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 Urine Samples

Urine

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 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			%		%
Urine Module Total			**%**		**%**
Urine 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 urine?	Y / N		

B. Technical Information

U.A How many urine cultures were performed last year[3,4]?

	MSU				Catheter				Suprapubic			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Hospital-acquired[5]												
K. pneumoniae												
E. coli												
Other isolates												
• Gram positive cocci												
• Gram negative bacilli												
• Yeast												
Community-acquired[6]												
K. pneumoniae												
E. coli												
Other isolates												
• Gram positive cocci												
• Gram negative bacilli												
• Yeast												
Unknown/ referred[7]												
K. pneumoniae												
E. coli												
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] 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).
[6] Community-acquired infections are defined as ambulatory patients and hospitalized patients from which a sample was collected less than 48 hours after admission.
[7] If the laboratory can't distinguish between hospital & community acquired infections, the number of organisms isolated should be recorded as "Unknown/referred".

	MSU				Catheter				Suprapubic			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
cocci												
• Gram negative bacilli												
• Yeast												
TOTAL ISOLATES												
TOTAL NUMBER OF URINE CULTURES PERFORMED												
TOTAL NUMBER OF CONTAMINATED URINE CULTURES												
TOTAL NUMBER OF NEGATIVE URINE CULTURES												

MSU = Mid-stream urine. Q = Quarter

U.B How many molecular tests[8] for urine pathogens were performed last year (Please specify)[9]?

	MSU				Catheter				Suprapubic			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Hospital-acquired												
K. pneumoniae												
E. coli												
Other isolates												
Community-acquired												
K. pneumoniae												
E. coli												
Other isolates												
Unknown/ referred												
K. pneumoniae												
E. coli												
Other isolates												
TOTAL												

MSU = Mid-stream urine. Q = Quarter

U.C Are there any significant variations (> 20%) in the number of urine culture tests performed or organisms isolated each quarter? If 'Yes', please explain[10]

[8] Molecular tests performed on urine for the detection of urine pathogens.
[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.
[10] 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	U1.1	Does the laboratory have documentation covering the following processes?						
		a) Production of Blood Agar, MacConkey Agar or other media for urine pathogen isolation						
		b) Microscopic examination and urine cell count						
		c) Processing of urine culture and molecular tests						2
		d) Detection, identification and AST of urinary pathogens						
		e) Reporting of urine culture and molecular test results						
		f) Interlaboratory comparison or proficiency testing (PT)						
		g) Laboratory safety						
1.5	U1.2	Are the documents complete, in-date and witnessed by all staff performing urine culture and molecular tests[11]?						2
1.5	U1.3	Are the following processes documented?						
		a) Rejection criteria for urine?						
		b) Semi-quantitative culture for urine samples?						
		c) Which organisms to identify based on relative quantities (> 10^4 CFU/ml)?						3
		d) Instructions for handling samples received after hours?						
		e) Instructions for referral of urine culture and molecular tests for AST						

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

SLIPTA			NA	Y	P	N	Comments	Score
		not performed at the laboratory?						
		f) Turnaround time for urine culture and molecular tests[12]?						
		g) Instructions on how to perform AST conversions for automated, disk diffusion, Etest / Gradient and microdilution AST?						
		h) Definition of rare / unexpected AST results?						
		i) Confirmatory tests for unusual or unexpected patient AST results?						
Section 1: Documents & Records Subtotal								7

Section 2: Management Reviews

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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	U3.1	Is there evidence that laboratory staff have been trained in the following[13]:						
		a) Microscopic examination and urine cell count						
		b) Processing of urine samples for culture and molecular tests						3
		c) Detection / identification and AST of urinary pathogens						
		d) Interpretation of						

[12] From sample collection to reporting.

[13] 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
		urine culture and molecular test results						
		e) Reporting of urine culture and molecular test results						
		f) QC for urine culture and molecular tests						
		g) Laboratory safety						
3.7	U3.2	Is there evidence that laboratory staff are following the procedures described in the laboratory documentation?[14]						
		a) Microscopic examination and urine cell count						
		b) Processing of urine samples for culture and molecular tests						3
		c) Interpretation of urine culture and molecular test results						
		d) Identification and AST of urinal pathogens						
		e) Reporting of urine culture 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	U4.1	Is there evidence that the laboratory has provided clients information / instructions on urine collection, storage and transportation to the						3

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

SLIPTA			NA	Y	P	N	Comments	Score
		laboratory?						
4.1	U4.2	Is there evidence that the laboratory has provided clients information / instructions on interpretation of urine 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	U7.1	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						
		• UriSelect / CLED / or equivalent						
		• Mueller Hinton						
Section 7: Purchasing & Inventory Subtotal								2

[15] 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
SPECIMEN COLLECTION								
8.2 & 8.3	U8.1	Does the Laboratory Request Form have space to distinguish between MSU, suprapubic and urine collected from catheters[16]?						2
8.5	U8.2	If urine samples will reach the laboratory more than 2 hours post collection, are they transported to the laboratory on ice?						2
MEDIA QUALITY CONTROL								
8.8	U8.3	Does the laboratory perform QC testing on all media before use[17]?						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						

[16] Sample types must be distinguished to allow for correct processing & disaggregation of data.
[17] 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?						
		UriSelect or equivalent						
		Do QC records for UriSelect or equivalent agar plates demonstrate their ability to visualize lactose fermentation and Gram -positive organisms?						
		CLED or equivalent						
		Do QC records for CLED or equivalent agar plates demonstrate their ability to visualize lactose fermentation and Gram -positive organisms?						
		Mueller Hinton Agar (MHA)						
		Do QC records demonstrate that MHA plates are checked for their ability to grow *S. aureus* & *E. coli*?						
8.8	U8.4	Does the laboratory:						3
		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 supplier?						
8.10	U8.5	Does the laboratory determine the cause of failed QC (root cause analysis), perform corrective actions and measure the effectiveness thereof?						2

SLIPTA			NA	Y	P	N	Comments	Score
BACTERIAL URINE CULTURE PROCEDURE								
8.5	U8.6	Are all urine samples processed within 2 hours of collection, or a maximum of 4 hours after collection if transported on ice?						2
8.7	U8.7	Does the laboratory perform a cell count on all urine specimens prior to inoculation on culture media in order to determine the number of white blood cells in the urine?						2
8.7	U8.8	Does the laboratory have a procedure for rechecking cell counts to ensure consistency of microscopic observations/ interpretations among all personnel performing microscopy (wet prep and concentrated)?						2
8.7	U8.9	Does the laboratory examine the urine for parasites?						2
8.7	U8.10	Are reference materials, such as permanent mounts, photomicrographs, NCCLS documents M15-A and M28-A2, or printed atlases available at the work bench to assist with identification of parasites?						2
8.7	U8.11	Does the laboratory perform a bacterial culture on all urine samples (or those with cell counts > 10^5 white blood cells/mL) as per their policy?						2
5.9	U8.12	Are MSU and urine collected from catheters plated using a calibrated 1µL loop?						2
5.9	U8.13	Are suprapubic urines plated using a calibrated						2

SLIPTA			NA	Y	P	N	Comments	Score
		10µL loop?						
8.7	U8.14	Which of the following media are used for primary culture of urine?						
		• Blood Agar or equivalent						2
		• MacConkey Agar or equivalent						
		• UriSelect / CLED or equivalent[18]						
8.7	U8.15	Are media used for primary culture of urine incubated aerobically at 35-37°C for at least 18 hours?						2
8.7	U8.16	Does the lab use appropriate criteria for determining contamination of a urine culture specimen? (polymicrobial culture / no predominant colonies > 10^4 CFU)						2
GRAM NEGATIVE BACILLI ID & AST USING CONVENTIONAL METHODS								
8.7	U8.17	Does the laboratory perform identification tests (ID) for at least the following urinary pathogens? • *K. pneumoniae* • *E. coli*						2
8.7	U8.18	Does the laboratory perform AST on at least the following urinary pathogens using an approved test method? • *K. pneumoniae* • *E. coli*						2
8.7	U8.19	Is the following testing performed to identify Gram negative bacilli? • Oxidase • Indole • Methyl Red • Voges Proskauer • Citrate • Triple Sugar Iron or Kligler Iron						2

[18] UriSelect, cysteine-, lactose-, and electrolyte-deficient (CLED), if available, may replace Blood Agar and MAC

SLIPTA			NA	Y	P	N	Comments	Score
		• Urease • Motility						
8.7	U8.20	Does the lab follow the latest CLSI /EUCAST guidelines for AST of Gram negative bacilli?[19]						2
8.7	U8.21	Does the laboratory use Combination Disk Test or another equivalent method for Extended Spectrum Beta-Lactamase (ESBL) screening[20]?						2
8.7	U8.22	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	U8.23	Is the laboratory enrolled in an interlaboratory comparison or PT program for urine culture and molecular test organism identification, and AST?						2
8.14	U8.24	Did the laboratory pass the last 3 rounds of interlaboratory comparison or PT program testing?						2
8.14	U8.25	Does the laboratory receive onsite supervision visits as part of the EQA program for urine culture and molecular tests?						2
Section 8: Process Control Subtotal								52

[19] https://www.clsi.org / www.eucast.org/
[20] 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	U9.1	Does the final report for urine culture list the organisms for which the specimen was and was not cultured[21]?						2
9.3	U9.2	Does the laboratory report alert organisms which include at least[22]? • Imipenem resistant *K. pneumoniae* • Carbapenem resistant *Enterobacteriaceae* • ESBL producing organisms						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	U11.1	Are the following performance indicators collected[23]?						3
		• Number of urine culture and molecular tests performed (disaggregated by type)						
		○ Hospital-acquired[24]						
		○ Community-acquired[25]						

[21] 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.
[22] Alert organisms are organisms with significant public health threat and / or organisms that are notifiable.
[23] 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.
[39] 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
		○ Unknown/ referred[26]						
		• Number and percentage of samples for bacterial urine culture or molecular tests rejected (disaggregated by reason e.g. leaked, insufficient volume) (target <1%)						
		• Number and percentage of urine cultures with cell counts > 10^5 cells/ml						
		• Number of urine culture and molecular tests where pathogens were identified / isolated (disaggregated by type)						
		○ *K. pneumoniae*						
		○ *E. coli*						
		• Number and percentage of contaminated urine culture tests (disaggregated by in-patient/out-patient / unknown/referred)						
		• Urine culture and molecular test TAT[27] (disaggregated by in-patient & out-patient and type)						
Section 11: Occurrence/Incident Management & Process Improvement Subtotal								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)

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

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