African Union

AFRICA CDC
Centres for Disease Control and Prevention
Safeguarding Africa's Health

AMR
TECHNICAL SCORECARD

HUMAN

General Procedures

General

Version 1.2 – August 2021

IN PARTNERSHIP WITH

FIND
Diagnosis for all

ASLM
AFRICAN SOCIETY FOR LABORATORY MEDICINE

Score

Section	Sum of maximum points[1]	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			%		%
General Module Total			**%**		**%**
General Module 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		
Type of laboratory	☐ National ☐ Reference ☐ Provincial / County ☐ District / Sub-district ☐ Zonal ☐ Field ☐ Other (specify) _____	☐ Public ☐ Private ☐ Academic ☐ NGO
Does the microbiology laboratory meet minimum space and infrastructure requirements?		
How many hospitals and/or other health care facilities does the laboratory serve?		
Location of laboratory being assessed (City/Town, County / District / Sub-district and Country)		
Details of contact person at laboratory		
Name		
Position		
Qualification		
Email		
Phone		
Is there a clinical microbiologist and / or pathologist with experience in microbiology on staff?	Y / N	
If "Y", how many years' experience do they have?		
If, "N", what is the highest qualified member of the laboratory staff?		
Is the laboratory accredited?	Y / N	
Name of accrediting body?		
What tests is the laboratory accredited for?		
Date of last assessment visit?		
Internal		
External		
Date of last SLIPTA assessment and star rating		
Date of last AMR assessment visit		
Date of this AMR assessment visit		

B. Technical Information

A What procedures are available for the detection and/or identification of bacterial pathogens?

	Yes	No	Specify
Conventional methods (e.g., Gram stain, biochemical tests)			
Automated systems[3]			
Kit-based[4] / serological methods			
Anaerobic methods			
Molecular detection assays (commercial) (please specify)[5]			
Molecular detection assays (non-commercial) (please specify)[5]			
MALDI-TOF Mass spectrometry (MS)			

B What methods are available for Antimicrobial Susceptibility Tests (AST) of bacterial pathogens?

Method	Yes	No	Specify
Automated systems			
Gradient / Disk diffusion / Etest			
Manual broth dilution			
Molecular AST assays (commercial) (please specify)[5]			
Molecular AST assays (non-commercial / in-house) (please specify)[5]			

C Does the laboratory routinely perform AST on bacterial pathogens? If so, which methods are used for:

	Automated	Gradient/ Disk Diffusion	Etest	Manual broth dilution	Molecular AST assays (commercial)	Molecular AST assays (non-commercial / in-house)
E. coli						
K. pneumoniae						
Salmonella sp.						
Shigella sp.						
S. aureus						
S. pneumoniae						
A. baumannii						
N. gonorrhoeae						
S. pyogenes						
M. catarrhalis						
C. diphtheriae						

[3] E.g. Vitek, Microscan, Phoenix.
[4] E.g. BioMérieux's API identification and other similar products.
[5] E.g. Molecular detection platforms for detection and AST including real-time PCR and sequencing. Equipment may include thermocyclers, electrophoresis and gel documentation systems.

	Automated	Gradient/ Disk Diffusion	Etest	Manual broth dilution	Molecular AST assays (commercial)	Molecular AST assays (non-commercial / in-house)
H. influenzae						
M. pneumoniae						
Enterococcus						
Enterobacteriaceae						
P. aeruginosa						

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

	Available	Functional[6]	Monitored[7]	Serviced[8]	Maintained[9]
Automated blood culture instrument					
Ruler or caliper with millimeter markings					
Bunsen burner or micro-incinerator					
Wire loops for streaking					
Turbidity meter					
Microscope					
Thermometers					
Incubator (Aerobic)					
Incubator (Anaerobic)					
Incubator (CO_2)					
Refrigerator (2-8°C)					
Freezer (-20 - -80°C)					
Balance / scale					
Autoclave					
Biosafety Cabinet Class II					
MALDI-TOF MS					
Molecular platforms					
Other equipment (please specify):					
•					
•					
•					

NA = Not applicable

[6] Is the equipment in working order?
[7] Is the functionality of equipment regularly checked (e.g. temperature / calibrated)?
[8] Is the equipment regularly serviced by a qualified service technician? Review equipment logbook
[9] Is the equipment regularly maintained according to the manufacturer's recommendations (e.g. cleaning)? Review SOP and equipment logbook

E How does the laboratory obtain media for bacterial culture ?

	Urine	Feces	Blood	Genital	Pulmonary	Wound
Media is prepared on-site (non-commercial)						
Media is prepared off-site (non-commercial)						
If Blood Agar is prepared (non-commercial), what is the source of the blood?[10]						
Ready-made media is procured from a media supplier (commercial)						

F Which AST interpretation standard (and version) does the laboratory use (check all that apply)?

Standard[11]	Yes	No	Version
Clinical & Laboratory Standards Institute (CLSI) (https://www.clsi.org)			
European Committee on Antimicrobial Susceptibility Testing (EUCAST) (www.eucast.org/)			
Other- please specify			

G How does the laboratory report results?

Method	Yes	No
Electronic		
Paper		

H GLASS reporting and feedback

	NA	Yes	No
Does the laboratory report cumulative pathogen & AST data to GLASS?[12]			
If yes, how frequently per year?			
Does the laboratory receive feedback from GLASS?			
If yes, how frequently per year?			

[10] Assess the QC records to determine the quality of the blood
[11] Determine whether the laboratory has constant access, either online or offline
[12] Either directly or through a supervising reference or central laboratory in case of an AMR surveillance network.

Section 1: Documents & Records

All generic requirements apply, see SLIPTA Section 1. In addition, assessors should review the following:

SLIPTA			NA	Y	P	N	Comments	Score
1.5	G1.1	If the laboratory uses **automated methods**[13] for organism identification and AST (e.g. MS, molecular, Vitek, Microscan, Phoenix):						
		a) Does the documentation provide instructions for preparing the inoculum in the correct medium and at the correct density?						
		b) Does the documentation provide guidance on interpreting results generated by the software?						
		c) Does the documentation provide guidance on how to recognize unacceptable results?						3
		d) Does the documentation outline what actions to take when unusual or unexpected AST results are documented from patient samples (e.g., reconfirm organism ID, reconfirm relevant QC, repeat testing, notify supervisor)?						
		e) Does the documentation describe the defined QC organisms, QC						

[13] Including MS & molecular methods.

SLIPTA			NA	Y	P	N	Comments	Score
		frequency and expected QC results for use with the instrument?						
1.5	G1.2	If the laboratory uses **kit-based methods** for organism identification[14]:						3
		a) Does the documentation provide instructions for preparing the inoculum in the correct medium and at the correct density?						
		b) Does the documentation provide guidance on interpreting results?						
		c) Does the documentation provide guidance on how to recognize unacceptable results?						
		d) Does the documentation describe the defined QC organisms, QC frequency and expected QC results for each test?						
1.5	G1.3	If the laboratory uses **conventional methods** for organism identification and AST:						3
		a) Does the documentation provide instructions for preparing the inoculum in the correct medium and at the correct density?						
		b) If manual MIC methods are used, does the documentation						

[14] E.g. BioMérieux's API identification and other similar products

SLIPTA			NA	Y	P	N	Comments	Score
		describe specific criteria for measuring and determining the MIC endpoints?						
		c) Does the documentation describe criteria for interpretation of the endpoint or zone size?						
		d) Does the documentation provide guidance on how to recognize unacceptable results?						
		e) Does the documentation describe the defined QC organisms, QC frequency and expected QC results for each test?						
1.5	G1.4	Does the laboratory provide restrictive (selective or cascade) reporting of AST[15]?						2
Section 1: Documents & Records Subtotal								11

Section 2: Management Reviews

All generic requirements apply, see SLIPTA Section 2. In addition, assessors should review the following:

SLIPTA			NA	Y	P	N	Comments	Score
2.2	G2.1	Does the laboratory have representation on all the following? • Antimicrobial Stewardship Committee / Anti-Microbial Coordination Committee						2

[15] In cascade reporting, antimicrobial agents of each class are ranked based on a spectrum of activity, popularity or potential for the over-prescribing risk of drug resistance and cost. Thus, the reported AST should include the most appropriate and least expensive drugs, provided the organism is susceptible. Higher risk agents are only released if alternative options are lacking.
In selective reporting, the susceptibilities of broad-spectrum agents and those drugs at risk for over-prescription are deliberately withheld.

SLIPTA			NA	Y	P	N	Comments	Score
		• Infection Control Committee • Drug and Therapeutics Committee • Hospital Surveillance / Outbreak Team						
2.2	G2.2	Does the laboratory report findings / trends and other related important information regarding bacterial culture and AST results to the oversight committees regularly?						2
2.2	G2.3	Does the laboratory report cumulative antibiogram results to oversight committees at least annually?						2
2.2	G2.4	Do laboratory management reviews include review of feedback or recommendations from the: • Antimicrobial Stewardship Committee / Anti-Microbial Coordination Committee • Infection Control Committee • Drug and Therapeutics Committee • Hospital Surveillance / Outbreak Team						2
Section 2: Management Reviews Subtotal								8

Section 3: Organization & Personnel

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Section 4: Client Management & Customer Service

All generic requirements apply, see SLIPTA Section 4. In addition, assessors should review the following:

SLIPTA			NA	Y	P	N	Comments	Score
4.3	G4.1	Does the laboratory provide feedback to clinicians (directly or via oversight committees, see G2.1) regarding sample quality & sample rejection rates? • Sample quality & rejection rates • Identity & frequency of isolated or identified pathogens						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 following:

SLIPTA			NA	Y	P	N	Comments	Score
5.3	G5.1	Does the laboratory use verified / validated methods for isolation / detection / identification and AST of pathogens[16]?						5
5.1	G5.2	Is all equipment for isolation / detection / identification and AST of pathogens installed and placed in a suitable environment?						2
5.11	G5.3	Does the laboratory maintain all equipment for isolation / detection / identification and AST of pathogens? (see D)?						3
Section 5: Equipment Subtotal								10

[16] Includes all conventional, automated, kit-based, serological, MS and molecular (commercial & non-commercial) methods.

Section 6: Evaluation and Audits

All generic requirements apply, see SLIPTA Section 6. In addition, assessors should review the following:

SLIPTA			NA	Y	P	N	Comments	Score
6.1 & 1.5	G6.1	Evaluations and audits[17]:						
		a) Do the laboratory policies require audits to be performed?						
		b) Does the laboratory regularly conduct internal audits?						
		c) Are external audits regularly conducted?						5
		d) Are audit recommendations and action plans followed up within the timeframe defined by the laboratory?						
Section 6: Evaluation and Audits Subtotal								5

Section 7: Purchasing & Inventory

All generic requirements apply, see SLIPTA Section 7. In addition, assessors should review the following:

SLIPTA			NA	Y	P	N	Comments	Score
7.2	G7.1	Does the laboratory provide specifications for supplies and consumables and are they followed during the procurement process?						2
7.8	G7.2	Are storage areas for reagents and supplies setup, maintained and monitored according to manufacturer's requirements[18]?						2
Section 7: Purchasing & Inventory Subtotal								4

[17] It is recommended that internal audits be conducted at least annually. External audits are conducted less frequently-assessors should use the recommendation of local accrediting body to determine the frequency of external audits.

[18] Ensure all supplies/reagents have not expired. Antibiotic packages not in use should be stored in a non-defrosting freezer, unopened and in their original packaging. Once opened, the antibiotic disks must be stored in such a way that the lot number and expiration date of each disk is always traceable. The antibiotic disk cartridges and strips should be stored in a tightly sealed container with active desiccants-the desiccants should be replaced or recharged at least monthly.

Section 8: Process Control

All generic requirements apply, see SLIPTA Section 8. In addition, assessors should review the following:

SLIPTA			NA	Y	P	N	Comments	Score
SPECIMEN COLLECTION								
8.2 & 8.3	G8.1	Does the Laboratory Request Form:						3
		• require the date and time of sample collection to be recorded?						
		• have space for the date of hospital admission?						
		• have space for the presumptive diagnosis?						
BACTERIAL DETECTION AND/OR IDENTIFICATION								
8.8	G8.2	For automated, kit-based, molecular[19], MS or conventional methods:						3
		• Is QC performed on every new lot number/shipment of automated test reagents/ ID cards/cartridges/conventional media before they are placed into use?						
		• Is the lab using the inoculation medium appropriate for the procedure being performed?						
8.10 & 9.9	G8.3	For automated methods only:						3
		• Is the instrument software up to date?						
		• Does the laboratory confirm the detection / identification result by another method[20]?						

[19] Refer to instructions for use for commercial and non-commercial molecular identification assays.

[20] Follow-up or confirmatory testing should be performed if the software flags a questionable result and if testing is performed using a non-commercial method (or commercial method on a non-validated sample type).

SLIPTA			NA	Y	P	N	Comments	Score
8.10 & 7.4	G8.4	For kit-based methods only:						3
		• Is the manufacturer's database used for result interpretation up to date?						
		• When an ID result does not reach the acceptable threshold, is there evidence that appropriate action is taken, such as repeating the test by another method or performing additional biochemical tests?						
8.10a	G8.5	For conventional methods only: • When an identification result does not reach the acceptable threshold, is there evidence that appropriate action is taken, such as repeating the test by another method or performing additional biochemical tests?						2
BACTERIAL AST								
8.9	G8.6	For automated, kit-based, molecular[21] or conventional methods:						3
		• When performing AST, are fresh isolates (<24 hours old) used?						
		• When performing AST, are well-isolated, pure colonies (as evidenced by Gram stain, colony						

[21] Refer to instructions for use for commercial and non-commercial molecular AST assays.

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SLIPTA			NA	Y	P	N	Comments	Score
		morphology, etc.) used?						
		• Has the lab completed a QC conversion plan for all antibiotics in use?						
		• When preparing a bacterial inoculum for AST, is a 0.5 McFarland suspension used?						
		• After inoculation, are purity plates always made from the remaining suspension?						
		• Are control organisms tested with each batch of AST performed?						
Section 8: Process Control Subtotal								17

Section 9: Information Management

All generic requirements apply, see SLIPTA Section 9. In addition, assessors should review the following:

SLIPTA			NA	Y	P	N	Comments	Score
9.3	G9.1	Does the laboratory liaise with the clinical site when there is a suspected Hospital Acquired Infection (HAI) and / or nosocomial outbreak[22?]						2
Section 9: Information Management Subtotal								2

[22] E.g. Cluster of identical organisms isolated from a ward.

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Section 10: Identification of Non-conformities, Corrective and Preventive Actions

All generic requirements apply, see SLIPTA Section 10. In addition, assessors should review the following:

SLIPTA			NA	Y	P	N	Comments	Score
10.1	G10.1	Are all identified nonconforming activities identified and documented adequately?						5
10.2	G10.2	Is root cause analysis performed and corrective action taken for all non-conforming work?						3
Section 10: Identification of Non-conformities, Corrective and Preventive Actions Subtotal								8

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	G11.1	Are all reports shared periodically with clinicians and AMR surveillance authorities (as applicable)?[23]						2
11.4 / 11.5	G11.2	Do reports for clinicians and AMR surveillance authorities include at a minimum the number of samples, isolated or identified organisms and AST patterns?						2
Section 11: Occurrence/Incident Management & Process Improvement Subtotal								4

[23] Assessors should review the guidance documents of the surveillance committees to determine the frequency that the laboratory should share its reports. If no recommendations exist, this should be at least quarterly.

Section 12: Facilities and Biosafety

All generic requirements apply, see SLIPTA Section 12. In addition, assessors should review the following:

SLIPTA			NA	Y	P	N	Comments	Score
12.16	G12.1	Are the following PPE items used when processing samples?						2
		• Gloves						
		• Laboratory coat						
12.4	G12.2	Waste management						
		• Does the laboratory handle waste appropriately including disposal media and infectious material generated during testing?						
		• Are suitable disinfectants available for use when processing samples, are they freshly prepared, and is there evidence of their use[24]?						2
Section 12: Facilities and Biosafety Subtotal								4

The Antimicrobial Resistance (AMR) Laboratory Quality Scorecard was developed in collaboration with and support from Becton Dickinson and Company (BD)

[24] Clinical Microbiology Reviews, Jan. 1999, p. 147–179

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