB-LAMP assay provided by its manufacturer.
GLI TB-LAMP information note	GLI Practical consideration on the implementation of TB-LAMP.
Other	
WHO Policy guidance on TB-LAMP	Policy guidance on the use of TB-LAMP for the diagnosis of pulmonary TB.

Information on completing the Lateral Flow Urine Lipoarabinomannan Assay (LF-LAM) scorecard

Part A: General Information

Similar to other scorecards, part A of this scorecard is limited to adding details about this assessment (incl. name and affiliation of the assessor and the laboratory being assessed, and information about the previous assessment, if any).

Part B: Technical information

Part B of the LF-LAM scorecard starts with the collection of quantitative data on the number of tests performed last year, stratified by outcome. It is recommended to ask the laboratory to complete this table in advance and verify the information during the assessment, as there will be not be sufficient time available during the assessment for completion of this table.

The remainder of this scorecard contains questions related to:

- Section 1: Documents & Records
  Containing questions about documentation of LF-LAM-specific procedures.
- Section 4: Client Management & Customer Service
  Containing one question asking about provision of information on correct interpretation of LF-LAM results to laboratory clients.
- Section 7: Purchasing & Inventory
  Containing a question on storage of LF-LAM tests.
- Section 8: Process Control
  Containing questions on technical aspects of LF-LAM testing, including quality control.
- Section 11: Occurrence/Incidence Management & Process Improvement
  Contains a question related to LF-LAM-specific quality indicators.

Most questions are self-explicatory and assessors complying with the assessor profile described in section 3.4 should be able to answer them. Below, several useful resources are listed that provide essential (technical) information about LF-LAM testing.

Resource	Description
LF-LAM procedure	
Movie on LF-LAM	A short movie on how to do the Fujifilm SILVAMP TB LAM test.
GLI LF-LAM information note	GLI Practical information on the LF-LAM test.
Other	
WHO Policy update on LF-LAM	Background, justification and objectives for the revision of WHO policy on LF-LAM.

Information on completing the Line Probe Assay (LPA) scorecard

Part A: General Information

Similar to other scorecards, part A of this scorecard is limited to adding details about this assessment (incl. name and affiliation of the assessor and the laboratory being assessed, and information about the previous assessment, if any).

Part B: Technical information

Part B of the LPA scorecard starts with the collection of quantitative data on the number of tests (categorized by MTBDRplus and MTBDRsl, and CM) performed last year, stratified by outcome. It is recommended to ask the laboratory to complete this table in advance and verify the information during the assessment, as there will be not be sufficient time available during the assessment for completion of this table. An additional question is included to collect information about the LPA equipment availability, functionality, and maintenance.

The remainder of this scorecard contains questions related to:

- Section 1: Documents & Records
  Containing questions about documentation of LPA-specific procedures.
- Section 4: Client Management & Customer Service
  Containing one question asking about provision of information on correct interpretation of LPA results to laboratory clients.
- Section 7: Purchasing & Inventory
  Containing a question on storage of LPA test reagents.
- Section 8: Process Control
  Containing questions on technical aspects of LPA testing, including quality control, extraction, amplification and detection.
- Section 11: Occurrence/Incidence Management & Process Improvement
  Contains a question related to LPA-specific quality indicators

Most questions are self-explicatory and assessors complying with the assessor profile described in section 3.4 should be able to answer them. Below, several useful resources are listed that provide essential (technical) information about LPA testing.

Resource	Description
LPA procedure	
Movie on LPA	Demonstration of LPA (direct detection of MTB and resistance to isoniazid and rifampicin) in sputum.
GLI guide on LPA interpretation and reporting	Interpretation and reporting guide for laboratory staff and clinicians.
TBfacts.org	Information on the LPA for TB testing.
Standard Operating Procedures for Culture DST and Molecular Resistance Testing	This zipped package of files (1.8 MB) contains new SOPs on GeneXpert, MGIT960, DST Solid and LPA.
GLI Training Package on DST by Phenotypic and Molecular Methods	Zipped file (34 MB) with training materials on DST.
Other	
GLI Laboratory Safety Handbook	Includes information on biosafety specifically for LPA.
Other	
WHO Policy update on LPA	Policy update on the use of molecular line probe assays for the detection of resistance to isoniazid and rifampicin.
WHO Policy update on LPA for second line anti-TB drugs	Policy update on the use of molecular line probe assays for the detection of resistance to second line anti-TB drugs.

Information on completing the Truenat scorecard

Part A: General Information

Similar to other scorecards, part A of this scorecard is limited to adding details about this assessment (incl. name and affiliation of the assessor and the laboratory being assessed, and information about the previous assessment, if any).

Part B: Technical information

Part B of the Truenat scorecard starts with the collection of quantitative data on the number of tests performed last year, stratified by outcome. It is recommended to ask the laboratory to complete this table in advance and verify the information during the assessment, as there will be not be sufficient time available during the assessment for completion of this table. An additional question is included to collect information about the Truenat equipment availability, functionality, and maintenance.

The remainder of this scorecard contains questions related to:

- Section 1: Documents & Records
  Containing questions about documentation of Truenat-specific procedures.
- Section 4: Client Management & Customer Service
  Containing one question asking about provision of information on correct interpretation of Truenat results to laboratory clients.
- Section 7: Purchasing & Inventory
  Containing a question on storage of Truenat reagents.
- Section 8: Process Control
  Containing questions on technical aspects of Truenat testing, including quality control.
- Section 11: Occurrence/Incidence Management & Process Improvement
  Contains a question related to Truenat-specific quality indicators.

Most questions are self-explicatory and assessors complying with the assessor profile described in section 3.4 should be able to answer them. Below, several useful resources are listed that provide essential (technical) information about Truenat testing.

Resource	Description
Truenat procedure	
Announcement of WHO ensorsement of the Truenat assay	Announcement that WHO has endorsed the Truenat assay for initial diagnosis of TB and detection of rifampicin resistance.
WHO Rapid Communication: Molecular assays as initial tests for the diagnosis of tuberculosis and rifampicin resistance	This document aims to inform national TB programmes and other stakeholders about the key implications of the latest evidence on the use of specific molecular assays, including Truenat, as initial diagnostic tests of pulmonary and extrapulmonary TB and RR-TB, in adults and children.
StopTB Partnership Practical considerations for implementation of Truenat	Provides practical considerations for implementation of Truenat, including the test procedure and operational considerations.
TBfacts.org	Information on the Truenat assay for TB testing.

3.5 Reporting the assessment

During the assessment:

1. Fill in the General Procedures-scorecard and the test-specific scorecards for all TB tests performed in the laboratory. Do this either using the paper-based version or insert answers and findings directly into the e-tool (except when observing TB testing in the BSL 3 facility where the use of electronic devices should be avoided for safety reasons, see section 3.4.1).
2. Optional: fill in the SLIPTA checklist

At the end of the assessment, the assessor must:

3. Transcribe all scores from the paper-based versions into the e-tool (if applicable).
4. The e-tool will automatically calculate the score and the number of stars for each of the TB Lab Quality Scorecards (see "TB summary report" worksheet).
   If the SLIPTA checklist has also been completed the e-tool will automatically calculate the SLIPTA score, incorporating the scores on the TB Lab Quality Scorecards.
   NOTE: Calculating the score by hand is extremely complex due to the possibility of not applicable-answers that influence the total number of points that can be scored (see section 3.3.2). Calculating the score by hand is thus prone to errors. We therefore strongly recommend using the e-tool to calculate the score. Another advantage of using the e-tool is that it directly visualizes the scoring and the progress since the previous assessment, if applicable.
5. Identify recommendations for improvement (for questions with "No" and "Partial" answers), and report these to the laboratory during the meeting with the laboratory management (point 6) and in the final report (point 7).
6. Where possible, the assessor should support their findings with tools and guidance materials as referred in section 3.3.3 to help the laboratory address the areas for improvement. Assessors are responsible for ensuring that the resources supplied to the laboratory are most current.
   Meet with the laboratory staff and management and communicate the overall findings of the assessment. The assessor should use the format suggested in the SLIPTA checklist (Summary). i.e. report noted commendations, noted challenges and recommendations. Where possible, the assessor should support the commendations & challenges with examples from the assessment. The assessor can also present the number of stars scored on the TB Lab Quality Scorecards and the SLIPTA checklist, if applicable (see point 4).

After the assessment:

7. Within two weeks after the assessment, the assessor must submit a final report to the laboratory. The report should include a copy of the completed TB Lab Quality Scorecards (and SLIPTA checklist if applicable) as well as the observed challenges and recommendations.

The list of recommendations for improvement should be communicated in the form of nonconformities and must be graded as major or minor:

- Major nonconformities are those non-conformities that directly influence the quality of the work performed and therefore require urgent action.
- Minor nonconformities are those that may indirectly compromise quality of the work performed and should be addressed after major nonconformities have been resolved.

Further to this it is advisable to prioritize the recommendations to assist the laboratory with implementing/improving its QMS in a logical and rational way.

The laboratory is responsible for addressing the nonconformities through its own corrective action system. Support to the laboratory to address nonconformities is beyond the scope of the assessment but can be provided in the form of a mentor program.

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