No. 4

Tuberculosis Technical Scorecard

Phenotypic Drug Susceptibility Testing (DST)

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				%		%
DST Total				**%**		**%**
DST 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 DST?	Y / N		

B. Technical Information

DA. How many tests performed last year?

	Phenotypic[3]				
Isoniazid	**Q1**	**Q2**	**Q3**	**Q4**	**Total**
Resistant					
Susceptible					
Total					
Rifampicin					
Resistant					
Susceptible					
Total					

Q = Quarter

[3]Phenotypic DST e.g. MGIT.

Other drug sensitivities	**Method:**					**Method:**				
Drug:	**Q1**	**Q2**	**Q3**	**Q4**	**Total**	**Q1**	**Q2**	**Q3**	**Q4**	**Total**
Resistant										
Susceptible										
Total										
Drug:										
Resistant										
Susceptible										
Total										
Drug:										
Resistant										
Susceptible										
Total										
Drug:										
Resistant										
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Total										
Drug:										
Resistant										
Susceptible										
Total										
Drug:										
Resistant										
Susceptible										
Total										
Drug:										
Resistant										
Susceptible										
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	D1.1	Does the laboratory have documentation covering the following processes?						3
		1. Preparation of drug concentrations and dilutions						
		2. Processing of samples for DST						
		3. Recording & reporting DST results						
		4. Quality control procedures for DST						
		5. EQA for DST						
		6. Laboratory safety required for DST						
1.5	D1.2	Are the documents complete, in-date and witnessed by all staff performing DST[4]?						2
Section 1: Documents & Records Subtotal								**5**

[4]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	D4.1	Is there evidence that the laboratory has provided clients information / instructions on interpretation of DST test 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	D7.1	Are all media and consumables for DST testing stored at the correct temperature[5] and in date[6]?						2
		1. Antibiotics						
		2. Media						
Section 7: Purchasing & Inventory Subtotal								**2**

[5]Antibiotics should be stored in a non-defrosting freezer
[6]According to manufacturer's requirements. Antibiotic dis cartridges and strips should be stored in a tightly sealed container with active desiccants that are replaced or recharged at least monthly.

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	D8.1	Does the laboratory perform QC testing on all media before use[7]?						3
		Do QC records for liquid culture media demonstrate their ability to support growth of MTB[8]?						
8.10	D8.2	Does the laboratory:						3
		1. Perform sterility and performance tests for every batch of culture media using certified reference strains as controls?						
		2. Are reference strains sourced from an authorized supplier (MTB H37Rv)?						
		3. Are the reference strains stored, cultured and sub-cultured in accordance with the specification from the supplier?						
8.10	D8.3	Does laboratory record all samples in batches along with controls on a processing worksheet?						3

[7]This includes in-house made or purchased from commercial sources.
[8]E.g. MTB H37Rv

SLIPTA			NA	Y	P	N	Comments	Score
Phenotypic DST								
8.10	D8.4	Are all antibiotic reconstitution/addition steps performed in a biosafety cabinet?						
		Is each tube or plate labelled with the relevant drug, concentration, laboratory number and date?						
		Are all antibiotics reconstituted and/ or diluted according to the SOP and / or manufacturer's instructions?						
		Is a separate pipette tip used for reconstitution and/or dilution of each antibiotic?						
		Is 0.8 ml MGIT SIRE Supplement to each SIRE tube and the SIRE growth control tube?						5
		Are the appropriate reconstituted antibiotic solutions added into each of the corresponding labeled tubes or plate?						
		Is no antibiotic added to the control tube or plate?						
		Is a 1:100 dilution of the MTB inoculum prepared for the control tube or plate (except for PZA, for which the dilution should be 1:10)?						
		Is the MTB inoculum for the drug tests prepared according to the SOP and / or manufactures instructions?						

SLIPTA			NA	Y	P	N	Comments	Score
Solid Culture Procedure								
8.10	D8.4	Does the SOP cover the following details? - For the direct method, adjusting inoculum size based on the number of bacilli observed in a smear? - For the indirect method: • Ensuring that the inoculum is representative for the original culture (scrapping growth from as many colonies as possible), • Standardization based on the density of cells compared with the McFarland 1.0 standard • Preparation of the inoculum for the growth control (1% of the inoculum for the drug-containing media)						5
		Is the prepared MTB inoculum added to the plates, tubes and control plates or tubes?						
		Are the tubes or plates incubated according to the SOP and / or manufacturer's instructions?						
		Are the DST results read / interpreted according to the SOP and / or manufacturer's instructions?						
		Are materials discarded in accordance with local biosafety recommendations?						
Section 8: Process Control Subtotal								**14**

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	D11.1	Are the following performance indicators collected?						
		1. Number of DST tests performed						
		2. Number of invalid DST results						
		3. Number and proportion of antibiotic resistance tests performed by DST tests (disaggregated by antibiotic)						5
		4. Number and type of discordant results						
		5. Average DST test 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).

[9]From sample collection to reporting.