African Union

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

AMR
TECHNICAL SCORECARD

HUMAN

Bacterial Culture, Detection, Identification and Antimicrobial Susceptibility Testing of Wound Samples

Wound

Version 1.0 – August 2021

IN PARTNERSHIP WITH

FIND
Diagnosis for all

ASLM
AFRICAN SOCIETY FOR LABORATORY MEDICINE

Score

Section	Sum of maximum points[2]	Current Audit Date:		Previous audit 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			%		%
Wound Module Total			**%**		**%**
Wound Module 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 scope of last assessment?	Date	Type	Score
Internal			
External			
Did the last assessment include assessment of bacterial culture of wound samples?	Y / N		

B. Technical Information

W.A How many wound culture tests and molecular tests were performed last year[4,5]?

	Culture				Molecular			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Hospital-acquired[6]								
S. aureus								
S. pyogenes								
Enterococcus sp.								
Enterobacteriaceae								
P. aeruginosa								
Community-acquired[7]								
S. aureus								
S. pyogenes								
Enterococcus sp.								
Enterobacteriaceae								
P. aeruginosa								
Unknown/referred[8]								
S. aureus								
S. pyogenes								
Enterococcus sp.								
Enterobacteriaceae								
P. aeruginosa								
TOTAL ISOLATES								
TOTAL NUMBER OF WOUND TESTS PERFORMED								
TOTAL NUMBER OF WOUND CULTURES WITH NO PATHOGENS ISOLATED OR IDENTIFIED								

Q = Quarter

[4] It is highly recommended that assessors obtain the necessary permission to review the laboratory data. However, if assessors are unable to review the laboratory data this question is NOT compulsory for completion of the assessment.
[5] http://www.who.int/glass/en/ and other frequently isolated pathogens.
[6] Hospital-acquired infections are defined as bacterial infections in hospitalized patients (i.e. pathogenic bacterial isolated from a sample collected more than 48 hours after admission).
[7] Community-acquired infections are defined as ambulatory patients and hospitalized patients from which a sample was collected less than 48 hours after admission.
[8] If the laboratory can't distinguish between hospital & community acquired infections, the number of organisms isolated should be recorded as "Unknown/referred".

W.B Are there any significant variations (> 20%) in the number of wound culture tests performed or organisms isolated or identified each quarter? If 'Yes', please explain[9]

[9] It is highly recommended that assessors obtain the necessary permission to review the laboratory data. However, if assessors are unable to review the laboratory data this question is NOT compulsory for completion of the assessment.

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	W1.1	Does the laboratory have documentation covering the following processes?						2
		a) Production of Blood Agar, MacConkey Agar or other media for wound culture pathogen isolation?						
		b) Processing of wound samples						
		c) Detection, identification and AST of wound pathogens						
		d) Reporting of wound culture and molecular test results						
		e) Interlaboratory comparison or proficiency testing (PT)						
		f) Laboratory safety						
1.5	W1.2	Are the documents complete, in-date and witnessed by all staff performing wound culture and molecular tests[10]?						2
1.5	W1.3	Are the following processes documented?						3
		a) Rejection criteria for wound samples?						
		b) A policy for reporting critical results?						
		c) Instructions for reporting wound culture tests with mixed bacterial growth?						
		d) Instructions for referral of wound culture or molecular tests at the						

[10] See ISO15189:2012 Clause 5.5.3 for minimum requirements for a technical Standard Operating Procedure (SOP).

SLIPTA			NA	Y	P	N	Comments	Score
		laboratory?						
		e) Instructions for handling samples received after hours?						
		f) Instructions for referral of bacterial isolates for identification and AST?						
		g) Instructions on how to perform AST conversions for automated, disk diffusion, Etest / Gradient and microdilution AST?						
		h) Turnaround time for wound culture or molecular tests[11]?						
		i) Definition of rare / unexpected AST results?						
		j) Confirmatory tests for unusual or unexpected patient AST results?						
Section 1: Documents & Records Subtotal								7

Section 2: Management Reviews

Section 3: Organization & Personnel

All generic requirements apply, see SLIPTA Section 3. In addition, assessors should review the following:

SLIPTA			NA	Y	P	N	Comments	Score
3.6	W3.1	Is there evidence that laboratory staff have been trained in the following[12]:						3
		a) Processing of wound samples for culture and molecular tests						
		b) Identification and AST of wound pathogens						

[11] From sample collection to reporting.

[12] Review training records, competency assessment forms and duty rosters. Pay attention to date of training and scope of training compared with techniques being performed.

SLIPTA			NA	Y	P	N	Comments	Score
		c) Interpretation of wound culture and molecular test results						
		d) Reporting of wound culture and molecular test results						
		e) QC, EQA & PT for wound culture and molecular tests						
		f) Laboratory safety						
3.7	W3.2	Is there evidence that laboratory staff are following the procedures described in the laboratory documentation?[13]:						
		a) Processing of wound for culture and molecular tests						3
		b) Interpretation of wound culture test results						
		c) Identification and AST of wound pathogens						
		d) Reporting of wound culture test and molecular test results						
Section 3: Organization & Personnel Subtotal								6

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
4.1	W4.1	Is there evidence that the laboratory has provided clients information / instructions on wound sample collection, storage and transportation to the laboratory? Does the information / instructions include:						3
		a) Use of sterile techniques for collecting wound samples from sterile sites?						
		b) Collection procedures for culture of anaerobic						

[13] Directly observe procedures being performed compared to the SOP.

SLIPTA			NA	Y	P	N	Comments	Score
		organisms?						
		c) Interpretation of contaminated results?						
4.1	W4.2	Is there evidence that the laboratory has provided clients information / instructions on interpretation of wound culture results and AST?						2
Section 4: Client Management & Customer Service Subtotal								5

Section 5: Equipment

Section 6: Evaluation and Audits

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
7.10	W7.1	Is all media for bacterial culture isolation, identification and AST stored correctly and in date (from date of manufacture media must be stored at 2-8 °C)[14]?						2
		• Blood Agar						
		• MacConkey agar						
		• Mueller Hinton						
		• CNA agar						
Section 7: Purchasing & Inventory Subtotal								2

[14] According to manufacturer's requirements.

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
MEDIA QUALITY CONTROL								
8.8	W8.1	Does the laboratory perform QC testing on all media before use[15]?						3
		Blood agar						
		Do QC records for blood agar plates demonstrate that they are checked for their ability to support growth of fastidious organisms such as *S. pneumoniae*?						
		Do QC records for blood agar plates demonstrate that they are checked for their ability to show beta, alpha, and gamma hemolysis?						
		MacConkey agar (MAC)						
		Do QC records for MAC plates demonstrate that they are checked for their ability to suppress growth of Gram-positive organisms while allowing the growth of Gram-negative organisms?						
		Do QC records for MAC plates demonstrate that they are checked for their ability to allow visualization of lactose fermentation?						
		Mueller Hinton Agar (MHA)						
		Do QC records demonstrate that MHA plates are checked for their ability to grow *S. aureus* & *E. coli*?						
		CNA agar[16]						
		Do QC records for CNA agar plates demonstrate that they are checked for their ability to suppress growth of Gram-negative organisms while allowing						

[15] This includes in-house made or purchased from commercial sources.
[16] See user guide for more information.

SLIPTA			NA	Y	P	N	Comments	Score
		the growth of Gram-positive organisms?						
		Do QC records demonstrate that CNA agar plates are checked for their ability to grow *S. pyogenes* & *S. aureus*?						
8.8	W8.2	Does the laboratory: • Perform sterility and performance tests for every batch of culture media using certified reference strains as controls? • Are reference strains sourced from an authorized supplier (e.g. ATCC)? • Are the reference strains stored, cultured and sub-cultured in accordance with the specification from the supplier?						2
8.10	W8.3	Does the laboratory determine the cause of failed QC (root cause analysis), perform corrective actions and measure the effectiveness thereof?						3
WOUND CULTURE PROCEDURE[17]								
8.7	W8.4	Are wound cultures plated onto non-selective media including (at least): • Blood Agar • MacConkey						2
8.7	W8.5	Are wound culture plates incubated at 35-37 degrees Celsius aerobically and anaerobically if applicable?						2
8.7	W8.6	Does the laboratory report wound cultures as contaminated if they contain organisms that should be considered contaminants (e.g. *Bacillus* sp., Coagulase-negative *Staphylococcus*,						2

[17] For complete recommended procedure, see the User Guide.

SLIPTA			NA	Y	P	N	Comments	Score
		Corynebacterium sp.)?						
BACTERIAL ID & AST								
8.7	W8.7	Is the following testing performed for *S. aureus* identification:[18] • Catalase • Coagulase (slide or tube) • Mannitol Salt Agar (MSA) • Dnase						2
8.7	W8.8	Does *S. aureus* AST include the following antibiotics[19]: • Cefoxitin • Vancomycin						2
8.7	W8.9	Does the laboratory detect methicillin/nafcillin resistance in *S. aureus* using oxacillin disk?						2
8.7	W8.10	Is the following testing performed for *Streptococcus sp.* and *Enterococcus sp.* Identification: • Bacitracin • Pyrrolidonyl Arylamidase (PYR) • Bile solubility • Optochin • *S. pneumoniae* latex						2
8.7	W8.11	Does *Streptococcus sp.* AST include the following antibiotics: • Oxacillin[20] • Co-trimoxazole • Ceftriaxone or cefotaxime						2
8.7	W8.12	Is the following testing performed to identify Gram negative bacilli: • Oxidase • Indole						2

[18] If the laboratory performs penicillin AST, it is recommended that *S. aureus* isolates with penicillin zones sizes or MICs in the susceptible range are tested for B-lactamase production using the zone-edge test or a nitrocefin test before being reported as penicillin susceptible.

[19] If oxacillin and cefoxitin results are discrepant for *S. aureus* (one is susceptible and one is resistant), the laboratory should repeat the testing. Note: oxacillin testing should always be tested by MIC (not disc diffusion). If the results remain discrepant, oxacillin should be reported as resistant.

[20] If the laboratory uses an oxacillin disk (1ug) to screen for penicillin resistance (Penicillin G or Benzylpenicillin, the IV formulation) in *S. pneumoniae* and the zone size < 20, then the laboratory must do an MIC method before reporting penicillin as resistant (CLSI recommendation). EUCAST recommends that if the zone size is < 20mm to do a MIC, if ≧ 20 mm the result should be reported as susceptible.

SLIPTA			NA	Y	P	N	Comments	Score
		• Methyl Red • Voges Proskauer • Citrate • Triple Sugar Iron or Kligler Iron • Urease • Motility						
8.7	W8.13	Does the lab follow the latest CLSI /EUCAST guidelines for AST of Gram negative bacilli[21]?						2
8.7	W8.14	Does the laboratory use Combination Disk Test or another equivalent method for Extended Spectrum Beta-Lactamase (ESBL) screening[22]?						2
8.7	W8.15	Does the laboratory use Combination Disk Test or another equivalent method for carbapenemase screening?						2
INTERLABORATORY COMPARISON, PT AND EXTERNAL QUALITY ASSURANCE (EQA)								
8.14	W8.16	Is the laboratory enrolled in an interlaboratory comparison or PT program for wound culture and molecular tests for organism identification, and AST?						2
8.14	W8.17	Did the laboratory pass the last 3 rounds of interlaboratory comparison or PT program testing?						2
8.14	W8.18	Does the laboratory receive onsite supervision visits as part of the EQA program for wound culture and molecular tests?						2
Section 8: Process Control Subtotal								38

[21] https://www.clsi.org / www.eucast.org/)
[22] J Clin Microbiol. 2013 Sep; 51(9): 2986–2990.

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	W9.1	Does the final report for wound culture list the organisms for which the specimen was and was not cultured[23]?						2
9.3	W9.2	Does the laboratory report alert organisms which include at least[24]? • Methicillin resistant *S. aureus* • Carbapenem resistant *Enterobacteriaceae* • ESBL producing organisms • Multidrug resistant *Pseudomonas*						2
Section 9: Information Management Subtotal								4

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

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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	P11.1	Are the following performance indicators collected[25]?						3
		• Number of wound culture and molecular tests performed (disaggregated by type)						
		○ Hospital-acquired[26]						

[23] The laboratory should inform the clinician on the report what organisms were excluded during the culture process. This may be either by choice of media or incubation conditions (e.g. anaerobic organisms). Assessors should review a number of laboratory reports to determine how results are reported. Procedures should be consistent with the laboratory's SOPs.
[24] Alert organisms are organisms with significant public health threat and / or organisms that are notifiable.
[25] It may not be possible for laboratories to distinguish between community and hospital acquired infection if this is not collected on the laboratory requisition form.
[26] Hospital-acquired infections are defined as bacterial infections in hospitalized patients (i.e. pathogenic bacterial isolated from a sample collected more than 48 hours after admission).

SLIPTA			NA	Y	P	N	Comments	Score
		○ Community-acquired[27]						
		○ Unknown/ referred[28]						
		• Number of wound culture and molecular tests where pathogens were isolated (disaggregated by type)						
		○ *S. aureus*						
		○ *S. pyogenes*						
		○ *Enterococcus* sp.						
		○ *Enterobacteriaceae*						
		○ *P. aeruginosa*						
		Total number of wound cultures with no pathogens Isolated or identified						
		Wound culture and molecular test TAT[29] (disaggregated by in-patient & out-patient and by type)						
Section 11: Occurrence/Incident Management & Process Improvement Subtotal								3

Section 12: Facilities and Biosafety

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

[27] Community-acquired infections are defined as ambulatory patients and hospitalized patients from which a sample was collected less than 48 hours after admission.
[28] If the laboratory can't distinguish between hospital & community acquired infections, the number of organisms isolated should be recorded as "Unknown/referred".
[29] From sample collection to reporting.

Africa Centres for Disease Control and Prevention (Africa CDC),
African Union Commission
Roosevelt Street W21 K19, Addis Ababa, Ethiopia

+251 11 551 7700 africacdc@africa-union.org www.africacdc.org africacdc @AfricaCDC