No. 2

Tuberculosis Technical Scorecard

Smear Microscopy

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				%		%
Smear Microscopy Total				**%**		**%**
Smear Microscopy 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 Smear Microscopy?	Y/N		

B. Technical Information

SA. How many tests performed last year?

Smear Microscopy (Diagnostic)	Q1	Q2	Q3	Q4	Total
Number of samples received					
Number of samples rejected					
Scanty positive					
Positive					
Negative					
Sub-Total					
Smear Microscopy (Follow-up)	**Q1**	**Q2**	**Q3**	**Q4**	**Total**
Number of samples received					
Number of samples rejected					
Scanty positive					
Positive					
Negative					
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	S1.1	Does the laboratory have documentation covering the following processes?						3
		1. Production of stains for Ziehl Neelsen (ZN) and or fluorescent (Auramine O) staining						
		2. Sample collection and transport						
		3. Processing of samples and conducting smear microscopy						
		4. Recording & reporting procedures smear microscopy results conforming to WHO standards						
		5. Interlaboratory comparison, blinded rechecking or proficiency testing (PT) for smear microscopy						
		6. Laboratory safety related to smear microscopy						
1.5	S1.2	Are the documents complete, in-date and witnessed by all staff performing smear microscopy[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 to the General Procedures (Section 4), assessors should review the following:

SLIPTA			NA	Y	P	N	Comments	Score
4.1	S4.1	Is there evidence that the laboratory has provided clients information / instructions on interpretation of smear microscopy 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	S7.1	Are all reagents stored at the correct temperature, under the right conditions (in the dark where appropriate) and in date[4]?						2
		- ZN stains						
		- Fluorescent stains						
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	S8.1	Do QC records for ZN stains demonstrate their ability to stain acid-fast organisms?						2
		Do QC records for fluorescent stains demonstrate their ability to stain acid-fast organisms?						
		Do QC records show that QC is performed for each batch of slides						
Smear Microscopy Procedure								
8.10	S8.2	Are smears prepared on clean, un-used glass slides?						5
		Before making the smear, is the slide cleaned with alcohol and clearly labelled with the laboratory number?						
		Is a new swab-stick (or loop) used to collect from the specimen sediment (pellet) a representative portion of the sample for smearing?						
		Is the smear approx. 2cm x 1cm and in the center of the slide?						
		After drying, is fixation done by gentle heating?						
		Are materials discarded in accordance with biosafety recommendations?						

SLIPTA			NA	Y	P	N	Comments	Score
8.10	S8.2	Is ZN staining performed according to the laboratory's SOP:						
		Heated & filtered Ziehl Neelsen Carbolfuchsin 3-5 minutes						
		Decolorizing solution (e.g. 3% acid alcohol) for a maximum of 3 minutes						
		Counterstain (e.g. Methylene blue) 1 minute						
		Is fluorescent staining performed according to the laboratory's SOP:						5
		Auramine-O 15-20 minutes						
		Decolorizing solution (e.g. 3% acid alcohol) for a maximum of 2 minutes						
		Counterstain (e.g. potassium permanganate) 2 minutes						
		Are QC results reviewed before test results are reported?						
Section 8: Process Control Subtotal								**7**

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	S11.1	Are the following performance indicators collected?						5
		Number of smears performed disaggregated by diagnostic and follow-up						
		Number and proportion of positive, scanty and negative smears disaggregated by diagnostic and follow-up						
		Smear microscopy TAT[5]						
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).

[5]From sample collection to reporting.