No. 7

Tuberculosis Technical Scorecard

Loop-Mediated Isothermal Amplification (TB-LAMP)

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]	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				%		%
TB-LAMP Total				**%**		**%**
TB-LAMP 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-LAMP?	Y / N		

B. Technical Information

TA. How many tests performed last year?

TB-LAMP	Q1	Q2	Q3	Q4	Total
Number of samples received					
Number of samples rejected					
Positive					
Negative					
Indeterminate					
Sub-Total					

Q = Quarter

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

	Available	Functional[3]	Monitored[4]	Serviced[5]	Maintained[6]
LAMP amplification					
LAMP visualization					

[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)?

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	T1.1	Does the laboratory have documentation covering the following processes?						
		1. Sample collection and transport						
		2. Processing of samples and conducting TB-LAMP						
		3. Quality control procedures for TB-LAMP						3
		4. Recording & reporting test results TB-LAMP conforming to WHO standards						
		5. Interlaboratory comparison or proficiency testing (PT) for TB-LAMP						
		6. Laboratory safety related to TB-LAMP						
1.5	T1.2	Are the documents complete, in-date and witnessed by all staff performing TB-LAMP testing[7]?						2
Section 1: Documents & Records Subtotal								**5**

[7]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. 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).

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	T4.1	Is there evidence that the laboratory has provided clients information / instructions on interpretation of TB-LAMP 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	T7.1	Are all media and consumables stored at the correct temperature and in date[8]?						2
		- TB-LAMP reagents						
Section 7: Purchasing & Inventory Subtotal								**2**

[8]According to manufacturer's requirements.

Section 8: Process Control

All generic requirements apply, see SLIPTA Section 7. In addition to the General Procedures (Section 8), assessors should review the following:

SLIPTA			NA	Y	P	N	Comments	Score
Quality Control								
8.8	T8.1	Is lot-to-lot testing performed?						2
		Do QC records for TB-LAMP demonstrate reagent ability to detect positive MTB?						
TB-LAMP Testing Procedure[9]								
DNA Extraction								
8.10	T8.2	Is 60 µL of a suitable sputum containing a purulent portion pipetted to the Heating Tube?						5
		Is 60 µL of the negative control pipetted to the negative control Heating Tube?						
		Are the Heating Tubes mixed three to five times?						
		Are the Heating Tubes loaded onto a pre-heated heating block and inactivated for 5 minutes?						
		Are the Heating Tubes cooled at room temperature for 2 minutes?						
		Are the Heating Tubes connected to the Absorbent Tube?						
		Is the Heating Tube - Absorbent Tube assembly mixed 20 times (until the powder becomes slurry)?						
		Is the Injection Cap attached to the Absorbent Tube?						
		Is 30 µL of the DNA solution dispensed to the Reaction Tube?						
		Are DNA extraction materials discarded in accordance with local biosafety recommendations?						

[9]This procedure describes Loopamp PURE DNA Extraction and MTBC detection (Eiken Chemical Co Ltd.)

SLIPTA			NA	Y	P	N	Comments	Score
MTBC Detection								
8.10	T8.3	Is 30 µL of positive control reagent transferred to the positive control Reaction Tube using the dropper provided?						
		Are all Reaction Tubes spun down?						
		Are the reagents in the Reaction Tubes reconstituted by inverting the Tubes 5 times?						
		Are all Reaction Tubes spun down (a second time)?						
		Is the amplification procedure performed at 67°C for 45 minutes?						5
		Are the results interpreted according to the manufacturer's instructions?						
		Are indefinite / invalid tests repeated?						
		Are QC results reviewed before test results are reported?						
		Are MTBC detection materials discarded in accordance with local biosafety recommendations?						
Section 8: Process Control Subtotal								**12**

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	T11.1	Are the following performance indicators collected?						5
		Number of TB-LAMP tests performed						
		Number and proportion of positive, negative and invalid TB-LAMP results						
		TB-LAMP TAT[10]						
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).

[10]From sample collection to reporting.