No. 1

Tuberculosis Technical Scorecard

General Procedures

Version 2.0 – 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

Score

Section	Sum of maximum points[1]	Current audit		Previous audit	
		Date:		Date:	
		Current audit score		Previous audit score	
1. Documents and Records			%		%
2. Management Reviews			%		%
3. Organization and Personnel			%		%
4. Client Management and Customer Service			%		%
5. Equipment			%		%
6. Evaluation and Audits			%		%
7. Purchasing and Inventory			%		%
8. Process Control and Internal and External Quality Assessment			%		%
9. Information Management			%		%
10. Corrective Action			%		%
11. Occurrence Management and Process Improvement			%		%
12. Facilities and Safety			%		%
General Procedure Scorecard Total			**%**		**%**

[1]Total number of points of all questions minus points for questions answered with NA.

A. General Information

Name of assessor(s)		
Title & organization of assessor		
Name of laboratory being assessed		
Type of laboratory	☐ National ☐ Reference ☐ Provincial / County ☐ District / Sub-district ☐ Zonal/ peripheral ☐ Field ☐ Other (specify) _____	☐ Public ☐ Private ☐ Academic ☐ NGO ☐ Other (specify) _____
Details of contact person at laboratory		
Name		
Position		
Qualification		
Email		
Phone		
Does the TB laboratory meet minimum space and infrastructure requirements?[2]		
How many hospitals and/or other health care facilities does the laboratory serve?		
Location of laboratory being assessed (City/Town, County / District / Sub-district and Country)		
Is there a clinical microbiologist and / or pathologist with experience in microbiology on staff?	Y/N	
If "Y", how many years' experience do they have?		
If "N", what is the highest qualified member of the laboratory staff?		
Is the laboratory accredited?	Y/N	
Name of accrediting body?		
What tests is the laboratory accredited for?		

[2]In addition to the GLI Laboratory Safety Handbook, refer to national/local regulations, if any.

B. Technical Information

GA. Is the following equipment available, and if so, is it functional, monitored, serviced and maintained? Answer each question with yes, no or not applicable (Y or N or NA)

	Available	Functional[3]	Monitored[4]	Serviced[5]	Maintained[6]
Bright field microscope					
Fluorescence microscope					
Thermometers					
Incubator (Aerobic)					
Incubator (CO_2)					
Refrigerator (2-8°C)					
Centrifuge					
Vortex					
Shaker					
Hot air oven					
Inspissator					
Water bath					
pH meter					
Magnetic stirrer					
Freezer (-20 - -80°C)					
Balance / scale					
Autoclave					
Incinerator					
Micropipette (0.02 ml 0.1 ml, 1 ml)					
Biosafety Cabinet Class I					
Biosafety Cabinet Class II					
Other equipment (Please specify) _____					
Auxiliary/emergency power system or standby generator					
Access to sink with running water					

[3]Is the equipment in working order?
[4]Is the functionality of equipment regularly checked (e.g. temperature / calibrated)?
[5]Is the equipment regularly serviced or calibrated by a qualified service technician?
[6]Is the equipment regularly maintained according to the manufacturer's recommendations (e.g. cleaning)?

GB. How does the laboratory report results?

	Manual, paper-based	Electronic, commercial LIS	Electronic, in-house LIS	(Smart)phone	E-mail
Smear Microscopy					
TB Culture					
DST					
Xpert MTB/RIF					
TB-LAMP					
LF-LAM					
LPA					
Truenat					

Section 1: Documents & Records

The following section of the checklist is the same for all TB technical checklists. Complete this section only once if evaluating multiple TB tests during one assessment. The score for this section will apply to all methods being evaluated.

All generic requirements apply, see SLIPTA Section 1. In addition, assessors should review the following:

SLIPTA			NA	Y	P	N	Comments	Score
1.5	G1.1	Are the following processes documented?						
		1. Rejection criteria specific for TB samples and tests						
		2. A policy for reporting critical TB test results						
		3. Instructions for referral of samples						
		4. Instructions for extra-pulmonary sample criteria for collection and testing						3
		5. Instructions for handling samples received after hours						
		6. Realistic turnaround time for TB tests[7]						
		7. Definition of result categories (rare / unexpected/discordant results)[8]						
		8. Confirmatory tests for unusual, discordant or unexpected TB results						
Section 1: Documents & Records Subtotal								**3**

[7]From sample collection to reporting.
[8]Look if there is something in the lab documents that explains what for example a rare DST pattern is that needs to be repeated etc.

Section 2: Management Reviews

The following section of the checklist is the same for all TB technical checklists. Complete this section only once if evaluating multiple TB tests during one assessment. The score for this section will apply to all methods being evaluated.

All generic requirements apply, see SLIPTA Section 2. In addition, assessors should review the following:

SLIPTA			NA	Y	P	N	Comments	Score
2.2	G2.1	Does the laboratory report findings / trends and other related important information to NTRL / NTP regarding:						2
		Test quality indicators						
		Sample rejection rates						
		Other clinically relevant changes in the laboratory such as changes to testing information, PT results, and equipment downtime?						
2.2	G2.2	Does the laboratory report cumulative test quality indicators to NTRL / NTP at least annually?						2
Section 2: Management Reviews Subtotal								**4**

Section 3: Organization & Personnel

The following section of the checklist is the same for all TB technical checklists. Complete this section only once if evaluating multiple TB tests during one assessment. The score for this section will apply to all methods being evaluated.

All generic requirements apply, see SLIPTA Section 3. In addition, assessors should review the following:

SLIPTA			NA	Y	P	N	Comments	Score
3.6	G3.1	Is there evidence that laboratory staff have been trained on the following[9]:						
		1. Sample collection and transport						
		2. Sample accession and registration						
		3. Processing of pulmonary samples and conducting TB testing						
		4. Processing of extra-pulmonary samples and conducting TB testing						3
		5. Interpretation of TB test results						
		6. Recording & reporting of TB test results						
		7. QC, EQA & PT for TB tests						
		8. Laboratory safety related to TB testing						

[9]Review training records, competency assessment forms and duty rosters. Pay attention to date of training and scope of training compared with techniques being performed.

SLIPTA			NA	Y	P	N	Comments	Score
3.7	G3.2	Is there evidence that laboratory staff are following the procedures described in the laboratory documentation[10]:						3
		1. Sample collection and transport						
		2. Sample accession and registration						
		3. Processing of pulmonary samples and conducting TB testing						
		4. Processing of extra-pulmonary samples and conducting TB testing						
		5. Interpretation of TB test results						
		6. Reporting of TB test results						
		7. QC, EQA & PT for TB tests						
		8. Laboratory safety related to TB testing						
Section 3: Organization & Personnel Subtotal								**6**

[10]Directly observe procedures being performed compared to the SOP. See Section 8.

Section 4: Client Management & Customer Service

The following section of the checklist is the same for all TB technical checklists. Complete this section only once if evaluating multiple TB tests during one assessment. The score for this section will apply to all methods being evaluated.

All generic requirements apply, see SLIPTA Section 4. In addition, assessors should review the following:

SLIPTA			NA	Y	P	N	Comments	Score
4.1	G4.1	Is there evidence that the laboratory has provided clients information / instructions on sample collection, storage and transportation to the laboratory?						3
		Is there evidence that laboratory enforces the criteria for sample volume, container type and storage conditions?						
4.3	G4.2	Does the laboratory provide feedback to clinicians regarding?						2
		1. Sample quality & rejection rates						
		2. Appropriateness of test requisition						
		3. Identity & frequency of isolated or identified MTB and NTMs						
		4. DST including MDR / XDR-TB						
Section 4: Client Management & Customer Service Subtotal								**5**

Section 5: Equipment

The following section of the checklist is the same for all TB technical checklists. Complete this section only once if evaluating multiple TB tests during one assessment. The score for this section will apply to all methods being evaluated.

All generic requirements apply, see SLIPTA Section 5. In addition, assessors should review the following:

SLIPTA			NA	Y	P	N	Comments	Score
5.3	G5.1	Does the laboratory use verified / validated methods for MTB detection and DST[11]?						5
5.1	G5.2	Is all equipment installed and placed correctly in a suitable environment?						2
5.11	G5.3	Does the laboratory maintain all equipment for TB testing (See GA)?						3
Section 5: Equipment Subtotal								**10**

[11]Includes all conventional, automated and molecular (commercial & non-commercial) methods.

Section 6: Evaluation and Audits

The following section of the checklist is the same for all TB technical checklists. Complete this section only once if evaluating multiple TB tests during one assessment. The score for this section will apply to all methods being evaluated.

All generic requirements apply, see SLIPTA Section 6. In addition, assessors should review the following:

SLIPTA			NA	Y	P	N	Comments	Score
6.1/ 1.5	G6.1	Evaluations and audits[12]:						
		Does the laboratory regularly conduct internal audits including the TB laboratory?						
		Are external audits regularly conducted including the TB section?						5
		Are audit recommendations and action plans followed up within the timeframe defined by the laboratory?						
Section 6: Evaluation and Audits Subtotal								**5**

[12]It is recommended that internal audits be conducted at least annually. External audits are conducted less frequently–assessors should use the recommendation of local accrediting bodies to determine the frequency of external audits.

Section 7: Purchasing & Inventory

The following section of the checklist is the same for all TB technical checklists. Complete this section only once if evaluating multiple TB tests during one assessment. The score for this section will apply to all methods being evaluated.

All generic requirements apply, see SLIPTA Section 7. In addition, assessors should review the following:

SLIPTA			NA	Y	P	N	Comments	Score
7.2	G7.1	Has the laboratory formulated specifications for supplies and consumables and are they followed during the procurement process?						2
7.8	G7.2	Are storage areas for reagents and supplies set up, maintained and monitored according to manufacturer's requirements[13]?						2
Section 7: Purchasing & Inventory Subtotal								**4**

[13]Ensure all supplies/reagents have not expired.

Section 8: Process Control

The following section of the checklist is the same for all TB technical checklists. Complete this section only once if evaluating multiple TB tests during one assessment. The score for this section will apply to all methods being evaluated.

All generic requirements apply, see SLIPTA Section 8. In addition, assessors should review the following:

SLIPTA			NA	Y	P	N	Comments	Score
8.2 & 8.3	G8.1	Does the laboratory request form require the date and time of sample collection to be recorded?						3
	G8.2	Does the laboratory request form have space for the diagnosis / reason for testing?						2
8.10	G8.3	Does the laboratory determine the cause of failed QC (root cause analysis) for all TB tests, perform corrective actions and measure the effectiveness thereof?						2
	G8.4	Does the laboratory refrain from reporting in case of failed QC?						2
8.14	G8.5	Is the laboratory enrolled in an interlaboratory comparison, (blinded) rechecking or PT program for all TB tests evaluated?						5
		Did the laboratory pass the last 3 rounds of interlaboratory comparison or PT program testing?						
		Does the laboratory receive onsite supervision visits as part of the National EQA program for TB testing?						
Section 8: Process Control Subtotal								**14**

Section 9: Information Management

The following section of the checklist is the same for all TB technical checklists. Complete this section only once if evaluating multiple TB tests during one assessment. The score for this section will apply to all methods being evaluated.

All generic requirements apply, see SLIPTA Section 9. In addition, assessors should review the following:

SLIPTA			NA	Y	P	N	Comments	Score
9.3	G9.1	Does the laboratory report TB test results on an NTP approved TB report form?						3
		Are all results recorded correctly from the instruments and laboratory register to the report form?						
		Are all positive results and DST resistance results reported to NTP / NTRL?						
Section 9: Information Management Subtotal								**3**

Section 10: Identification of Non-conformities, Corrective and Preventive Actions

The following section of the checklist is the same for all TB technical checklists. Complete this section only once if evaluating multiple TB tests during one assessment. The score for this section will apply to all methods being evaluated.

All generic requirements apply, see SLIPTA Section 10.

SLIPTA			NA	Y	P	N	Comments	Score
10.1	G10.1	Are all nonconforming activities identified and documented adequately?						5
10.2	G10.2	Is root cause analysis performed and corrective action implemented for all non-conforming work?						3
Section 10: Identification of Non-conformities, Corrective and Preventive Actions Subtotal								**8**

Section 11: Occurrence/Incident Management & Process Improvement

The following section of the checklist is the same for all TB technical checklists. Complete this section only once if evaluating multiple TB tests during one assessment. The score for this section will apply to all methods being evaluated.

All generic requirements apply, see SLIPTA Section 11. In addition, assessors should review the following:

SLIPTA			NA	Y	P	N	Comments	Score
11.4 / 11.5	G11.1	Is the following performance indicator collected: - Number of samples for TB testing rejected (disaggregated by type of test and origin)						2
11.4 / 11.5	G11.2	Are aggregate reports shared periodically with clinicians / NTP / NTRL (as applicable)[14]?						2
11.4 / 11.5	G11.3	Do reports for clinicians / NTP / NTRL (as applicable) include at a minimum the number of samples, isolated or identified organisms and DST patterns?						2
Section 11: Occurrence/Incident Management & Process Improvement Subtotal								**6**

[14]Assessors should review the guidance documents of the relevant authorities such as MoH, NTP and/or surveillance committees to determine the frequency that the laboratory should share their reports. If no recommendations exist, this should be at least quarterly.

Section 12: Facilities and Biosafety

The following section of the checklist is the same for all TB technical checklists. Complete this section only once if evaluating multiple TB tests during one assessment. The score for this section will apply to all methods being evaluated.

All generic requirements apply, see SLIPTA Section 12. In addition, assessors should review the following:

SLIPTA			NA	Y	P	N	Comments	Score
12.16	G12.1	Are the following PPE items used when processing sputum and extra-pulmonary samples?						2
		Gloves						
		Laboratory coat or gown						
		N95 respirator						
12.4	G12.2	Does the laboratory handle waste appropriately including disposal of media and infectious materials generated during testing?						2
		Are suitable disinfectants available for use when processing samples, are they freshly prepared, and is there evidence of their use[15]?						
12.8	G12.3	Is a biological safety cabinet (BSC) or hood available, functional, maintained and serviced for handling specimens or organisms considered to be highly contagious by air borne routes?						2
Section 12: Facilities and Biosafety Subtotal								**6**

[15]Clinical Microbiology Reviews, Jan. 1999, p. 147–179