No.**6**

Tuberculosis Technical Scorecard

Lateral Flow Urine Lipoarabinomannan Assay (LF–LAM) 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				%		%
LF-LAM Total				**%**		**%**
LF-LAM 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 LF-LAM?	Y / N		

B. Technical Information

LA. How many tests performed last year?

LF-LAM	Q1	Q2	Q3	Q4	Total
Number of samples received					
Number of samples rejected					
Positive					
Negative					
Invalid					
Sub-Total					

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	L1.1	Does the laboratory have documentation covering the following processes?						3
		1. Sample collection and transport						
		2. Processing of samples and conducting LF-LAM testing on urine samples						
		3. Quality control procedures for LF-LAM						
		4. Recording & reporting results of LF-LAM conforming to WHO standards						
		5. Interlaboratory comparison or proficiency testing (PT) for LF-LAM						
		6. Laboratory safety related to LF-LAM						
1.5	L1.2	Are the documents complete, in-date and witnessed by all staff performing LF-LAM testing[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. 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	L4.1	Is there evidence that the laboratory has provided clients information / instructions on collection of samples and interpretation of LF–LAM results?	■					2
		Do urine collection instructions to patients include wiping and mid–stream catch?	■					
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	L7.1	Are all media and consumables stored at the correct temperature and in date[4]?						2
		– LF-LAM tests						
Section 7: Purchasing & Inventory Subtotal								**2**

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	L8.1	Is lot to lot testing performed?						2
DNA Extraction								
8.10	L8.2	Is a timer available and used?						5
		Are unused kits stored resealed with desiccant?						
		Is the correct volume of urine pipetted directly onto the inoculation pad?						
		Is the test is read within the appropriate timeframe?						
		Are test results interpreted correctly?						
		Are indefinite / invalid tests repeated?						
		Are materials discarded in accordance with local biosafety recommendations?						
Section 8: Process Control Subtotal								**7**

[4]According to manufacturer's requirements

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	L11.1	Are the following performance indicators collected?	■					
		LF–LAM Procedure						
		Number of LF–LAM tests performed	■		■			5
		Number and proportion of positive, negative, indefinite and invalid results	■					
		LF–LAM TAT[5]	■		■			
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).

[5]From sample collection to reporting.