



# AMR TECHNICAL SCORECARD

# **HUMAN**

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

**Faeces** 

Version 4.4 - August 2021





#### Score

Section	Sum of	Current A	udit	Previou	Previous audit	
	maximum	Date:		Date:		
	points <sup>1</sup>	Current au	ıdit		ıs audit	
		score		SC	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			%		%	
Feces Module Total			%		%	
Feces Module Stars <sup>2</sup>						

 $<sup>^1</sup>$  Total number of points of all questions minus points for questions answered with NA.  $^2$  No Stars < 55%  $_{\dot{}}$ 

<sup>1</sup> Star 55% - 64%

<sup>2</sup> Stars 65% - 74%

<sup>3</sup> Stars 75% - 84%

<sup>4</sup> Stars 85% - 94%

<sup>5</sup> 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 feces?		Y/N	

#### **B.** Technical Information

F.A How many feces culture and molecular tests were performed last year<sup>3,4</sup>?

		Faeces	culture			Mole	cular⁵	
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Hospital-acquired <sup>6</sup>								
Salmonella sp.								
Shigella sp.								
Other isolates								
Community-acquired <sup>7</sup>								
<ul> <li>Salmonella sp.</li> </ul>								
Shigella sp.								
Other isolates								
Unknown/ referred <sup>8</sup>								
<ul> <li>Salmonella sp.</li> </ul>								
<ul> <li>Shigella sp.</li> </ul>								
Other isolates								
TOTAL ISOLATES								
TOTAL NUMBER OF FECES								
CULTURES PERFORMED								
TOTAL NUMBER OF NEGATIVE								
FECES CULTURES								

Q = Quarter

F.B	Are there any significant variations (> 20%) in the number of bacterial feces cultures performed or organisms isolated each quarter? If 'Yes', please explain <sup>9</sup>

<sup>&</sup>lt;sup>3</sup> http://www.who.int/glass/en/ and other frequently isolated pathogens.

<sup>&</sup>lt;sup>4</sup> 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.

<sup>&</sup>lt;sup>5</sup> Molecular tests performed on feces for the detection of bacterial fecal pathogens.

<sup>&</sup>lt;sup>6</sup> 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).

<sup>&</sup>lt;sup>7</sup> 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".

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:

following:							
SLIPT		N	Υ	Р	N	Comments	Score
Α		Α					
1.5 F1.1	Does the laboratory						
	have documentation						
	covering the following						
	processes?						
	a) Production of						
	Salmonella Shigella						
	(SS) Agar, Selenite F						
	broth or other media						
	for fecal pathogen						
	isolation?						
	b) Microscopic examination of feces						
	[raw]						
	c) Processing of feces						
	culture and						2
	molecular tests						2
	d) Detection,						
	identification and						
	AST of fecal						
	pathogens						
	e) Reporting of feces	-					
	culture and						
	molecular test						
	results						
	f) Interlaboratory						
	comparison or						
	proficiency testing						
	(PT)						
	g) Laboratory safety						
1.5 F1.2	Are the documents						
	- T						2
1.5							
1.5   F1.3	1						
	•						
							3
							3
	proceed when a						
1.5 F1.3	results f) Interlaboratory comparison or proficiency testing (PT) g) Laboratory safety Are the documents complete, in-date and witnessed by all staff performing feces culture and molecular tests¹0? Are the following processes documented? a) How to identify potential pathogens on all primary media? (SOP should describe colony appearance of potential pathogens and define how to						2

<sup>10</sup> See ISO15189:2012 Clause 5.5.3 for minimum requirements for a technical Standard Operating Procedure (SOP)

4

	potential pathogen is encountered)	
	b) Instructions for referral of feces culture and molecular tests not performed at the laboratory?	
	c) Instructions for handling samples received after hours?	
	d) Instructions for referral of bacterial isolates for identification and AST?	
	e) Instructions on how to perform AST conversions for automated, disk diffusion, Etest / Gradient and microdilution AST?	
	f) Turnaround time for feces culture or molecular tests <sup>11</sup> ?	
Section 1: Docum	nents & 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:

SLIPT A			N A	Υ	Р	N	Comments	Score
3.6	F3.1	Is there evidence that laboratory staff have been trained in the following <sup>12</sup> :						3
		a) Processing of feces culture and molecular tests						

<sup>&</sup>lt;sup>11</sup> From sample collection to reporting <sup>12</sup> Review training records, competency assessment forms and duty rosters. Pay attention to date of training and scope of training compared with techniques being performed.

		b) Detection / identification and	
		AST of fecal pathogens	
		c) Interpretation of	
		feces culture and molecular test	
		results	
		d) Reporting of feces	
		culture and	
		molecular test	
		results	
		e) QC for feces culture and molecular tests	
		f) Laboratory safety	
3.7	F3.2	Is there evidence that	
		laboratory staff are	
		following the procedures	
		described in the	
		laboratory documentation? <sup>13</sup> :	
		a) Processing of feces	
		culture and	
		molecular tests	
		b) Interpretation of	3
		feces culture and	3
		molecular test	
		results	
		c) Identification and	
		AST of feces pathogens	
		d) Reporting of feces	
		culture and	
		molecular test	
		results	
Sectio	n 3: Orga	anization & Personnel Subtotal	6

# **Section 4: Client Management & Customer Service**

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

SLIPT A	<u> </u>		N A	Υ	Р	N	Comments	Score
4.1	F4.1	Is there evidence that the laboratory has provided clients information / instructions on feces collection, storage and						3

 $<sup>^{\</sup>mbox{\tiny 13}}$  Directly observe procedures being performed compared to the SOP.

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

		transportation to the laboratory?						
4.1	F4.2	Is there evidence that the laboratory has provided clients information / instructions on interpretation of feces culture test results and AST?						2
Section	4: Clier	nt Management & Custom	er Ser	vice S	Subto	tal	•	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:

SLIPT A	~		N A	Υ	Р	N	Comments	Score
7.10	F7.1	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) <sup>14</sup> ?						2
		SS Agar or equivalent						
		Selenite F broth or equivalent						
		XLD or equivalent						
		Mueller Hinton						
Section	7: Purc	hasing & Inventory Subtot	al					2

7

<sup>&</sup>lt;sup>14</sup> According to manufacturer's requirements.

#### **Section 8: Process Control**

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

SLIPT	9'		N	Υ	Р	N.I.	Commonto	Сооно
A			A	ľ	Г.	N	Comments	Score
	OLIALIT	Y CONTROL						
8.8	F8.1	Does the laboratory perform QC testing on all media before use <sup>15</sup> ?						
		SS / XLD Agar or equiva	lont					
		Do QC records demonstrate that they are checked for their ability to suppress growth of Enterobacteriaceae						
		while allowing the growth of Salmonella & Shigella?						
		Selenite F broth or equiv	alent					
		Do QC records demonstrate that Selenite F is checked for their ability to suppress growth of Enterobacteriaceae while allowing the growth of Salmonella & Shigella?						3
		Mueller Hinton (MHA)						
		Do QC records demonstrate that MHA plates are checked for their ability to grow S. aureus & E. coli?						
8.8	F8.2	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)?  c) Are the reference strains stored, cultured and subcultured in						3

 $<sup>^{\</sup>mbox{\tiny 15}}$  This includes in-house made or purchased from commercial sources.

		accordance with the						
		specification from						
0.10	F0.0	the supplier?						
8.10	F8.3	Does the laboratory						
		determine the cause of						
		failed QC (root cause						
		analysis), perform						2
		corrective actions and						
		measure the						
		effectiveness thereof?						
		AECES CULTURE PROCEDI	JRE	ı				
8.5	F8.4	Does the laboratory						
		perform a microscopic						
		examination [wet prep &						2
		concentrated] for						
		parasites on all feces						
		specimens?						
8.7	F8.5	Are reference materials,						
		such as permanent						
		mounts,						
		photomicrographs,						
		NCCLS documents M15-						2
		A and M28-A2, or						
		printed atlases available						
		at the work bench to						
		assist with identification						
		of parasites?			_			
8.7	F8.6	Does the laboratory						
		procedure include						
		rechecking microscopic						
		observations/						2
		interpretations among						
		all personnel performing						
		microscopy (wet prep						
		and concentrated)?						
8.7	F8.7	Are the following media						
		used for primary culture						
		of feces <sup>16</sup> ?						
		SS Agar or						
		equivalent						2
		Selenite F broth or						
		equivalent						
		XLD agar or						
0 =	<b>F</b> 2 2	equivalent						
8.7	F8.8	In cholera endemic						
		areas, does the						
		laboratory perform an						2
		isolation procedure for						
		Vibrio using TCBS and						
		alkaline peptone water?						

<sup>16</sup> Either SS agar or XLD agar or equivalent and Selenite F broth or equivalent.

8.7	F8.9	Does the feces						
		processing procedure						
		include plating from						2
		Selenite F broth or						_
		equivalent to SS / XLD						
		agar or equivalent?	_					
8.7	F8.10	Are media used for						
		primary culture of feces						2
		incubated at 35-37°C for						_
		at least 18 hours?						
8.7	F8.11	Are media used for						
		primary culture of feces						2
		incubated aerobically?						
SALMO	NELLA 8	& SHIGELLA IDENTIFCATION	IA NC	ID AS	T BY	CON	VENTIONAL METHODS	
8.7	F8.12	Does the laboratory						
		perform identification						
		tests (ID) for at least the						
		following enteric						2
		pathogens?						
		Salmonella sp.						
		Shigella sp.						
8.7	F8.13	Does the laboratory						
		perform AST on at least						
		the following enteric						
		pathogens using an						2
		approved test method?						
		Salmonella sp.						
		Shigella sp.						
8.7	F8.14	Is the following testing	-					
		performed for						
		Salmonella & Shigella						
		identification:						
		Oxidase						
		Indole						
		Methyl Red						
		Voges Proskauer						2
		Citrate						
		Triple Sugar Iron or						
		Kligler Iron						
		Urease						
		Motility						
		Shigella serology						
		Salmonella serology						
8.7	F8.15	Is Salmonella AST done						
	, 5,,,0	as per current						
		CLSI/EUCAST						2
		guidelines? <sup>17</sup>						
8.7	F8.16	Is Shigella AST done as						
5.7	7 5.10	per current						2
	1	per current					I.	

<sup>17</sup> www.clsi.org / www.eucast.org/)

		OLOU/ELIOA OT				I	
		CLSI/EUCAST					
		guidelines? <sup>18</sup>					
8.7	F8.17	Does the laboratory use					
		Combination Disk Test					
		or another equivalent					
		method for Extended					2
		Spectrum Beta-					
		Lactamase (ESBL)					
		screening <sup>19</sup> ?					
8.7	F8.18	Does the laboratory use					
		Combination Disk Test					
		or another equivalent					2
		method for					_
		carbapenemase					
		screening?					
INTER	LABORA	TORY COMPARISON, PT A	ND E	XTER	<b>NAL QUAL</b>	LITY ASSESSMENT (EQA	)
8.14	F8.19	Is the laboratory enrolled					
		in an interlaboratory					
		comparison or PT					
		program for feces					2
		culture and molecular					
		tests for organism					
		identification, and AST?					
8.14	F8.20	Did the laboratory pass					
		the last 3 rounds of					
		interlaboratory					2
		comparison or PT					
		program testing?					
8.14	F8.21	Does the laboratory					
		receive onsite					
		supervision visits as part					2
		of the EQA program for					2
		feces culture and					
		molecular tests?					
Sectio	n 8: Proc	ess Control Subtotal					44

<sup>18</sup> www.clsi.org / www.eucast.org/)
19 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:

SLIPT A	-		N A	Υ	Р	N	Comments	Score
9.3	F9.1	Does the final report for feces culture list the organisms for which the specimen was and was not cultured <sup>20</sup> ?						2
9.3	F9.2	Does the laboratory report alert organisms which include at least <sup>21</sup> ? • ESBL producing organisms • Carbapenem resistant Salmonella & Shigella						2
Section	9: Infor	mation Management Subt	otal					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:

SLIPT A	S		N A	Υ	Р	N	Comments	Score
11.4 / 11.5	F11.1	Are the following performance indicators collected <sup>22</sup> ?  • Number of feces culture and molecular tests performed (disaggregated by type)						3
		<ul> <li>Hospital-         acquired<sup>23</sup></li> <li>Community-         acquired<sup>24</sup></li> </ul>						

<sup>&</sup>lt;sup>20</sup> 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.

<sup>&</sup>lt;sup>21</sup> Alert organisms are organisms with significant public health threat and / or organisms that are notifiable.

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.

<sup>&</sup>lt;sup>23</sup> 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).

SLIPT A	N A	Υ	Р	N	Comments	Score
o Unknown/						
referred <sup>25</sup>					_	
Number and						
percentage of feces	3					
culture tests						
rejected						
(disaggregated by						
reason e.g. leaked,						
insufficient volume)						
(target <1%)	_				-	
Number and						
percentage of feces						
culture tests where						
parasites were						
observed	_				_	
Number of feces						
culture tests where						
pathogens were isolated or identifie	_					
	a					
(disaggregated by						
type)					-	
o Salmonella sp.	_				_	
o Shigella sp.					_	
o V. cholerae					_	
Feces culture and     TAT	16					
molecular test TAT <sup>2</sup>	.~					
(disaggregated by						
in-patient & out-	,					
patient and by type  Section 11: Occurrence/Incident Manage		D. D.				3

# **Section 12: Facilities and Biosafety**

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

<sup>&</sup>lt;sup>24</sup> Community-acquired infections are defined as ambulatory patients and hospitalized patients from which a sample was collected less than 48 hours after admission.

<sup>25</sup> If the laboratory can't distinguish between hospital & community acquired infections, the number of organisms isolated should be recorded as "Unknown/referred".

<sup>&</sup>lt;sup>26</sup> From sample collection to reporting.





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









