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 Pulmonary Samples

Pulmonary

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: Current audit score		Previous audit Date: 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			%		%
Pulmonary Module Total			**%**		**%**
Pulmonary 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 pulmonary samples?	Y / N		

B. Technical Information

P.A How many pulmonary sample 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. pneumoniae								
S. pyogenes								
Moraxella catarrhalis								
C. diphtheriae								
H. influenzae								
K. pneumoniae								
Mycoplasma pneumoniae								
Community-acquired[7]								
S. aureus								
S. pneumoniae								
S. pyogenes								
Moraxella catarrhalis								
C. diphtheriae								
H. influenzae								
K. pneumoniae								
Mycoplasma pneumoniae								
Unknown / referred[8]								
S. aureus								
S. pneumoniae								
S. pyogenes								
Moraxella catarrhalis								
C. diphtheriae								

[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".

H. influenzae								
K. pneumoniae								
Mycoplasma pneumoniae								
TOTAL ISOLATES								
TOTAL NUMBER OF PULMONARY TESTS PERFORMED								
TOTAL NUMBER OF PULMONARY SAMPLE CULTURES WITH NO PATHOGENS ISOLATED / IDENTIFIED								

Q = Quarter

P.B Are there any significant variations (> 20%) in the number of pulmonary sample 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	P1.1	Does the laboratory have documentation covering the following processes?						
		a) Production of Blood Agar, MacConkey Agar or other media for pulmonary pathogen isolation?						
		b) Processing of pulmonary samples						
		c) Detection, identification and AST of pulmonary pathogens						2
		d) Reporting of pulmonary sample culture and molecular test results						
		e) Interlaboratory comparison or proficiency testing (PT)						
		f) Laboratory safety						
1.5	P1.2	Are the documents complete, in-date and witnessed by all staff performing pulmonary sample culture and molecular tests[10]?						2
1.5	P1.3	Are the following processes documented?						
		a) Rejection criteria for pulmonary samples?						
		b) A policy for reporting critical pulmonary results?						
		c) Instructions for reporting pulmonary sample culture tests with mixed bacterial growth?						3
		d) Instructions for referral of pulmonary sample						

[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
		culture or molecular tests at the 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 pulmonary sample 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

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[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	P3.1	Is there evidence that laboratory staff have been trained in the following[12]:						3
		a) Processing of pulmonary samples for culture and molecular tests						
		b) Identification and AST of pulmonary pathogens						
		c) Interpretation of pulmonary sample culture and molecular test results						
		d) Reporting of pulmonary sample culture and molecular test results						
		e) QC, EQA & PT for pulmonary sample culture and molecular tests						
		f) Laboratory safety						
3.7	P3.2	Is there evidence that laboratory staff are following the procedures described in the laboratory documentation?[13]:						3
		a) Processing of pulmonary for culture and molecular tests						
		b) Interpretation of pulmonary sample culture test results						
		c) Identification and AST of pulmonary pathogens						
		d) Reporting of pulmonary sample 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	P4.1	Is there evidence that the laboratory has provided clients information / instructions on pulmonary sample collection, storage and transportation to the laboratory? Does the information include:						3
		a) Selection of appropriate type of specimen?						
4.1	P4.2	Is there evidence that the laboratory has provided clients information / instructions on interpretation of pulmonary sample culture results and AST?						2
Section 4: Client Management & Customer Service Subtotal								5

Section 5: Equipment

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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	P7.1	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-						2

SLIPTA			NA	Y	P	N	Comments	Score
		8°C)[14]?						
		• Blood Agar						
		• MacConkey agar						
		• Chocolate agar						
		• Tellurite agar (or equivalent)						
		• New York City medium (or equivalent)						
		• 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	P8.1	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						

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

SLIPTA			NA	Y	P	N	Comments	Score
		they are checked for their ability to allow visualization of lactose fermentation?						
		Chocolate agar						
		Do QC records for Chocolate agar plates demonstrate that they are checked for their ability to support growth of fastidious organisms such as *H. influenzae*?						
		Tellurite agar (or equivalent)						
		Do QC records for Tellurite agar plates demonstrate that they are checked for their ability to support growth of fastidious organisms such as *C. diphtheriae*?						
		New York City medium (or equivalent)						
		Do QC records for New York City medium (or equivalent) demonstrate that they are checked for their ability to support growth of fastidious organisms such as *M. pneumoniae*?						
		Mueller Hinton Agar (MHA)						
		Do QC records demonstrate that MHA plates are checked for their ability to grow *S. aureus* & *E. coli*?						
8.8	P8.2	Does the laboratory:						2
		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)?						
		c) Are the reference strains stored, cultured and sub-cultured in accordance with the specification from the						

SLIPTA			NA	Y	P	N	Comments	Score
		supplier?						
8.10	P8.3	Does the laboratory determine the cause of failed QC (root cause analysis), perform corrective actions and measure the effectiveness thereof?						2
PULMONARY SAMPLE CULTURE PROCEDURE[16]								
8.7	P8.4	Are pulmonary sample cultures plated onto selective and non-selective media including (at least)[17]:						2
		• Blood Agar						
		• MacConkey						
		• Chocolate agar						
		• Tellurite agar (or equivalent)						
		• New York City medium (or equivalent)						
8.7	P8.5	Are pulmonary sample culture plates incubated at 35-37 degrees Celsius?						2
8.7	P8.6	Does the laboratory report pulmonary sample cultures as contaminated if they contain organisms that should be considered contaminants (e.g. *Streptococcus viridans*)?						2
BACTERIAL ID & AST								
8.7	P8.7	Is the following testing performed for *S. aureus* identification?[18] • Catalase • Coagulase (slide or tube) • Mannitol Salt Agar (MSA) • Dnase						2
8.7	P8.8	Does *S. aureus* AST include the following antibiotics[19]: • Cefoxitin • Vancomycin						2

[16] For complete recommended procedure, see the User Guide.
[17] Media used for primary isolation may be adapted for sample type, 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.
[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.

SLIPTA			NA	Y	P	N	Comments	Score
8.7	P8.9	Does the laboratory detect methicillin/nafcillin resistance in *S. aureus* using oxacillin disk?						2
8.7	P8.10	Is the following testing performed for *Streptococcus sp.* identification? • Bacitracin • Pyrrolidonyl Arylamidase (PYR) • Bile solubility • Optochin • *S. pneumoniae* latex						2
8.7	P8.11	Does *Streptococcus sp.* AST include the following antibiotics: • Oxacillin[20] • Co-trimoxazole • Ceftriaxone or cefotaxime						2
8.7	P8.12	Is the following testing performed to identify Gram negative bacilli? • Oxidase • Indole • Methyl Red • Voges Proskauer • Citrate • Triple Sugar Iron or Kligler Iron • Urease • Motility						2
8.7	P8.13	Is the following testing performed to identify *Moraxella catarrhalis*? • Oxidase • Tributyrin (CATScreen) • Dnase						2
8.7	P8.14	Does *Moraxella catarrhalis* AST include the following antibiotics: • Amoxicillin/clavulanic acid • Ceftriaxone or cefotaxime						2

[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
8.7	P8.15	Is the following testing performed to identify *C. diphtheriae*: • Cystinase • Pyrazinamidase						2
8.7	P8.16	Does *C. diphtheriae* AST include the following antibiotics: • Penicillin • Erythromycin						2
8.7	P8.17	Is the following testing performed to identify *H. influenzae*: • X and V factor • *H. influenzae* serotyping						2
8.7	P8.18	Does *H. influenzae* AST include the following antibiotics: • Amoxicillin • Ceftriaxone or cefotaxime						2
8.7	P8.19	Does the lab follow the latest CLSI /EUCAST guidelines for AST of Gram negative bacilli[21]?						2
8.7	P8.20	Does the laboratory use Combination Disk Test or another equivalent method for Extended Spectrum Beta-Lactamase (ESBL) screening[22]?						2
8.7	P8.21	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	P8.22	Is the laboratory enrolled in an interlaboratory comparison or PT program for pulmonary sample culture and molecular tests for organism identification, and AST?						2
8.14	P8.23	Did the laboratory pass the last 3 rounds of interlaboratory comparison or PT program testing?						2

[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
8.14	P8.24	Does the laboratory receive onsite supervision visits as part of the EQA program for pulmonary sample culture and molecular tests?						2
Section 8: Process Control Subtotal								50

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	P9.1	Does the final report for pulmonary sample culture list the organisms for which the specimen was and was not cultured[23]?						2
9.3	P9.2	Does the laboratory report alert organisms which include at least[24]? • Methicillin resistant *S. aureus* • Carbapenem resistant *Enterobacteriaceae* • ESBL producing organisms • *K. pneumoniae*						2
Section 9: Information Management Subtotal								4

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

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[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.

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]?						
		• Number of pulmonary sample culture and molecular tests performed (disaggregated by type)						
		○ Hospital-acquired[26]						
		○ Community-acquired[27]						
		○ Unknown/ referred[28]						
		• Number of pulmonary sample culture and molecular tests where pathogens were isolated (disaggregated by type):						3
		○ *S. aureus*						
		○ *S. pneumoniae*						
		○ *S. pyogenes*						
		○ *Moraxella catarrhalis*						
		○ *C. diphtheria*						
		○ *H. influenza*						
		○ *K. pneumoniae*						
		○ *Mycoplasma pneumoniae*						
		• Pulmonary sample culture and molecular test TAT[29] (disaggregated by in-patient & out-patient and by type)						
Section 11: Occurrence/Incident Management & Process Improvement Subtotal								3

[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).
[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.

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	P12.1	Is a biological safety cabinet (BSC) or hood available and used for handling specimens or organisms considered to be highly contagious by air borne routes?						2
Section 12: Facilities and Biosafety Subtotal								2

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

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