No. 3

Tuberculosis Technical Scorecard

TB Culture for Detection and Identification of Mycobacteria

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	Total General Procedures	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				%		%
TB Culture Total				**%**		**%**
TB Culture Stars[2]						

[1]Total number of points of all questions minus points for questions answered with NA.
[2]No Stars < 55%
1 Star 55% - 64%
2 Stars 65% - 74%
3 Stars 75% - 84%
4 Stars 85% - 94%
5 Stars ≥95%

A. General Information

Name of assessor(s)			
Title & organization of assessor			
Name of laboratory being assessed			
Date type and score of last assessment?	**Date**	**Type**	**Score**
Internal			
External			
Did the last assessment include assessment of TB Culture?	Y / N		

B. Technical Information

CA. How many tests performed last year?

	Q1	Q2	Q3	Q4	Total
Number of samples rejected					
Solid Culture					
Positive MTB					
Positive NTM					
Negative					
Contaminated					
Mix culture (NTM & TB)					
Sub-Total					
Liquid Culture					
Positive MTB					
Positive NTM					
Negative					
Contaminated					
Sub-Total					
Total					

MTB = Mycobacterium tuberculosis Complex
NTM = Non-tuberculosis mycobacteria
Q = Quarter

Section 1: Documents & Records

All generic requirements apply, see SLIPTA Section 1. In addition to the General Procedures (Section 1), assessors should review the following:

SLIPTA			NA	Y	P	N	Comments	Score
1.5	C1.1	Does the laboratory have documentation covering the following processes?						
		1. Preparation of media for solid culture and or QC on solid & liquid media						
		2. Sample collection and transport						
		3. Processing of pulmonary samples and conducting TB culture including decontamination and inoculation of media						
		4. Processing of extra-pulmonary samples and conducting TB culture including decontamination and inoculation of media						3
		5. Identification of MTB from positive cultures						
		6. Recording & reporting TB culture and MTB identification test results						
		7. Quality control procedures for TB culture						
		8. Interlaboratory comparison, retesting or proficiency testing (PT) for all TB tests						
		9. Laboratory safety related to TB testing						
1.5	C1.2	Are the documents complete, in-date and witnessed by all staff performing TB culture and identification of MTB[3]?						2
Section 1: Documents & Records Subtotal								**5**

[3]See ISO15189:2012 Clause 5.5.3 for minimum requirements for a technical Standard Operating Procedure (SOP).

Section 2: Management Reviews

All generic requirements apply, see SLIPTA Section 2. In addition, assessors should review the General Procedures (Section 2).

Section 3: Organization & Personnel

All generic requirements apply, see SLIPTA Section 3. In addition, assessors should review the General Procedures (Section 3).

Section 4: Client Management & Customer Service

All generic requirements apply, see SLIPTA Section 4. In addition, assessors should review the General Procedures (Section 4).

SLIPTA			NA	Y	P	N	Comments	Score
4.1	C4.1	Is there evidence that the laboratory has provided clients information / instructions on interpretation of culture test results?						2
Section 4: Client Management & Customer Service Subtotal								**2**

Section 5: Equipment

All generic requirements apply, see SLIPTA Section 5. In addition, assessors should review the General Procedures (Section 5).

Section 6: Evaluation and Audits

All generic requirements apply, see SLIPTA Section 6. In addition, assessors should review the General Procedures (Section 6).

Section 7: Purchasing & Inventory

All generic requirements apply, see SLIPTA Section 7. In addition to the General Procedures (Section 7), assessors should review the following:

SLIPTA			NA	Y	P	N	Comments	Score
7.10	C7.1	Are all media and consumables for TB culture and MTB identification testing stored at the correct temperature and in date[4]?						2
		- Liquid media						
		- Solid media						
		- MTB identification tests						
Section 7: Purchasing & Inventory Subtotal								**2**

[4]According to manufacturer's requirements.

Section 8: Process Control

All generic requirements apply, see SLIPTA Section 8. In addition to the General Procedures (Section 8), assessors should review the following:

SLIPTA			NA	Y	P	N	Comments	Score
Quality Control								
8.8	C8.1	Does the laboratory perform QC testing on all media before use[5]?						3
		Do QC records for liquid culture media demonstrate their ability to support growth of MTB?						
		Do QC records for solid culture media demonstrate their ability to support growth of MTB?						
		Do QC records for solid culture media demonstrate their sterility?						
		Do QC records for decontamination reagents demonstrate that they are sterile?						
		Do QC records for MTB identification tests indicate their ability to identify MTB from NTM?						
8.10	C8.2	Does the laboratory:						3
		1. Perform sterility and performance tests for every batch of culture media using certified reference strains as controls?						
		2. Are reference strains (MTB H37Rv) sourced from an authorized supplier?						
		3. Are the reference strains stored, cultured and sub-cultured in accordance with the appropriate guidelines?						
8.10	C8.3	Does laboratory record all samples in batches along with controls on a processing worksheet?						2

[5]This includes in-house made or purchased from commercial sources.

SLIPTA			NA	Y	P	N	Comments	Score
TB Culture Procedure – Decontamination								
8.10	C8.4	Is TB culture performed in batches corresponding to the number of centrifuge buckets possible?						5
		Is the correct concentration of decontamination solution used?						
		Is the volume of the specimen checked and equal volume of digestion-decontamination reagent added and thoroughly mixed?						
		Are the decontamination-digestion mixtures incubated at room temperature (20°C to 25°C) for 15 minutes?						
		Is buffer added to fill the tube?						
		Are measures in place to ensure that the buffer is not contaminated with sample material?						
		Are the samples centrifuged at a Relative Centrifugal Force (RCF) of 3000g for 15–20 minutes?						
		Are centrifuge buckets opened in the biological safety cabinet (BSC) after allowing aerosols to settle?						
		Is the supernatant decanted into a flask with tuberculocidal disinfectant?						
		Is the correct buffer solution used?						
		Are the samples re-suspended in the recommended volume of buffer?						
		During processing, is only one specimen tube open at a time?						

SLIPTA			NA	Y	P	N	Comments	Score
TB Culture Procedure – Decontamination								
8.10	C8.4	Is a fresh pipette used at every step to avoid transfer of bacilli from one specimen to the other?						5
		Are the transfers between tubes done without tubes touching each other to avoid cross-contamination?						
		Is aerosol production minimized by avoiding splashes and squirting from pipettes?						
		Are materials discarded in accordance with local biosafety recommendations?						
Liquid Culture Procedure								
8.10	C8.5	Is MGIT tube loading / unloading performed according to the SOP?						5
		Is smear made from remaining pellet and results used in result interpretation?						
		Is the remaining sample stored appropriately for potential inoculation if contamination is detected?						
		Are MGIT tubes incubated for 42 days before being reported as negative?						
		Is a ZN smear prepared from MGIT positive tubes prior to speciation?						
		Is the MGIT tube re-incubated if the culture is instrument positive, ZN microscopy negative?						
		Are materials discarded in accordance with local biosafety recommendations?						

SLIPTA			NA	Y	P	N	Comments	Score
Solid Culture Procedure								
8.10	C8.6	Is a disposable pipette used to inoculate each slant with 3–4 drops ensuring that the entire surface of the slant is inoculated?						5
		Is a smear made from the remaining pellet and results used in result interpretation?						
		Is the remaining sample stored appropriately for potential re-testing if contamination is detected?						
		Is solid media initially incubated for up to one week in a slanted position such that the surface of the solid media is horizontal and facing upwards?						
		Are LJ caps tightened after one day drying time?						
		Are slants checked at least weekly for early signs of MTB growth / contamination?						
		Is solid media incubated for 56 days before being reported as negative?						
		Are materials discarded in accordance with local biosafety recommendations?						
Mtb Identification Procedure								
8.10	C8.7	Is MTB identification performed according to the SOP or manufacturer's instructions?						5
		Are materials discarded in accordance with local biosafety recommendations?						
Section 8: Process Control Subtotal								**28**

Section 9: Information Management

All generic requirements apply, see SLIPTA Section 9. In addition, assessors should review the General Procedures (Section 9).

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

All generic requirements apply, see SLIPTA Section 10. In addition, assessors should review the General Procedures (Section 10).

Section 11: Occurrence/Incident Management & Process Improvement

All generic requirements apply, see SLIPTA Section 11. In addition to the General Procedures (Section 11), assessors should review the following:

SLIPTA			NA	Y	P	N	Comments	Score
11.4 / 11.5	C11.1	Are the following performance indicators collected?						
		1. Number of TB cultures performed (disaggregated by type)?						
		2. Number and proportion of positive, negative and contaminated / mixed TB cultures (disaggregated by type)?						5
		3. Number and proportion of MTB and NTM isolated (disaggregated by type)?						
		4. Number and proportion of MTB and NTM isolated (disaggregated by patient group)?						
		5. Liquid and/or solid culture TAT[6]						
Section 11: Occurrence/Incident Management & Process Improvement Subtotal								**5**

Section 12: Facilities and Biosafety

All generic requirements apply, see SLIPTA Section 12. In addition, assessors should review the General Procedures (Section 12).

[6]From sample collection to reporting.