No. 5

Tuberculosis Technical Scorecard

Xpert MTB/RIF[1]

Version 2.0 – July 2020

[1]Includes Xpert MTB/RIF Ultra

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				%		%
Xpert MTB/RIF Total				**%**		**%**
Xpert MTB/RIF 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 Xpert MTB/RIF?	Y / N		

B. Technical Information

XA. How many tests were performed last year?

Number of samples rejected	Q1	Q2	Q3	Q4	Total
Number of samples received					
Number of samples rejected					
MTB detected[4] (T)					
MTB not detected (N)					
MTB detected Trace (TT)					
MTB detected RIF resistance detected (RR)					
MTB detected RIF resistance indeterminate (TI)					
Error (I)					
Invalid (I)					
No results (I)					
Subtotal					
Of the MTB detected samples, how many were:					
Rif Not detected					
Rif Detected					
Rif indeterminate (not trace)					

Q = Quarter

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

GeneXpert					
If Yes, how many modules are functional?	_____ of _____ modules				

[4]MTB detected (High, medium, low & very low).

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	X1.1	Does the laboratory have documentation covering the following processes?						3
		1. Processing of pulmonary samples and conducting Xpert MTB/RIF testing						
		2. Processing of extra-pulmonary samples and conducting Xpert MTB/RIF testing						
		3. Recording & reporting procedures Xpert MTB/RIF results conforming to WHO standards						
		4. Interlaboratory comparison, retesting or proficiency testing (PT) for Xpert MTB/RIF						
		5. Laboratory safety related to Xpert MTB/RIF						
1.5	X1.2	Are the documents complete, in-date and witnessed by all staff performing Xpert MTB/RIF testing[5]?						2
Section 1: Documents & Records Subtotal								**5**

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).

[5]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	X4.1	Is there evidence that the laboratory has provided clients information / instructions on interpretation of Xpert MTB/RIF 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	X7.1	Are all media and consumables stored at the correct temperature and in date[6]?						2
		- Xpert MTB/RIF reagents & cartridges						
Section 7: Purchasing & Inventory Subtotal								**2**

[6]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	X8.1	Do QC records for Xpert MTB/RIF indicate that incoming batches of Xpert MTB/RIF cartridges have been tested?						2
Xpert MTB/RIF Procedure								
8.10	X8.2	Is the correct volume of SR[7] added to the sample (1:2 ratio)?						5
		Is the sample mixed twice before the end of incubation time?						
		Is the sample incubated for 15 – 30 minutes?						
		Is the correct (2 ml) input volume transferred to the cartridge?						
		Is the patient data entered correctly on the GeneXpert instrument?						
8.10	X8.3	Is there proof that actions are undertaken in case of errors, invalid results and no results?						2
Section 8: Process Control Subtotal								**9**

[7]Substrate Reagent

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	X11.1	Are the following performance indicators collected?						
		Xpert MTB/RIF Procedure						
		Number and proportion of Xpert MTB/RIF test results disaggregated by:						
		MTB detected[8] (T)						
		MTB not detected (N)						
		MTB detected Trace (TT)						
		MTB detected RIF resistance detected (RR)						5
		MTB detected RIF resistance indeterminate (TI)						
		Error (I)						
		Invalid (I)						
		No results (I)						
		Number of extra-pulmonary samples tested disaggregated by type						
		Xpert MTB/RIF TAT[9]						
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).

[8]MTB detected (High, medium, low & very low).
[9]From sample collection to reporting.