No. 9

Tuberculosis Technical Scorecard

Truenat[1]

Version 2.0 – July 2020

[1]Includes Truenat MTB, Truenat MTB Plus and Truenat MTB-Rif Dx

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				%		%
Truenat Total				**%**		**%**
Truenat 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 Truenat?	Y / N		

B. Technical Information

NA. How many tests performed last year?

LPA (MTBDRplus & MTBDRsl)	Q1	Q2	Q3	Q4	Total
Number of samples received					
Number of samples rejected					
Positive					
Negative					
Invalid					
Error					
Subtotal					
Truenat MTB-Rif Dx					
Number of samples processed					
Rif resistance detected					
Rif resistance indeterminate					
Rif resistance not detected					
Error					
Subtotal					

Q = Quarter

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

	Available	Functional[4]	Monitored[5]	Serviced[6]	Maintained[7]
Trueprep Auto					
Truelab Uno Dx					
Truelab Duo					
Truelab Quattro					

[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	N1.1	Does the laboratory have documentation covering the following processes?						3
		1. Sample collection and transport						
		2. Processing of samples and conducting Truenat						
		3. Quality control procedures for Truenat						
		4. Recording & reporting results of Truenat conforming to WHO standards						
		5. Interlaboratory comparison or proficiency testing (PT) for Truenat						
		6. Laboratory safety related to Truenat						
1.5	N1.2	Are the documents complete, in-date and witnessed by all staff performing Truenat testing[8]?						2
Section 1: Documents & Records Subtotal								**5**

[8]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	N4.1	Is there evidence that the laboratory has provided clients information / instructions on interpretation of Truenat 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	N7.1	Are all media and consumables stored at the correct temperature and in date[9]?						2
		- Truenat reagents						
Section 7: Purchasing & Inventory Subtotal								**2**

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	N8.1	Do QC records for LPA demonstrate the ability to detect MTB mutations?						2

[9]According to manufacturer's requirements

SLIPTA			NA	Y	P	N	Comments	Score
Truenat Testing Procedure								
8.10	N8.2	Are 2 drops of liquefaction buffer added to the sputum?						5
		Is the sputum & liquefaction buffer mixed and then incubated for 5 minutes?						
		Is 0.5 ml of the liquified sputum transferred to the lysis buffer bottle?						
		Are 2 drops of liquefaction buffer added to the lysis buffer bottle?						
		Is the lysis bottle mixed and incubated for 3 minutes?						
		Are the entire contents of lysis buffer bottle transferred to the sample chamber of the cartridge using the provided transfer pipette?						
		Is the cartridge correctly inserted into the Trueprep Auto instrument?						
		Is extraction started by pressing the start button on the Trueprep Auto instrument?						
		After extraction, is the elute chamber seal on the cartridge pierced with the filter barrier tip of the 50µl Trueprep™ Precision Micropipette?						
		Is 50 µl of the elute transferred into the ECT tube before mixing well?						
		Is 6 µl of elute from ECT tube dispensed onto the centre of the white reaction well (MTB or MTB-Rif)?						
Section 8: Process Control Subtotal								**7**

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	N11.1	Are the following performance indicators collected?						
		Truenat Procedure						
		Number of Truenat tests performed						5
		Number and proportion of positive, negative, invalid and error Truenat results						
		Number and proportion of Rif resistance detected, Rif not detected, Rif indeterminate and error Truenat MTB-Rif Dx results						
		Truenat 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.