No. 8

Tuberculosis Technical Scorecard

Line Probe Assay (LPA)[1]

Version 2.0 – July 2020

[1]Includes MTBDRplus and MTBDRsl & CM [for speciation]

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[2]	Total General Procedures	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				%		%
LPA Total				**%**		**%**
LPA Stars[3]						

[2]Total number of points of all questions minus points for questions answered with NA.
[3]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 LPA?	Y / N		

B. Technical Information

PA. How many tests performed last year?

LPA (MTBDRplus & MTBDRsl)	Q1	Q2	Q3	Q4	Total
Isoniazid					
Resistant					
Susceptible					
Total:					
Rifampicin					
Resistant					
Susceptible					
Total:					
Ethambutol					
Resistant					
Susceptible					
Total:					
Injectables					
Resistant					
Susceptible					
Total:					
Quinolones					
Resistant					
Susceptible					
Total:					

Q = Quarter

PA. How many tests performed last year?

LPA (CM)	Q1	Q2	Q3	Q4	Total
Total:					

Q = Quarter

PC. Is the following equipment available, and if so, is it functional, monitored, serviced and maintained?

	Available	Functional[4]	Monitored[5]	Serviced[6]	Maintained[7]
GT-Blot	Y / N				
Thermocycler	Y / N				

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

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	P1.1	Does the laboratory have documentation covering the following processes?						
		1. Processing of LPA samples						
		2. Recording & reporting LPA results						
		3. Quality control procedures for LPA						3
		4. Interlaboratory comparison or proficiency testing (PT) for LPA						
		5. Laboratory safety required for LPA from positive culture						
1.5	P1.2	Are the documents complete, in-date and witnessed by all staff performing LPA[8]?						2
Section 1: Documents & Records Subtotal								**5**

Section 2: Management Reviews

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

Section 3: Organization & Personnel

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

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

Section 4: Client Management & Customer Service

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

SLIPTA			NA	Y	P	N	Comments	Score
4.1	P4.1	Is there evidence that the laboratory has provided clients information / instructions on interpretation of LPA test results?						2
Section 4: Client Management & Customer Service Subtotal								**2**

Section 5: Equipment

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

Section 6: Evaluation and Audits

All generic requirements apply, see SLIPTA Section 6. 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	P7.1	Are all media and consumables for LPA testing stored at the correct conditions[9], temperature and in date[10]?						2
		1. LPA test reagents						
Section 7: Purchasing & Inventory Subtotal								**2**

[9]LPA light sensitive reagents should be stored in the dark.
[10]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								
8.9	P8.1	Do QC records for LPA demonstrate the ability to detect MTB mutations?						2
	P8.2	Does the laboratory determine the cause of failed QC (root cause analysis) for LPA, perform corrective actions and measure the effectiveness thereof?						2
	P8.3	Does laboratory record all samples in a batch along with controls on a processing worksheet?						2

SLIPTA			NA	Y	P	N	Comments	Score
LPA Procedure								
Decontamination procedure from direct sputum								
Refer to TECHNICAL SCORECARD: TB culture for detection and identification of mycobacteria								
Extraction Method								
8.10	P8.4	Are samples used correctly collected, stored and received in timely fashion for testing according to SOPs?						
		Are cultures checked for contamination before use?						
		Is a positive and negative extraction control included with each batch?						
		Is the appropriate volume of liquid culture and/ or solid isolates and/ or decontaminated sample material used for extraction?						
		Are filter tips used to avoid cross contamination?						5
		Is heater block/water bath set to correct temperature for extraction?						
		Are correct incubation times observed used for each step of the extraction?[11]						
		Are correct centrifuge speeds used for each step of the extraction?						
		Is DNA reconstituted in correct volume of buffer?						
		Is extracted DNA stored in case retesting is required?						

[11]GenoLyse® kit for extraction of bacterial DNA – Instructions for Use, Hain Lifescience, 10/2011.

SLIPTA			NA	Y	P	N	Comments	Score
Amplification and Detection DST								
8.10	P8.5	Are samples used correctly collected, stored and received in timely fashion for testing according to SOPs?						5
		Are cultures checked for contamination before use?						
		Is a positive and negative extraction control included with each batch?						
		Is the appropriate volume of liquid culture and/ or solid isolates and/ or decontaminated sample material used for extraction?						
		Are filter tips used to avoid cross contamination?						
		Is heater block/water bath set to correct temperature for extraction?						
		Are correct incubation times observed used for each step of the extraction?[11]						
		Are correct centrifuge speeds used for each step of the extraction?						
		Is DNA reconstituted in correct volume of buffer?						
Section 8: Process Control Subtotal								**16**

Section 9: Information Management

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

SLIPTA			NA	Y	P	N	Comments	Score
11.4 / 11.5	P11.1	Are the following performance indicators collected?						5
		1. Number of LPA tests performed						
		2. Number of invalid results						
		3. Number NTM identified by disaggregated by type if available						
		4. Number and proportion of drug resistance performed by LPA (disaggregated by mutation / drug)						
		5. Number and type of discordant results						
		6. Average LPA test TAT[12]						
Section 11: Occurrence/Incident Management & Process Improvement Subtotal								**5**

Section 12: Facilities and Biosafety

All generic requirements apply, see SLIPTA Section 10. Assessors should review the General Procedures (Section 12).

[12]From sample collection to reporting.