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 Genital Samples

Genital

Version 2.4 – 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			%		%
Genital Module Total			**%**		**%**
Genital 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 genital samples?	Y / N		

B. Technical Information

N.A How many genital culture and other tests were performed last year[3,4]?

	Culture				Molecular				Others			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Adult vs. congenital												
Male adult												
Female adult												
Congenital (children)												
Symptomatic vs. contact tracing												
Symptomatic												
Contacts												
TOTAL												

Q = Quarter

N.B Are there any significant variations (> 20%) in the number of genital culture tests performed or organisms isolated or identified each quarter? If 'Yes', please explain[5]

[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] 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	N1.1	Does the laboratory have documentation covering the following processes?						
		a) Production of selective agar (Thayer-Martin, Martin-Lewis, GC-lect® or similar) and non-selective agar (chocolate agar or similar) for *N. gonorrhoeae* isolation?						
		b) Microscopic examination of smears						2
		c) Processing of samples for culture and molecular tests						
		d) Detection, identification and AST of *N. gonorrhoeae*						
		e) Reporting of *N. gonorrhoeae* culture and molecular test result						
		f) Interlaboratory comparison or proficiency testing (PT)						
		g) Laboratory safety						
1.5	N1.2	Are the documents complete, in-date and witnessed by all staff performing *N. gonorrhoeae* culture and molecular tests[6]?						2
1.5	N1.3	Are the following processes documented?						
		a) How to identify *N. gonorrhoeae* on all primary media? (SOP should						3

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

SLIPTA			NA	Y	P	N	Comments	Score
		describe colony appearance of *N. gonorrhoeae* and define how to proceed when potential *N. gonorrhoeae* is encountered)						
		b) Instructions for handling samples received after hours?						
		c) Instructions for referral of bacterial isolates for identification and AST?						
		d) Instructions on how to perform AST conversions for automated, disk diffusion, Etest / Gradient and microdilution AST?						
		e) Turnaround time for *N. gonorrhoeae* culture or molecular tests[7]?						
Section 1: Documents & Records Subtotal								7

Section 2: Management Reviews

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[7] 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	N3.1	Is there evidence that laboratory staff have been trained in the following[8]:						3
		a) Processing of samples for *N. gonorrhoeae* culture and molecular tests						
		b) Detection/ identification and AST of *N. gonorrhoeae*						
		c) Interpretation of microscopy smears for the detection of *N. gonorrhoeae*						
		d) Interpretation of *N. gonorrhoeae* culture and molecular test results taking into account any clinical information						
		e) Reporting of *N. gonorrhoeae* culture and molecular test results						
		f) QC, EQA & PT for *N. gonorrhoeae* culture and molecular tests						
		g) Laboratory safety						
3.7	N3.2	Is there evidence that laboratory staff are following the procedures described in the laboratory documentation?[9]:						3
		a) Processing of samples for *N. gonorrhoeae* culture and molecular tests						
		b) Interpretation of microscopy smears for the detection of						

[8] Review training records, competency assessment forms and duty rosters. Pay attention to date of training and scope of training compared with techniques being performed.
[9] Directly observe procedures being performed compared to the SOP.

SLIPTA			NA	Y	P	N	Comments	Score
		N. gonorrhoeae						
		c) Interpretation of *N. gonorrhoeae* culture and molecular test results						
		d) Identification and AST of *N. gonorrhoeae*						
		e) Reporting of *N. gonorrhoeae* 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	N4.1	Is there evidence that the laboratory has provided clients information / instructions on *N. gonorrhoeae* sample collection, storage and transportation to the laboratory?						3
4.1	N4.2	Is there evidence that the laboratory has provided clients information / instructions on interpretation of *N. gonorrhoeae* 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	N7.1	Is all media for *N. gonorrhoeae* culture, isolation, identification and AST stored correctly and in date (from date of manufacture media must be stored at 2-8 °C)[10]?						2
		• Selective media						
		• Non-selective media						
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
SPECIMEN COLLECTION								
4.1	N8.1	Does the laboratory request form have space for indicating gender, age, whether treatment has started (incl. start date) and whether the case is symptomatic or asymptomatic (contact tracing)?						2
4.1	N8.2	Are two samples collected (one for culture and one for PCR)?						2
4.1	N8.3	If multiple specimens are collected, are specimens for *N. gonorrhoeae* culture collected first?						2
4.1	N8.4	Has the laboratory ensured use of correct sample transportation systems (incl. transportation media)?						2
4.1	N8.5	Has the laboratory made sure that sample transportation time is kept						2

[10] According to manufacturer's requirements.

SLIPTA			NA	Y	P	N	Comments	Score
		under 12 hours?						
4.1	N8.6	Does the laboratory monitor sample rejection rate and take action when trends point to problems related to sample collection and transportation?						2
MEDIA QUALITY CONTROL								
8.8	N8.7	Does the laboratory perform QC testing on all media before use[11]?						3
		Selective media (Thayer-Martin/Martin-Lewis/GC-Lect® or equivalent)						
		Do QC records demonstrate that they are checked for their ability to suppress growth of normal flora (i.e. for anogential and/or nasopharyngyal samples) while allowing the growth of *N. gonorrhoeae*?						
		Non-selective media (GC-chocolate agar or equivalent)						
		Do QC records demonstrate that the nonselective media is checked for their ability to support growth of *N. gonorrhoeae*?						
8.8	N8.8	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 supplier?						
8.10	N8.9	Does the laboratory determine the cause of failed QC (root cause analysis), perform						2

[11] This includes in-house made or purchased from commercial sources.

SLIPTA			NA	Y	P	N	Comments	Score
		corrective actions and measure the effectiveness thereof?						
BACTERIAL GENITAL CULTURE PROCEDURE								
8.7	N8.10	Are the following media used for primary culture of genital samples? *Either Modified Thayer-Martin (MTM) agar, Martin-Lewis (ML) agar, GC-Lect® or equivalent, and GC-chocolate agar or equivalent.*						2
		• MTM agar, ML agar, GC-Lect® or equivalent						
		• GC-chocolate agar or equivalent						
8.7	N8.11	Are media used for primary culture of *N. gonorrhoeae* incubated at 35-37°C for at least 24 hours?						2
8.7	N8.12	Are media used for primary culture of *N. gonorrhoeae* incubated aerobically, in a humid environment with 5% CO_2?[12]						2
***N. GONORRHOEAE* IDENTIFICATION AND AST BY CONVENTIONAL METHODS**								
8.7	N8.13	For automated, kit-based, molecular or conventional methods for *N. gonorrhoeae* only: • When performing AST, are isolates used that have been incubated between 18 and 24 hours?						2
8.7	N8.14	Is identity of *N. gonorrhoeae* confirmed with biochemical tests to rule-out commensal *Neisseria* or *N. meningitidis?*						2
8.7	N8.15	Is the following testing performed for *N. gonorrhoeae* identification: • Gram stain • Oxidase • Catalase						2

[12] Use a CO_2 incubator or an alternative method.

SLIPTA			NA	Y	P	N	Comments	Score
		• Immunological tests • Biochemical identification tests						
8.7	N8.16	Is *N. gonorrhoeae* AST done as per current WHO or other approved guidelines?						2
INTERLABORATORY COMPARISON, PT AND EXTERNAL QUALITY ASSESSMENT (EQA)								
8.14	N8.17	Is the laboratory enrolled in an interlaboratory comparison or PT program for *N. gonorrhoeae* culture and molecular tests for organism identification and AST?						2
8.14	N8.18	Did the laboratory pass the last 3 rounds of interlaboratory comparison or PT program testing?						2
8.14	N8.19	Does the laboratory receive onsite supervision visits as part of the EQA program for *N. gonorrhoeae* culture and molecular tests?						2
Section 8: Process Control Subtotal								39

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	N9.1	Does the final report for *N. gonorrhoeae* culture list all the antibiotics for which the specimen was tested[13]?						2
Section 9: Information Management Subtotal								2

[13] The laboratory should inform the clinician for which antibiotics susceptibility was determined. Antibiotics to be tested for *N. gonorrhoeae* include 3rd generation cephalosporins (Cefixime and Ceftriaxone), fluoroquinolones (Ciprofloxacin), macrolides (Azithromycin), aminocyclitols (Spectinomycin), and aminoglycosides (Gentamycin). Assessors should review a number of laboratory reports to determine how results are reported. Procedures should be consistent with the laboratory's SOPs.

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	N11.1	Are the following performance indicators collected?						
		• Number of *N. gonorrhoeae* culture and molecular tests performed (disaggregated by type):						
		○ Male vs. female vs. congenital (children)						
		○ Symptomatic cases vs. contacts						
		○ By sample type						
		• Number and percentage of genital samples rejected (disaggregated by reason e.g. leaked, transportation time too long) (target <1%)						3
		• Number of culture tests *where N. gonorrhoeae* was isolated or identified						
		• *N. gonorrhoeae culture* and molecular tests TAT (disaggregated by in-patient/out-patient/unknown/ referred - from sample collection to reporting)						
Section 11: Occurrence/Incident Management & Process Improvement Subtotal								3

Section 12: Facilities and Biosafety

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

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