



AMR TECHNICAL SCORECARD

HUMAN

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

Pulmonary

Version 1.0 - August 2021





Score

Section	Sum of maximum		t Audit		ıs audit
	maximum points²	Date: Curren	nt audit	Date: Previou	ıs audit
		sco	ore	sco	ore
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	Туре	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.univ.gi.edu/min.gi.edu/

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				
O − Ouarter				

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:

followi					_			
SLIPT			N	Υ	Р	N	Comments	Score
Α		1-	A					
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						2
		AST of pulmonary						
		pathogens						
		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						2
		sample culture and						
		molecular tests10?						
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	-	_			_	3
		c) Instructions for reporting pulmonary						3
		sample culture tests						
		with mixed bacterial						
		growth?						
		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).

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			
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			
referral of bacterial isolates for identification and AST? g) Instructions on how to perform AST conversions for			
to perform AST conversions for			
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

.

 $^{^{\}rm 11}$ From sample collection to reporting.

Susceptibility Testing of Pulmonary Samples

Section 3: Organization & Personnel

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

followin	y. 						•	
SLIPT			N	Υ	Р	N	Comments	Score
Α	,		Α					
3.6	P3.1	Is there evidence that						
		laboratory staff have been						
		trained in the following ¹² :						
		a) Processing of						
		pulmonary samples for						
		culture and molecular						
		tests						
		b) Identification and AST						
		of pulmonary						
		pathogens						
		c) Interpretation of						_
		pulmonary sample						3
		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						
017	1 0.2	laboratory staff are						
		following the procedures						
		described in the laboratory						
		documentation? ¹³ :						
		a) Processing of						
		pulmonary for culture						
		and molecular tests						
		b) Interpretation of						3
		pulmonary sample						5
		culture test results						
		c) Identification and AST						
		of pulmonary						
		pathogens						
		d) Reporting of pulmonary						
		sample culture test and molecular test results						
Cootion	21 0 =====	II.	N.					6
Section	3: Orga	nization & Personnel Subtota	11					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:

SLIPT A	<i>⋑</i> .		N A	Υ	Р	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: a) Selection of appropriate type of specimen?						3
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: Clier	nt Management & Custome	er Ser	vice S	ubto	tal		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:

SLIPT A			N A	Υ	Р	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

Susceptibility Testing of Pulmonary Samples

SLIPT A		N A	Υ	Р	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: Pur	chasing & Inventory Subtot	al					2

Section 8: Process Control

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

SLIPT	ສ.		N	Υ	Р	N	Comments	Score
A			Α					
MEDIA	QUALIT	Y CONTROL						
8.8	P8.1	Does the laboratory perform QC testing on all media before use ¹⁵ ?						
		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 <i>S. pneumoniae?</i> Do QC records for blood agar plates demonstrate that they are checked for their ability to show beta, alpha, and gamma						3
		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.

SLIPT			N	Υ	Р	N	Comments	Score
A		they are checked for their ability to allow visualization	Α					
		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 <i>H. influenzae</i> ?						
		Tellurite agar (or equivalen	t)					
		Do QC records for Tellurite agar plates demonstrate that they are checked for their ability to support growth of fastidious organisms such as <i>C. diphtheriae</i> ?						
		New York City medium (or	equiva	alent)				
		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 <i>M. pneumoniae</i> ?						
		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:						
		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						

SLIPT			N	Υ	Р	N	Comments	Score
A			A					
		supplier?	'					
8.10	P8.3	Does the laboratory						
55	, 5.5	determine the cause of						
		failed QC (root cause						
		analysis), perform						2
		corrective actions and						_
		measure the effectiveness						
		thereof?						
PULMO	NARY S	AMPLE CULTURE PROCEDU	JRE ¹⁶					
8.7	P8.4	Are pulmonary sample						
"	,	cultures plated onto						
		selective and non-selective						
		media including (at least) ¹⁷ :						
		Blood Agar						
		MacConkey						2
		Chocolate agar						
		Tellurite agar (or						
		equivalent)						
		New York City medium						
		(or equivalent)						
8.7	P8.5	Are pulmonary sample						
"	, 5.5	culture plates incubated at						2
		35-37 degrees Celsius?						
8.7	P8.6	Does the laboratory report						
		pulmonary sample cultures						
		as contaminated if they						
		contain organisms that						2
		should be considered						
		contaminants (e.g.						
		Streptococcus viridans)?						
BACTE	RIAL ID	•						
8.7	P8.7	Is the following testing						
		performed for <i>S. aureus</i>						
		identification? ¹⁸						
		 Catalase 						
		 Coagulase (slide or 						2
		tube)						
		 Mannitol Salt Agar 						
		(MSA)						
		• Dnase						
8.7	P8.8	Does <i>S. aureu</i> s AST include						
		the following antibiotics19:						2
		Cefoxitin						2
		 Vancomycin 						

For complete recommended procedure, see the User Guide.

The 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.

SLIPT			N	Υ	Р	N	Comments	Score
Α			A					
8.7	P8.9	Does the laboratory detect methicillin/nafcillin resistance in <i>S. aureus</i> 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 \geq 20 mm the result should be reported as susceptible.

SLIPT			N	Υ	Р	N	Comments	Score
Α			Α					
8.7	P8.15	Is the following testing performed to identify <i>C. diphtheriae</i> : 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 <i>H. influenzae</i> : 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	P8.2 0	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
		TORY COMPARISON, PT ANI) EXT	EKNA	L QU	ALIT'	Y 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.

SLIPT A			N A	Υ	Р	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	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:

P9.1 Does the final report for pulmonary sample culture list the organisms for which the specimen was and was not cultured ²³ ? 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	OLIDT	a.						2	0
P9.1 Does the final report for pulmonary sample culture list the organisms for which the specimen was and was not cultured ²³ ? 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	SLIPT			N	Y	Р	N	Comments	Score
pulmonary sample culture list the organisms for which the specimen was and was not cultured ²³ ? 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	Α			Α					
report alert organisms which include at least ²⁴ ? • Methicillin resistant S. aureus • Carbapenem resistant Enterobacteriaceae • ESBL producing organisms • K. pneumoniae	9.3	P9.1	pulmonary sample culture list the organisms for which the specimen was and was						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						2
SECTION 3. INIONIATION MANAGEMENT SUDTOTAL	Section	9: Infor		otal					4

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

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:

SLIPT		N	Υ	Р	N	Comments	Score
SLIPT A 11.4 / P11.1 11.5	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): S. aureus S. pneumoniae S. pyogenes Moraxella catarrhalis C. diphtheria H. influenza K. pneumoniae Mycoplasma pneumoniae Mycoplasma pneumoniae Pulmonary sample culture and molecular test TAT ²⁹ (disaggregated by in-	N A		P		Comments	3
	patient & out-patient						
Continue 44: Con	and by type)	-105	\	- I		mant Cultatal	2
Section 11: Occ	urrence/Incident Manageme	nt & P	roces	ss Imp	orove	ment 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.

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:

SLIPT A			N A	Υ	Р	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	Section 12: Facilities and Biosafety Subtotal							

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









