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 Blood Samples

Blood

Version 4.4– 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			%		%
Blood Module Total			**%**		**%**
Blood 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			
Date, type and scope of last assessment?	Date	Type	Score
Internal			
External			
Did the last assessment include assessment of bacterial culture of blood?	Y / N		

B. Technical Information

B.A What blood culture system does the laboratory use?

Automated		Type:	
Manual			

B.B How many blood culture and molecular tests were performed last year[3,4]?

	Manual				Automated				Molecular[5]			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Hospital-acquired[6]												
S. aureus												
Coagulase-negative *Staphylococcus*												
S. pneumoniae												
Enterococcus sp.												
E. coli												
K. pneumoniae												
A. baumannii												
Salmonella sp.												
Other isolates												
• Gram positive cocci												
• Gram negative bacilli												
• Yeast												
Community-acquired[7]												
S. aureus												
Coagulase-negative *Staphylococcus*												
S. pneumoniae												
Enterococcus sp.												
E. coli												
K. pneumoniae												
A. baumannii												
Salmonella sp.												
Other isolates												
• Gram positive												

[3] 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.
[4] http://www.who.int/glass/en/ and other frequently isolated pathogens.
[5] Molecular tests performed on blood for the detection of bacterial blood 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.

cocci												
• Gram negative bacilli												
• Yeast												
Unknown / referred[8]												
S. aureus												
Coagulase-negative *Staphylococcus*												
S. pneumoniae												
Enterococcus sp.												
E. coli												
K. pneumoniae												
A. baumannii												
Salmonella sp.												
Other isolates												
• Gram positive cocci												
• Gram negative bacilli												
• Yeast												
TOTAL ISOLATES												
TOTAL NUMBER OF BLOOD CULTURES PERFORMED												
TOTAL NUMBER OF CONTAMINATED BLOOD CULTURES												
TOTAL NUMBER OF NEGATIVE BLOOD CULTURES												

Q = Quarter

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

Section 1: Documents & Records

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

[8] If the laboratory can't distinguish between hospital & community acquired infections, the number of organisms isolated should be recorded as "Unknown/referred".

[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.

SLIPTA			NA	Y	P	N	Comments	Score
1.5	B1.1	Does the laboratory have documentation covering the following processes?						
		a) Production of Blood Agar, MacConkey Agar or other media for blood culture pathogen isolation?						
		b) Processing of blood samples						
		c) Detection, identification and AST of blood pathogens						2
		d) Reporting of blood culture and molecular test results						
		e) Interlaboratory comparison or proficiency testing (PT)						
		f) Laboratory safety						
1.5	B1.2	Are the documents complete, in-date and witnessed by all staff performing blood culture and molecular tests[10]?						2
1.5	B1.3	Are the following processes documented?						
		a) Rejection criteria for blood?						
		b) A policy for reporting critical results?						
		c) Procedure for immediate reporting of Gram stain results of positive blood cultures?						3
		d) Instructions for reporting blood culture tests with mixed bacterial growth?						
		e) Instructions for						

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

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

Section 2: Management Reviews

[11] From sample collection to reporting.

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	B3.1	Is there evidence that laboratory staff have been trained in the following[12]:						3
		a) Processing of blood for culture and molecular tests						
		b) Identification and AST of blood pathogens						
		c) Interpretation of blood culture and molecular test results						
		d) Reporting of blood culture and molecular test results						
		e) QC, EQA & PT for blood culture and molecular tests						
		f) Laboratory safety						
3.7	B3.2	Is there evidence that laboratory staff are following the procedures described in the laboratory documentation?[13]:						3
		a) Processing of blood for culture and molecular tests						
		b) Interpretation of blood culture test results						
		c) Identification and AST of blood pathogens						
		d) Reporting of blood culture test and molecular test results						
Section 3: Organization & Personnel Subtotal								6

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

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	B4.1	Is there evidence that the laboratory has provided clients information / instructions on blood sample collection, storage and transportation to the laboratory? Does the information / instructions include:						
		a) Use of sterile techniques for drawing and handling of blood cultures?						
		b) Recommendations for the appropriate volume of blood per culture?[14]						3
		c) Collection procedures for culture of anaerobic organisms?						
		d) Collection procedures for blood cultures on pediatric patients?						
		e) Interpretation of contaminated results?						
		f) Frequency of sampling for blood culture?						
4.1	B4.2	Is there evidence that the laboratory has provided clients information / instructions on interpretation of blood culture results and AST?						2
Section 4: Client Management & Customer Service Subtotal								5

Section 5: Equipment

[14] In case of automated blood culture, the volume should be consistent with the manufacturer's instruction for use.

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Section 6: Evaluation and Audits

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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	B7.1	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)[15]?						2
		• Blood Agar						
		• MacConkey agar						
		• Mueller Hinton						
Section 7: Purchasing & Inventory Subtotal								2

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	B8.1	Does the laboratory perform QC testing on all media before use[16]?						
		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*?						3
		Do QC records for blood agar plates demonstrate						

[15] According to manufacturer's requirements.
[16] This includes in-house made or purchased from commercial sources.

		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*?						
8.8	B8.2	Does the laboratory:						
		a) Perform sterility and performance tests for every batch of culture media using certified reference strains as controls?						
		b) Are reference strains sourced from an authorized supplier (e.g. ATCC)?						2
		c) Are the reference strains stored, cultured and sub-cultured in accordance with the specification from the supplier?						
8.10	B8.3	Does the laboratory determine the cause of failed QC (root cause analysis), perform corrective actions and measure the effectiveness thereof?						2

BACTERIAL BLOOD CULTURE PROCEDURE[17]									
8.5	B8.4	Is blood incubated for a minimum of 5 days before being discarded if there is no visible sign of organism growth?							2
8.7	B8.5	Are incubating blood cultures visually examined each day for signs of growth (e.g. turbidity, hemolysis or gas production)?							2
BACTERIAL BLOOD CULTURE PROCEDURE (WORK-UP)									
8.7	B8.6	Are Gram stains performed for all blood cultures showing any sign of positive growth (e.g. turbidity, hemolysis, or gas production?)							2
8.7	B8.7	Is sub-culture of positive primary blood cultures done based on Gram stain result?							2
8.7	B8.8	Are blood culture subculture plates incubated at 35-37°C?							2
8.7	B8.9	Does the laboratory report blood cultures as contaminated if they contain organisms that should be considered contaminants? (e.g. *Bacillus* sp., Coagulase-negative *Staphylococcus*, *Corynebacterium* sp.)							2
8.7	B8.10	Are blood culture bottles which showed signs of positive growth, but from which no aerobic bacteria were isolated, sub-cultured to chocolate agar?							2
***STAPHYLOCOCCUS SP.* ID & AST BY CONVENTIONAL METHODS**									
8.7	B8.11	Is the following testing performed for *S. aureus* identification?[18]							2

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

		• Catalase • Coagulase (slide or tube) • Mannitol Salt Agar (MSA) • Dnase						
8.7	B8.12	Does *S. aureus* AST include the following antibiotics[19]: • Cefoxitin • Vancomycin						2
8.7	B8.13	Does the laboratory detect methicillin/nafcillin resistance in *S. aureus* using oxacillin disk?						2
***STREPTOCOCCUS SP.* ID & AST BY CONVENTIONAL METHODS**								
8.7	B8.14	Is the following testing performed for *Streptococcus sp.* identification? • Bacitracin • Pyrrolidonyl Arylamidase (PYR) • Bile solubility • Optochin • *S. pneumoniae* latex						2
8.7	B8.15	Does *Streptococcus sp.* AST include the following antibiotics: • Oxacillin[20] • Co-trimoxazole • Ceftriaxone or cefotaxime						2
GRAM NEGATIVE BACILLI ID & AST USING CONVENTIONAL METHODS								
8.7	B8.16	Is the following testing performed to identify Gram negative bacilli? • Oxidase • Indole • Methyl Red • Voges Proskauer • Citrate • Triple Sugar Iron or						2

[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.

		Kligler Iron • Urease • Motility						
8.7	B8.17	Does the lab follow the latest CLSI /EUCAST guidelines for AST of Gram negative bacilli[21]?						2
8.7	B8.18	Does the laboratory use Combination Disk Test or another equivalent method for Extended Spectrum Beta-Lactamase (ESBL) screening[22]?						2
8.7	B8.19	Does the laboratory use Combination Disk Test or another equivalent method for carbapenemase screening?						2
INTERLABORATORY COMPARISON, PT AND EXTERNAL QUALITY ASSESSMENT (EQA)								
8.14	B8.20	Is the laboratory enrolled in an interlaboratory comparison or PT program for blood culture and molecular tests for organism identification, and AST?						2
8.14	B8.21	Did the laboratory pass the last 3 rounds of interlaboratory comparison or PT program testing?						2
8.14	B8.22	Does the laboratory receive onsite supervision visits as part of the EQA program for blood culture and molecular tests?						2
Section 8: Process Control Subtotal								45

Section 9: Information Management

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

SLIPT	N	Y	P	N	Comments	Score

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

SLIPTA			NA	Y	P	N	Comments	Score
9.3	B9.1	Does the final report for blood culture list the organisms for which the specimen was and was not cultured[23]?						2
9.3	B9.2	Does the laboratory report alert organisms which include at least[24]? • Methicillin resistant *S. aureus* • Imipenem resistant *K. pneumoniae* • Carbapenem resistant *Enterobacteriaceae* • ESBL producing organisms • Multidrug resistant *Pseudomonas* • Multidrug resistant *Acinetobacter*						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	B11.1	Are the following performance indicators collected[25]?						3
		• Number of blood culture and molecular tests performed (disaggregated by type)						

[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.

		○ Hospital-acquired[26]						
		○ Community-acquired[27]						
		○ Unknown/ referred[28]						
		• Number of blood culture and molecular tests where pathogens were isolated (disaggregated by type)						
		○ *S. aureus*						
		○ *S. pneumoniae*						
		○ *K. pneumoniae*						
		○ *A. baumannii*						
		○ *E. coli*						
		○ *Salmonella sp.*						
		• Number and percentage of contaminated blood culture tests (disaggregated by in-patient & out-patient & unknown/referred)						
		• Blood 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

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

SLIPTA			NA	Y	P	N	Comments	Score
12.8	B12.1	Is a biological safety cabinet (BSC) or hood						2

[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).
[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.

		available and used for handling specimens or organisms considered to be highly contagious by air borne routes?						
12.18	B12.2	Post-exposure prophylaxis:						
		a) Does the laboratory have a policy for cases of needlestick injury?						
		b) Are Anti-retroviral drugs (ARV) available for post-exposure prophylaxis (PEP) in case of needlestick injury and, if yes, are the drugs in date?						2
Section 12: Facilities and Biosafety Subtotal								4

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

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