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Safeguarding Africa's Health

AMR
Laboratory Scorecard
USER GUIDE

Building AMR Testing and Management Capacity

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AFRICAN SOCIETY FOR LABORATORY MEDICINE

AMR

Laboratory Scorecard

USER GUIDE

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CONTENTS

Acronyms & Abbreviations

AMR	Antimicrobial Resistance
ASLM	African Society for Laboratory Medicine
AST	Antimicrobial susceptibility testing
BD	Becton Dickinson
CDC	Centers for Disease Control and Prevention
CFU	Colony Forming Units
CLSI	Clinical and Laboratory Standards Institute
EQA	External Quality Assurance
ESBL	Extended Spectrum Beta-Lactamase
EUCAST	European Committee on Antimicrobial Susceptibility Testing
FIND	FIND, the global alliance for diagnostics
GLASS	Global Antimicrobial Resistance Surveillance System
HAI	Hospital-acquired infection
ICMR	India Council for Medical Research
IFU	Instructions For Use
ISO	International Organization for Standardization
LIS	Laboratory Information System
LMIC	Low and middle-income countries
LQSI tool	Laboratory Quality Stepwise Implementation tool
MRSA	Methicillin-resistant Staphylococcus aureus
MSU	Mid-stream urine
NA	Not applicable
PEP	Post-exposure prophylaxis
PPE	Personal Protective Equipment
PT	Proficiency test
SLIPTA	Stepwise Laboratory Quality Improvement Process Towards Accreditation
SLMTA	Strengthening Laboratory Management Toward Accreditation
SOP	Standard Operating Procedure
WHO	World Health Organization
WHO-AFRO	World Health Organization Regional Office for Africa
XLD	Xylose Lysine Deoxycholate Agar

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The AMR Laboratory Scorecard draws from a number of existing tools, including Centers for Disease Control and Prevention Laboratory Assessment of Antimicrobial Resistance Testing Capacity checklist, ICMR (India Council for Medical Research) AMR Checklist, WHO-AFRO SLIPTA checklist and FIND's Score-TB package.

1. Guidance to the readers

This user guide instructs assessors on how to use the AMR Laboratory Scorecard for antimicrobial resistance (AMR) laboratory assessment. Chapter 2 starts with an explanation of the structure and contents of the AMR Laboratory Scorecard. Chapter 3 proceeds with a description of the required assessor competency profile, an explanation of how to schedule and perform assessments and describes the structure of the AMR Laboratory Scorecard. The chapter ends with instructions on how to report assessment findings.

Important: We assume that assessors are laboratory experts with experience in AMR testing and in Laboratory Quality Management. Therefore, this user guide does not provide detailed information on specific AMR tests. Instead, chapter 3 provides technical information and links to guidance and reference materials that provide essential background information for assessors. Specific technical information is also provided in the scorecards themselves. It is assumed that assessors using the AMR Laboratory Scorecard are already certified and competent in conducting laboratory assessments and that they comply with the required assessor competency profile described in section 3.1.

Background & rationale

The indiscriminate use and inappropriate and inadequate prescription of antibiotics, both in the human and animal health sectors, are primary contributing factors to the rapid increase of AMR worldwide [1]. AMR poses a serious challenge to global public health due to ineffective disease treatment options [2]. AMR is estimated to account for more than 700,000 deaths worldwide [1]. Successful treatment outcomes are significantly reduced due to the threat of rapidly increasing resistance of organisms to many antibiotics used in the treatment of infectious disease [3]. Recent reviews of AMR data from Africa have found a high level of resistance to commonly used antibiotics in the region [2-4]. The O'Neill report [2] highlights global gaps in surveillance, standardized procedures, and data management. Concerning is the lack of quality AMR data from many low- and middle-income countries (LMICs).

The role of the laboratory is to provide reliable, timely and accurate information for patient management and disease surveillance [5]. A functional surveillance system is essential for monitoring trends in antimicrobial susceptibility patterns to inform high-level decisions on national AMR policy [5]. Improving the quality of laboratory services and surveillance of AMR would contribute to better management, control, and prevention of infectious diseases [6]. However, implementing quality-assured clinical microbiology services faces numerous challenges, including infrastructure, equipment and supplies, technical and quality assurance [5]. Significant advances have been made in improving laboratory capacity and quality, for example through the Stepwise Laboratory Quality Improvement Process Towards Accreditation (SLIPTA) and Strengthening Laboratory Management Toward Accreditation (SLMTA) initiatives. Initiatives for improving quality of diagnostic services have tended to focus on the pre-analytical, analytical, and post-analytical phases of the laboratory testing process. However, the stages of the process that take place outside the laboratory have been shown to be key drivers of overall diagnostic quality and patient safety. Furthermore, in many settings, relationships between clinical and laboratory staff remain weak. Laboratory staff may not be fully represented in decision making processes and may not have adequate skills or status within the health system to advocate for the critical role of microbiology in patient management decisions. Poor quality laboratory services erode clinician trust in the value of laboratory testing to inform antimicrobial prescription, leading to reliance on empiric treatment. The SLIPTA initiative, while it has gone some way to facilitating laboratory improvement, it may not necessarily focus on quality specifically linked to laboratory processes involved in AMR (such as culture of specific samples, identification

and susceptibility testing). While implementing QMS elements is critical, improving the compliance to a technical standard of testing is equally important.

The ability to reliably isolate and identify bacterial pathogens and conduct antimicrobial susceptibility testing (AST) would enable selection of appropriate treatment leading to better patient outcomes, reduced cost and reduced antibiotic pressure for generation of AMR [6]. Data from such testing would enable local and national surveillance to inform treatment guidelines and allow aggregation of data and reporting to global surveillance mechanisms such as World Health Organization (WHO) Global Antimicrobial Surveillance System (GLASS) [7].

As such, the objective of this structured approach to building quality-assured AMR testing and management capacity is to: (1) provide tools for the assessment and quality improvement of microbiology laboratories to reliably isolate and identify priority bacterial pathogens and conduct AST in urine, feces, blood, genital, pulmonary and wound samples, and (2) to provide a tool to assess the effective use of laboratory data in antimicrobial stewardship practices, management of AMR/hospital-acquired Infections (HAI) and AMR outbreaks in health facilities.

The AMR Laboratory Scorecard focuses on the continuous improvement of technical procedures required for providing quality microbiology services:

- The modular structure ensures that the AMR Laboratory Scorecard can be used for internal or external assessment of a broad range of human and animal health microbiology laboratories, across a range of procedures;
- The AMR Laboratory Scorecard is ideally suited for assessment of microbiology laboratories that have a rudimentary QMS that wish to focus on improving their technical abilities;
- The AMR Laboratory Scorecard integrates into SLIPTA, enabling the assessment of the laboratory with both tools in parallel[1];
- A focus on data trends, providers assessors the opportunity to review the quality of technical testing through monitoring of key performance indicators.

Target audience

The AMR Laboratory Scorecard is intended to inform Ministry of Health officials, health facility- and laboratory managers, donors, implementing partners, quality assurance personnel, program managers and supervisory staff at national, regional and facility level on requirements for delivering quality-assured laboratory testing for AMR and ensuring effective use of laboratory resources as well as data for patient management and surveillance in LMIC.

1 *Note: The official star recognition system provided by ASLM can only be done through SLIPTA*

2. Overview

The collection, analysis and decimation of laboratory data to inform laboratory decision making and impact clinical patient care is a fundamental premise undergirding the use of the AMR Laboratory Scorecard. The scorecard supports the DIKW framework [8], namely:

- DATA: Reliably highlight abnormalities in laboratory data
- INFORMATION: Create new information by identifying data patterns
- KNOWLEDGE: Apply medical knowledge to interpret the clinical significance of patterns
- WISDOM: Translate clinical significance into an action that can improve outcome

The AMR Laboratory Scorecard focuses on the priority specimens and priority pathogens listed in GLASS [7]. It consists of the following components:

1. The User Guide
2. The AMR Laboratory Scorecard consisting of the following modules:

    a. General procedures
    Contains questions that are not related to one specific sample type but are relevant for all laboratories conducting AST on any type of sample. This scorecard should always be completed for each assessment.

    b. Bacterial culture, detection, identification and AST of blood samples
    Contains questions specific to S. aureus, coagulase-negative Staphylococcus, S. pneumoniae, Enterococcus sp., E. coli, K. pneumoniae, A. baumannii, Salmonella sp., Gram positive cocci, Gram negative bacilli and yeast testing on blood samples. Only applicable to laboratories that perform AST testing on these samples.

    c. Bacterial culture, detection, identification and AST of urine samples
    Contains questions specific to K. pneumoniae, E. coli, Gram positive cocci, Gram negative bacilli and yeast testing on urine samples. Only applicable to laboratories that perform AST testing on these samples.

    d. Bacterial culture, detection, identification and AST of feces samples
    Contains questions specific to Salmonella sp. and Shigella sp. testing on feces samples, only applicable to laboratories that perform AST testing on these samples.

    e. Bacterial culture, detection, identification and AST of genital samples
    Contains questions specific to Neisseria gonorrhoeae testing, only applicable to laboratories that perform this testing. This scorecard is only applicable for laboratories that perform identification, culture and AST for N. gonorrhoeae.

    f. Bacterial culture, detection, identification and AST of pulmonary samples
    Contains questions specific to S. aureus, S. pneumoniae, S. pyogenes, Moraxella catarrhalis, C. diphteriae, H. influenzae, K. pneumoniae and Mycoplasma pneumoniae testing on pulmonary samples. Only applicable to laboratories that perform AST testing on these samples.

    g. Bacterial culture, detection, identification and AST of wound samples
    Contains questions specific to S. aureus, S. pyogenes, Enterococcus sp., Enterobacteriaceae, and P. aeruginosa testing on samples from wounds.

Only applicable to laboratories that perform AST testing on these samples. The scorecard is available as hardcopy and in electronic format (referred to as the eTool).

3. The SLIPTA checklist
   In the AMR scorecards, references to SLIPTA checklist questions are given. In the eTool, the AMR scorecard questions are incorporated in the SLIPTA checklist, meaning that the scores on the AMR scorecard questions are incorporated in the calculation of the SLIPTA score.

Besides the AMR Laboratory Scorecard, FIND, the global alliance for diagnostics and BD also developed the Laboratory Clinical Interface AMR Assessment Scorecard. This scorecard specifically focuses on the interaction between the laboratory and the clinic and assesses quality and efficiency of processes in the pre-analytical phase (sample collection, transportation, reception at the laboratory) and the post-analytical phase (mainly reporting of results).

Additional resources

- WHO SLIPTA Checklist Version 2:2015

3. User Guide

This chapter explains how to schedule and perform assessments using the AMR Laboratory Scorecard and how to calculate and report assessment findings. In addition, references to essential guidance and reference materials are provided.

3.1 Required assessor competency profile

Assessments are objective measures to investigate compliance with standards and/or regulations. Assessments conducted using the AMR Laboratory Scorecard should yield detailed information on an AMR laboratory's quality in general, and the correct conduct of specific AMR diagnostic tests. It is therefore essential that assessors are competent and familiar with all the details of, and recommendations related to, the AMR tests he/she is going to assess. Therefore, the assessments using the AMR Laboratory Scorecard should only be conducted by SLIPTA certified assessors who, in addition, are:

- Familiar with AMR laboratory practice
- Well versed in, and knowledgeable of, the details related to the specific AMR tests included in the AMR Laboratory Scorecard.

3.2 Planning and performing assessments

Assessments are an effective means to: 1) determine if the AMR laboratory is providing accurate and reliable results for AMR; 2) determine if the AMR laboratory and clinical sites are well-managed and laboratory results are being reported and used effectively for clinical management and surveillance; and 3) identify areas for improvement.

The scorecard can be used in several ways:

1. For the assessment of a microbiology laboratory, the AMR Laboratory Scorecard can be used with or without the SLIPTA checklist as will be further explained below.
2. Assessors may elect to conduct the assessment using the paper-based scorecard with later entry of data into the eTool for score calculation, analysis, and reporting, or they may enter data directly into the eTool at the time of the assessment2. The eTool automatically calculates and presents the assessment results. When using the hardcopies the assessment scores should be calculated manually. It is therefore that the use of the eTool is recommended.
3. Assessors may elect to perform the SLIPTA assessment first and then the AMR assessment, or vice versa.
4. It is recommended that a minimum of two assessors perform the assessment, whereby one asks the questions and the second person records the answers.
5. The assessors should allow approximately 2-3 hours to complete each technical module.
6. The assessor should allow approximately 1.5 days to complete the SLIPTA checklist.
7. Assessors should discuss accessing data with the laboratory prior to performing the assessment. Laboratories should also be requested to provide key quality documents in advance of the assessment for review by the lead assessor. If the laboratory is unable to provide documentation in advance, assessors should schedule additional time to review documentation on-site. Alternatively, an additional assessor can be tasked with document review, while the other assessor(s) assess the technical

2 *Instructions on use of the eTool are provided within the eTool itself. Information and data collected in the paper-based scorecards and eTool are the same.*

aspects of the laboratory.

8. Laboratories should be requested to provide key quality indicator data (number of blood, urine, feces, genital, pulmonary and wound samples tested per test method, as well as the number of pathogens isolated and number of negative or contaminated cultures (where applicable). If these indicators are not being collected, assessors should schedule additional time to aggregate the data themselves.
9. For the assessment using the Laboratory Clinical Interface AMR Assessment Scorecard the assessment team should include a clinical microbiologist (if available) or a clinician with AMR experience. This assessment is estimated to take approximately four hours to complete depending on the size and complexity of the clinical facility and the number of departments to be included in the assessment (see the user guide of the Laboratory Clinical Interface AMR Assessment Scorecard).
10. Assessors should note that when planning assessments of multiple laboratories, the length of the visits will vary based upon four main factors:
    i. Number of laboratories to be assessed.
    ii. Size of the laboratories to be assessed.
    iii. Number of assessors on the assessment team.
    iv. Logistics and transportation considerations.

During the assessment, assessors should:

- Explain at the start of the assessment the scope of the assessment, the assessment method, and ensure that staff are comfortable to contribute to the assessment by making them understand that this is not a personal competency assessment but, instead, an assessment of the laboratory processes, and that the assessment is not intended to lead to disciplinary measures against individuals but to improve the functioning of the laboratory as a whole.
- Aggregate data and/or review existing quality indicator data to determine the number of tests by method type, as well as the number of positive results, AST outcomes and number of negative or contaminated cultures (where applicable).
- Review laboratory and documents to triangulate findings and verify that policies, manuals, Standard Operating Procedures (SOPs) and other documentation are complete, current, accurate, and annually reviewed.
- Review records and other relevant documents to verify that AMR policies are being followed.
- Observe laboratory operations to ensure:
    - laboratory testing follows written policies and procedures in pre-analytic, analytic and post-analytic phases of laboratory testing for AMR.
    - laboratory procedures are appropriate for the testing performed.
    - deficiencies and non-conformities identified are adequately investigated and resolved within the established timeframe.
- Ask open-ended questions to clarify documentation seen and observations made. Ask questions like, “show me how…” or “tell me about…” It is often not necessary to ask all the questions verbatim. An experienced assessor can often obtain answers to multiple questions at the same time through open-ended questions.
- Follow a patient specimen through the laboratory from collection through registration, preparation, analyzing, result verification, reporting, printing, and post-analytic handling and storing samples to determine the strength of laboratory systems and operations.
- Check whether proficiency testing (PT) results are reviewed and corrective action taken as required.
- Evaluate the quality and efficiency of supporting work areas (e.g., sample collection,

data registration and reception) and staff (phlebotomists, messengers, drivers, cleaners and IT) and oversight committees such as the Antimicrobial Stewardship Committee and the Hospital Surveillance/Outbreak Team[3].

3.3 The SLIPTA checklist

The AMR Laboratory Scorecard is designed to be used in parallel with the SLIPTA checklist (Version 2:2015). The SLIPTA checklist was developed by WHO Regional Office for Africa (WHO-AFRO), in collaboration with the African Society for Laboratory Medicine (ASLM), U.S. Centers for Disease Control and Prevention (CDC) and host countries. The objective of the checklist is to provide a framework for improving quality of (public) health laboratories in developing countries to achieve the requirements of the ISO 15189 standard. Since its inception in 2008, the SLIPTA checklist has undergone one revision in 2015. The current SLIPTA checklist (v2) can be downloaded from http://apps.who.int/iris/handle/10665/204423.

It is beyond the scope of this user guide to provide instructions on the use of the SLIPTA checklist. The SLIPTA checklist itself contains instructions for its use (see Part II of the SLIPTA checklist) and further instructions are provided in the SLIPTA Guide which can be downloaded at https://apps.who.int/iris/bitstream/handle/10665/333129/9789290234418-eng.pdf. Comprehensive training for SLIPTA auditors is provided by ASLM (http://www.aslm.org/what-we-do/slipta/).

3.4 The AMR Laboratory Scorecard

The AMR Laboratory Scorecard is available in hard-copy and electronic (eTool) formats. The eTool also contains a digital version of the SLIPTA checklist, whereby the AMR Laboratory Scorecard is merged with the SLIPTA checklist to enable calculation of one, overall, AMR-SLIPTA score for the laboratory. The Laboratory Clinical Interface Antimicrobial Resistance (AMR) Assessment Scorecard scoring is stand-alone.

3.4.1 Use of the scorecard

As indicated above: it is strongly recommended to use the eTool instead of the paper-based scorecard because the eTool enables automatic calculation of scores whereas with the paper-based scorecard this needs to be done manually, which is more prone to errors. The paper-based scorecard could, however, be convenient for use during the assessment to note findings on the printed scorecard with transcription into the eTool directly following the assessment. Moreover, it is not allowed to bring computers or tables into BSL3 facilities, necessitating the use of paper-based scorecards.

The AMR Laboratory Scorecard can be used in two ways when using the eTool:

1. One can use the AMR Laboratory Scorecard as a stand-alone scorecard while performing an internal audit for quality of testing for culture, identification and AST from blood, urine, fecal, genital, pulmonary and/or wound specimens.
2. One could use the AMR Laboratory Scorecard in parallel with SLIPTA as part of a comprehensive SLIPTA assessment to verify correct implementation of SLIPTA requirements, with a specific focus on AMR testing. The eTool will calculate scores for each module but will also calculate one, overall, SLIPTA score.

In the eTool, on the 'Set Audit Scope'-tab, the assessor can indicate which clinical materials are being tested. Based on the selection, the eTool will provide a list of links to modules that should be completed during the assessment.

3 *Names of these committees may vary between organizations and countries.*

In an assessment using the paper-based version of the scorecard, the answers to questions in the General Procedures technical scorecard should always be transcribed first into the "General AMR Module" of the eTool. When performing an assessment using the eTool, start with the "General AMR Module" before proceeding with the technical scorecards for the various sample types.

The Laboratory Clinical Interface AMR Assessment Scorecard is used in conjunction with the AMR Laboratory Scorecard and assesses the extent to which laboratory data is used effectively for patient management and surveillance within a health facility (-ies). Refer to the user guide of this scorecard for more detailed instructions.

3.4.2 Scoring

The AMR Laboratory Scorecard uses the same scoring system as the SLIPTA checklist. Each scorecard question has been awarded a point value of 2, 3, or 5 points—based on relative importance and/or complexity. Responses to all questions are rated as, "yes", "partial", or "no". Questions answered with "yes" receive the corresponding point value (2, 3, or 5 points). For questions with sub questions or "tick lists", all sub questions must be answered with "yes" to receive the maximum number of points.

- Questions marked "partial" receive 1 point.
- Questions marked "no" receive 0 points.
- When marking "partial" or "no", notes should be written in the comments field to explain why the requirement was not fulfilled.

Where a checklist question does not apply, this should be indicated as "NA". In this case, the question does not count for the calculation of the overall score. The eTool automatically omits questions answered with NA from the calculation of the overall score which is the reason for recommending the use the eTool to calculate the scores. If the paper-based scorecards are used instead of the eTool, the assessor should do this calculation manually. In this case, the assessor should calculate the sum of total possible points that can be scored with all questions answered with "NA" and subtract that from the total number of points that can be scored for the overall section. This prevents that laboratories for which certain questions are not applicable, are never able to reach the maximum score.

Example:

During an assessment, question F8.9 (of the Feces module): "In cholera endemic areas, does the laboratory perform an isolation procedure for Vibrio using TCBS and alkaline peptone water?" is answered with 'NA'. The total number of points that can be scored with this question is 2. The total number of points that can be scored in the Feces module is 146. But because this question is answered with 'NA', the two points for this question should be subtracted from the total number of points that can be scored in the Feces module, which, hence, becomes 144.

The scoring of the AMR technical modules is integrated into the SLIPTA scoring. The Laboratory Clinical Interface Antimicrobial Resistance (AMR) Assessment Scorecard scoring is stand-alone.

3.4.3 Information on the scorecard structure

The scorecard modules are used for assessing microbiology laboratories that analyze blood, urine, feces, wound and pulmonary samples for pathogenic bacteria and genital samples and other relevant samples for N. gonorrhoeae.

Below, detailed guidance is provided on completing each AMR Laboratory Scorecard module. The scorecard (with or without SLIPTA) can also be used for internal and external audits.

Scorecard structure

All modules have the same structure, consisting of three parts:

- Score
- Part A: General information
- Part B: Technical information

Score summarizes the scores for the assessment. This section should only be completed if the assessor uses the paper-based scorecard without the eTool as the eTool calculates the scores automatically.

If completing this section, assessors should note the date of the current assessment and the date of the previous assessment, if any. The total points scored for each module section should be transcribed to the place provided and the percentage for each section calculated (points of section divided by total points expressed as a percentage). Note that some questions may not be applicable which then affects the overall total of the module – assessors should replace the denominator and calculate score based on the percentage accordingly, as explained in paragraph 3.4.2. Once all the sections are completed, the total score and total percentage can be calculated. Stars are subsequently awarded based on the following thresholds:

	3 stars: 75% - 84%
1 star: 55% - 64%	4 stars: 85% - 94%
2 stars: 65% - 74%	5 stars: ≥95%

If a previous assessment has been performed, assessors should review the scores and note whether the laboratory has improved since the last assessment. Improvements and progress (or lack thereof) towards meeting laboratory assessment objectives should be reviewed with laboratory management (see 3.5 Reporting the assessment).

Part A: General information is compulsory for all assessments. The section is used to collect general information about the microbiology laboratory and provides the assessor the context for performing the assessment. The section is best completed by the facility manager (or equivalent) before the start of the assessment and verified at the start of the assessment at the laboratory.

Part B: Technical information, is the most elaborate part of the modules. The organisms listed in the various modules are priority organisms identified under GLASS (http://www.who.int/glass/en/), or frequently isolated pathogens.

In all modules, Part B starts with a section capturing quantitative data. In the General Procedures scorecard this part is most elaborate. Here, data is captured on procedures and methods used for detection, identification and AST of bacterial pathogens, on equipment availability, functioning, servicing and maintenance, and interpretation and reporting of results. In the sample-specific technical scorecards quantitative questions are mainly aimed at capturing data on the number of culture and molecular tests performed over the last year.

The question regarding equipment maintenance (General Procedures scorecard – question D) is common (with minor variations) to all the technical scorecards. Assessors need to ensure that all equipment used for testing has been assessed.

It is strongly recommended to ask the laboratory to complete the questions asking for quantitative data itself prior to the assessment, after which the assessors verify correct completion of this section at the start of the assessment. This is recommended because the collection of quantitative data will require time that might not be available during the assessment. It is also highly recommended that assessors obtain the necessary permission to review the laboratory data. However, if assessors are unable to review the laboratory,

quantitative data questions are NOT compulsory for completion of the assessments.

The remainder of Part B consists of 'closed'/multiple-choice questions. The same outline is used for all modules, following the SLIPTA checklist. The questions in each section supplement the questions of the SLIPTA checklist.

The closed/multiple-choice questions following the open-ended questions cover the following topics:

- **Section 1: Documents & Records**
  Questions covering documentation related to policies, processes, client instructions, and recording and reporting mechanisms specific for AMR testing. Documents can be requested and reviewed prior to the assessment. The answers are best verified together with the Laboratory Manager and/or the person responsible for the document control system.

- **Section 2: Management Reviews**
  Questions common to all testing procedures and covering the representation of the laboratory in, and the reporting of the laboratory to, various AMR-related committees. AMR oversight committees may be known by different names. Assessors should note that the relationship between the laboratory and the AMR oversight committees is bi-directional and review this relationship. The assessors should use their discretion to determine whether the requirements are met. Documents such as yearly reports can be requested and reviewed prior to the assessment. The answers are best verified together with the Laboratory Manager.

- **Section 3: Organization & Personnel**
  Questions covering staff training and whether staff are following procedures as described in the relevant SOPs. Training records, competency assessment reports and duty rosters can be requested and reviewed beforehand and verified with the Laboratory Manager and/or HR Manager. Whether staff follows procedures should be observed at the bench and directly observed with the SOP. Randomly choose a few techniques to observe.

- **Section 4: Client Management & Customer Service**
  Questions cover instructions for collection of samples and feedback to clinicians after testing. Instruction documents such as the Client Handbook can be requested and reviewed beforehand, feedback to clinicians can be discussed with the Laboratory Manager or Microbiologist and proof should be requested.

  Evidence that the laboratory has provided clients with information on blood, urine, feces, genital, pulmonary and wound sample collection and result interpretation may be difficult to determine. Assessors should ask for minutes of meeting or memos between the laboratory and oversight committees. If assessors will also be assessing the clinical site, evidence may be found during this assessment

- **Section 5: Equipment**
  Equipment questions covering the use of verified and validated methods, installation, location, and maintenance of equipment. These can best be discussed with the Equipment Officer (technical aspects) and the Quality Officer (verification and validation aspects).

- **Section 6: Evaluation and Audits**
  Questions related to internal & external audits. It is recommended that internal audits be conducted at least annually. External audits are conducted less frequently. These questions should be discussed with the Laboratory Manager or Quality officer.

- **Section 7: Purchasing and Inventory**
  Questions related to the use of correct specifications and the correct storage of reagents and supplies. These can be best discussed with the Stock Officer. Visit the storage area and observe a few reagents and supplies critical to correct performance, in particular antibiotics. Check storage conditions and expiration dates.

- **Section 8: Process Control**
  Process control is the most extensive section in all scorecards. Questions are related to the correct performance of the testing procedure, quality control, quality assurance and external quality.[4] Documents related to EQA scores can be requested and reviewed beforehand and discussed with the Laboratory Manager and/or Quality Officer. Execution of tests, including quality controls, should be discussed with the technical staff and observed at the bench and in the results recording ledger.

  IMPORTANT: Section 3.4.4 contains technical information for specific questions. When such information is available, this is indicated with the questions in the scorecard.

- **Section 9: Information Management**
  Questions covering the recording and reporting of individual test results and alerting authorities in case of organisms with significant public health threat and/or organisms that are notifiable. The questions can be best discussed and verified with the person responsible for report submission. The correct registration of results can best be checked for complex test result because transcription errors may be most prevalent there.

- **Section 10: Identification of Nonconformities, Corrective and Preventive Actions**
  Questions related to the identification and documentation of non-conformities, their analysis[5] and corrective actions. These questions can be best discussed with the Quality Officer. Documents describing non-conformities, their analysis and correction should be reviewed.

- **Section 11: Occurrence/Incident Management & Process Improvement**
  Questions related to the collection and reporting of performance indicators. Documents can be requested and reviewed beforehand and are best discussed and verified with the laboratory manager and/or person responsible for data management.

- **Section 12: Facilities and Biosafety**
  Questions covering the safe performance of testing and waste management. These can be best discussed with the Safety Officer and observed at the bench.

3.4.4 Technical details for specific scorecards

This section contains technical information for specific questions, or sets of questions, that can serve as background/reference for assessors to judge the situation and determine the answer to the questions.

4 *Quality Control: the activities undertaken during the testing procedure to ensure that results are reliable (in general: positive and negative controls).*
Quality Assurance: the activities undertaken before testing to ensure that results are reliable (such as trained staff, high quality materials and equipment, presence of documents such as SOPs).
External Quality Assessment: proficiency testing, blinded retesting and/or inspection visits by an external entity to assess the reliability of laboratory test results.

5 *Root Cause Analysis aims at identifying the underlying problem causing the non-conformity. Established techniques are the Ishikawa Diagram (https://en.wikipedia.org/wiki/Ishikawa_diagram) and the Five Times Why method (https://en.wikipedia.org/wiki/Five_whys).*

Question(s)	Technical information
General Procedures questions	
G1.4	Restrictive (selective or cascade) reporting is described in the following reference (Journal of Infection and Public Health, May. 2015, p. 234-241). Assessors should note that with cascade reporting, there is a risk that the suppressed AST results may be absent from the main data repository or Laboratory Information System (LIS), which can lead to highly biased AMR surveillance and cumulative antibiogram statistics. If the laboratory practices cascade reporting and has a LIS, it should be determined that that suppressed AST results are retained in the LIS or other main data repository.
G5.1	The main objective of validation and verification of methods is to demonstrate that an examination procedure is fit-for-purpose (J Laboratory Precis Med 2017;2:58). Use of non-validated / non-verified examination procedures are not uncommon in the laboratory. When used without modification, a validated examination procedure shall be **verified**, whilst non-standard methods, home brew methods, validated methods which have been modified or are being used outside their intended scope shall be **validated**. Assessors should note that ISO 15189 does not state any approach for method validation/verification, and the assessor will need to use their discretion when assessing the methods used to validate or verify an examination procedure: • What was the number of isolates tested (it is recommended that a minimum of 30 isolates are tested per panel for AST and a minimum of 20 isolates for identification)? • Did the identification & AST verification pass the reproducibility and accuracy testing for all antibiotics in use? • Did the identification & AST verification pass the minor error/ discrepancy and/or major error and very major error/ discrepancy for all antibiotics in use? In addition, assessors should pay special attention to QC methodology of each of the test methods, and cross-reference these with the procedures being performed (Section 8 of each module).
U8.4 / F8.2 / B8.2 / N8.8 / P8.2 / W8.2	Generally, long-term stock cultures of reference strains should be maintained at <-20°C in a freeze-dried state or in a suitable stabilizer (e.g. skimmed milk, 10% to 15% glycerol in tryptic soy broth, 50% fetal calf serum in broth, or defibrinated sheep blood). The first sub-culture (F1) from the frozen stock (reference stock culture) should be stored at 2-8°C for up to 4 weeks, then discarded. The F2 subculture from F1, or "Working stock culture" should be stored at 2-8°C for up to 1 week, then discarded. The F3 subculture from F2 should be performed daily (or as needed), and then discarded after one day of use. Consult the CLSI M100 manual and/or EUCAST QC tables for recommended ATCC strains for internal QC. Other useful overviews are provided by ATCC itself and NCTC (British National Collection of Type Cultures).

Question(s)	Technical information
General Procedures questions	
G8.6	These questions contain the requirements for performing conventional bacterial AST for the listed organisms. CLSI and EUCAST require that antibiotic disk QC is performed each day of patient testing, not only when a new lot number is received. Laboratories that wish to reduce the frequency of antibiotic disk QC from daily to weekly may do so after demonstrating satisfactory performance with daily QC using one of two plans (20-30-day plan or the 15-replicate (3 x 5-day plan)). These methods are described in CLSI M02, Section 4.7. Assessors should consider the following CLSI/EUCAST recommendations when assessing the AST procedures of the laboratory. When preparing the inoculum, the laboratory should use an appropriate, sterile inoculation medium (e.g. TSB or saline). A sterile swab used to inoculate the plate, and the inoculum should be spread in a way that will create an even lawn. Assessors should examine several random AST plates to determine whether the lawns of growth are confluent (no gaps or individual colonies showing). Before applying disks/strips, the plates should sit, lid-ajar, for three up to (but not more than) 15 minutes to allow absorption of excess surface moisture. Assessors should also determine the number of and proximity of disks on AST plates (there should be no more than 6 antibiotic disks per 100mm plate, 12 antibiotic disks per 150mm plate and the disks should be placed 24mm from center to center, with no overlapping zones, but not too close to the plate edge). Assessors should consider the following regards the reading of ASTs. ASTs should not be read in less than 16 hours or more than 24 hours of incubation. If individual colonies are apparent within the zone of inhibition, the laboratory should repeat the test from a fresh sub-culture of a single colony from the original plate. Assessors should determine whether the laboratory possesses a guidance document with photos describing how to measure zone sizes, such as the CLSI M02 or the EUCAST disk diffusion reading guides. Similar guides should be available for gradient strip endpoints if these are performed.
U8.17 – U8.22 / F8.12 – F8.18 / B8.11 – B8.19 / N8.13 – N8.16 / P8.7 – P8.21 / W8.7 – W8.15	These questions contain the requirements for performing conventional bacterial identification and AST for the listed organisms. Assessors should note that the tests (and the combination of tests) to identify bacteria vary considerably. Assessors should note the identification test(s) in use. Assessors should use their discretion in determining whether the identification tests performed are adequate to identify pathogen(s) in question. If the assessor determines that the test (or the combination of tests) is adequate to identify the pathogen then the question should be marked as "Yes", and the full points awarded. Similarly, if the assessor determines that the test (or the combination of tests) is inadequate to identify the pathogen then the question should be marked as "No", and no points should be awarded. Procedures should be consistent with the CLSI/EUCAST guidelines for AST (see question G in the General Procedures technical checklist), and the laboratory's SOPs (U1.1 / F1.1 / B1.1 / N1.1 / P1.1 / W1.1). Note that for *N. gonorrhoea* AST should be performed as per the current WHO or other approved guidelines.

Question(s)	Technical information
General Procedures questions	
U8.20 / F8.15 & F8.16 / B8.12, B8.13, B8.15, B8.17 / N8.16 / P8.8, P8.9, P8.11, P8.14 - P8.16, P8.18, P8.19 / W8.8, W8.9, W8.11, W8.13	Assessors should note that the antibiotics (and the combination of antibiotics) tested by laboratories vary considerably. Assessors should use their discretion in determining whether the antibiotics tested are appropriate for the pathogen(s) in question (e.g. antibiotics commonly used to test gram positive organisms are not being used to test gram negative organisms, and vice versa). If the assessor determines that the antibiotics being tested (or the combination of antibiotics) is appropriate, then the question should be marked as "Yes", and the full points awarded. Similarly, if the assessor determines that the antibiotics being tested (or the combination of antibiotics) is inappropriate, the question should be marked as "No", and no points should be awarded. Procedures should be consistent with the laboratory's SOPs (U1.1 / F1.1 / B1.1 / N1.1 / P1.1 / W1.1).
U8.21 / F8.17 / B8.18 / P8.20 / W8.14	If the laboratory does NOT use current cephalosporin and aztreonam breakpoints it must perform routine ESBL phenotypic testing. The ESBL phenotypic testing method should include testing both cefotaxime (or ceftriaxone) AND ceftazidime alone and in combination with clavulanic acid. For ESBL-positive isolates, all penicillins, cephalosporins, and aztreonam that test susceptible must be reported as resistant and there must be a practice in place for changing ESBL positive interpretations from susceptible to resistant. In addition, if the laboratory does use current aztreonam and cephalosporin breakpoints, it should attach a warning comment to the report for ESBL positive organisms: "ESBL-producers should be considered clinically resistant to all penicillins, cephalosporins, and aztreonam." (also see U9.2 / F9.2 / B9.2 / P9.2 / W9.2). For laboratories that DO use current cephalosporin and aztreonam breakpoints, CLSI and EUCAST no longer recommends routine testing for ESBL phenotype. Furthermore, if ESBL testing is performed and the test is positive, interpretations for beta-lactamase agents do NOT need to be changed from susceptible to resistant. Assessors should determine whether the laboratory has discontinued editing AST results based on the ESBL result. Finally, assessors should determine whether the laboratory uses both positive and negative control organisms for QC for the ESBL test in use. A commonly used ESBL positive strain is *Klebsiella pneumoniae* ATCC 700603 (also see U8.4 / F8.2 / B8.2 / N8.8 / P8.2 / W8.2).
U8.22 / F8.18 / B8.19 / P8.21 / W8.15	If the laboratory does NOT use current carbapenemase breakpoints it must perform routine testing for carbapenemase production (e.g. CarbaNP, mCIM, or a molecular assay). If a carbapenemase is detected, all carbapenems that test susceptible must be reported as resistant. The assessor should determine whether there is a practice of changing positive interpretations from susceptible to resistant based on positive carbapenemase test result. For laboratories that DO use current carbapenem breakpoints, CLSI and EUCAST no longer recommends routine testing for carbapenemase production. Furthermore, if such testing is performed and the test is positive, interpretations for carbapenems do NOT need to be changed from susceptible to resistant. Assessors should determine whether the laboratory has discontinued editing AST results based on the carbapenemase result.

Question(s)	Technical information
General Procedures questions	
	Finally, assessors should determine whether the laboratory uses both positive and negative control organisms to QC for the carbapenemase test in use. Commonly used carbapenemase positive strains include *Klebsiella pneumoniae* ATCC BAA-170S, CCUG I 56233, and NCTC 13438 (also see U8.4 / F8.2 / B8.2 / N8.8 / P8.2 / W8.2).
U8.23 – U8.25 / F8.19 – F8.21 / B8.20 – B8.22 / N8.17 – N8.19 / P8.22 – P8.24 / W8.16 – W8.18	Assessors should request inter laboratory, PT or EQA reports to determine whether the laboratory complies with the requirements. If the laboratory performs molecular methods for detection and / or identification, these must be included in PT testing. All laboratories should form part of a support monitoring / oversight / mentoring network. Reference laboratories should be overseen by other reference laboratories and / or international supranational reference laboratories. Reference laboratories should also be involved in monitoring / overseeing and mentoring laboratories lower in the network (e.g. regional laboratories).
Urine module	
U8.12 & U8.13	The minimum requirement for processing mid-stream urine (MSU) and urine collected from catheters is plating using a calibrated 1µL loop. The minimum requirement for processing suprapubic urines is plating using a calibrated 10µL loop. Assessors should determine whether the Laboratory Requisition Form makes provision for sample type (see U8.1). Review of a number of Laboratory Requisition Forms should be used to determine whether the forms are being correctly filled.
U8.14	Assessors should determine the media used for primary isolation of pathogens in urine. While Blood Agar and MacConkey Agar are recommended, if the laboratory uses equivalent media or selective media (e.g. Uriselect) this is acceptable. Assessors must use their discretion in determining whether media in use are adequate to isolate urine pathogens (also see U8.3).
U8.16	Assessors should note that a minimum requirement for the laboratory is the use of appropriate criteria for determining contamination of a urine culture specimen (e.g. polymicrobial culture / no predominant colonies > 10^4 colony forming units (CFU)). Procedures should also be consistent with the laboratory's SOPs (U1.1).
Feces module	
F8.7	Assessors should determine the media used for primary isolation of pathogens in feces. While SS Agar is recommended, if the laboratory uses equivalent media (e.g. Hektoen Enteric Agar, Xylose Lysine Deoxycholate Agar (XLD), or Deoxycholate Citrate Agar (DCA) this is acceptable. Assessors must use their discretion in determining whether media in use in adequate to isolate fecal pathogens. However, laboratories must use a selective broth (e.g. Selenite or GN) plated onto a selective media for fecal pathogen isolation (also see F8.1 & F8.9).
Blood module	
B8.4 – B8.10	Incubation of blood for a minimum of five days is a minimum standard requirement. Assessors should pay particular attention to incubation time if manual or non-validated blood cultures methods are performed. Typically, the laboratory should:

Question(s)	Technical information
General Procedures questions	
	• On each day of incubation, visually examine all bottles for signs of positivity (turbidity, hemolysis, gas production). • After 24 hours of incubation, subculture all bottles that appear negative. • After 48 hours of incubation, subculture all bottles that appear negative again (if the first subculture was negative). • Subculture bottles that appear negative to a chocolate agar plate (incubated in 5% $C0_2$) to ensure recovery of fastidious organisms. • Incubate all bottles between 5 and 7 days before issuing a final negative report. • On the final day of incubation, perform a terminal subculture before the final negative report is issued.
B8.12	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.
B8.12 & B8.13	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.
B8.15	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.
Genital module	
N8.16	Neither CLSI nor EUCAST provide specific guidelines for AST of *N. gonorrhoeae.* Therefore, this question refers to WHO or other *approved* guidelines for this pathogen.
Pulmonary module	
P8.4 – P8.6	More information on pulmonary culture procedures (for both upper and lower respiratory tract infections) can be found on the following web-pages: • Lower respiratory tract infections (S. pneumoniae, M. catarrhalis, S. aureus, H. influenzae, K. pneumoniae): http://helid.digicollection.org/en/d/Jwho01e/4.5.html • Upper respiratory tract infections (S. pyogenes & C. diphteriae): http://helid.digicollection.org/en/d/Jwho01e/4.6.html Culture procedures are rarely used for *M. pneumoniae*. Instead, immunoassays, serological assays and PCR are recommended.

Question(s)	Technical information
General Procedures questions	
P8.4	Several non-selective and selective media are used for bacterial culture of pulmonary specimens and identification of pathogens causing respiratory tract infections. • Blood agar: supports growth of fastidious organisms. • MacConkey agar: used for isolation of non-fastidious gram negative rods, including K. pneumoniae. See: https://microbenotes.com/macconkey-agar/ • Chocolate agar: promotes the growth of fastidious bacteria. Haemophilus species require this enriched medium, hence, chocolate agar is used to isolate H. influenzae. See: https://microbenotes.com/chocolate-agar/ • Tellurite agar: selective medium for the isolation of C. diphteriae. Tellurite inhibits the growth of most upper respiratory tract bacteria and gram-negative rods and is reduced by C. diphtheriae, producing characteristic gray to black color on agar. For the complete procedure see: https://microbenotes.com/laboratory-diagnosis-treatment-and-prevention-of-corynebacterium-diphtheriae/ • New York City medium: originally developed to for selective isolation of Neisseria species, it is also useful in the diagnosis of mycoplasma infections. See: https://microbenotes.com/new-york-city-agar/#more-3047 More information on pulmonary culture procedures (for both upper and lower respiratory tract infections) can be found on the following web-pages: • Lower respiratory tract infections (S. pneumoniae, M. catarrhalis, S. aureus, H. influenzae): http://helid.digicollection.org/en/d/Jwho01e/4.5.html • Upper respiratory tract infections (S. pyogenes & C. diphteriae): http://helid.digicollection.org/en/d/Jwho01e/4.6.html
Wound module	
W8.1	Columbia CNA Agar is recommended for use as a selective growth medium for the isolation and differentiation of gram-positive cocci from clinical and non-clinical specimens which contain mixed flora. Can be used for isolation of (among others) *S. pyogenes, S. aureus,* and *Enterococcus sp.*. See for more information, including quality control strains and result interpretation: https://www.bd.com/resource.aspx?IDX=8969.
W8.4 – W8.6	More information on wound culture procedures can be found on the following web pages: • https://www.asmscience.org/content/book/10.1128/9781555818814.chap3.13 • http://helid.digicollection.org/en/d/Jwho01e/4.8.6.html

3.4.5 Additional information

Testing methods may vary between laboratories. The most important factors to take into consideration when performing an assessment is that the laboratory performs testing according to validated methods (according to manufacturer's instructions where applicable) and follows SOPs. Reporting should follow the latest EUCAST or CLSI guidelines.

A list of background information is provided below:

Resource	Description
GLASS and partners	
Global Antimicrobial Resistance Surveillance System (GLASS)	Homepage of GLASS. GLASS promotes and supports a standardized approach to the collection, analysis and sharing of AMR data at a global level.
WHONET	WHONET landing page.
GLASS Laboratory page	References to microbiological standards and tools.
GLASS partnerships	Links to regional surveillance networks.
WHO AMR Resource page	Links to important WHO resources related to AMR.
CLSI and EUCAST	
CLSI Microbiology standards	Landing page to obtain CLSI microbiology standards.
CLSI M100 (30th edition)	Updated tables for the CLSI AST standards M02, M07, and M11.
EUCAST AST	Landing page for all information related to AST in bacteria.
AST using the EUCAST method	Videos on how to perform AST using EUCAST recommended methods and interpretation.
EUCAST clinical breakpoints and guidance (version 2020)	Links to PDF and Excel files with clinical breakpoints and guidance on how to use them.
WHO Guide: Laboratory diagnosis of sexually transmitted infections, including human immunodeficiency virus	Current WHO guideline for *N. gonorrhoeae.*
Laboratory Quality Management	
WHO Laboratory Quality Management System Handbook	Handbook for understanding the structure and requirements of a laboratory QMS based on international standards.
WHO Laboratory Quality Management System training toolkit	Training materials for understanding the structure and requirements of a laboratory QMS based on international standards.
WHO Laboratory Quality Stepwise Implementation (LQSI) tool	The LQSI tool provides a roadmap for stepwise implementation of a laboratory QMS based on international standards for (public) health laboratories
Biosafety	
WHO Laboratory Biosafety Manual	This manual provides information and explanation on biosafety requirements for medical laboratories.
Miscellaneous	
Overview of the phenotypic, genotypic, and emerging techniques for AST	Publication by Kha n et al., (2019) Diagnostics (Basel), 9(2):49
Restrictive reporting of AST	Publication by Al-Tawfiq et al., (2015). J. Inf Public Health, 8(3):234-241
Verification or validation	Publication by Antonelli et al., (2017). J. Laboratory. Prec. Med., 2:58
Stock maintenance	ATCC presentation of best practices for stock maintenance with regard to passage, storage, recovery, and microbial authentication, and how ATCC manages these through the seed stock concept

3.5 Reporting the assessment

During the assessment:

1. Fill in the General Procedures scorecard and the scorecards for all sample materials on which AST is performed in the laboratory as well as the Laboratory Clinical Interface AMR Assessment Scorecard. Do this either using the paper-based version or directly into the eTool (recommended).
2. Optional: fill in the SLIPTA checklist.

At the end of the assessment, the assessor must:

3. Transcribe all scores from the paper-based versions into the eTool (if applicable).
4. The eTool will automatically calculate the score and the number of stars for each of the AMR Laboratory Scorecards (see "AMR summary report" worksheet). If the SLIPTA checklist has also been completed the eTool will automatically calculate the SLIPTA score, incorporating the scores on the AMR Laboratory Scorecards.
   NOTE: Calculating the score by hand is complex due to the possibility of "not applicable" answers that influence the total number of points that can be scored (see section 3.4.2). Calculating the score by hand is thus prone to errors. We therefore strongly recommend using the eTool to calculate the score.
5. Identify recommendations for improvement (for questions with "No" and "Partial" answers), and report these to the laboratory during the meeting with the laboratory management (point 6) and in the final report (point 7). Where possible, the assessor should support their findings with tools which could the help the laboratory to address the areas for improvement (see also section 3.4.4 and 3.4.5 for guidance and reference materials).
6. Meet with the laboratory staff and management and communicate the overall findings of the assessment. The assessor should use the format suggested in the SLIPTA checklist (Summary). i.e. report noted commendations, noted challenges and recommendations. Where possible, the assessor should support the commendations & challenges with examples from the assessment. The assessor can also present the number of stars scored on the AMR Laboratory Scorecard and the SLIPTA checklist, if applicable (see point 4).

After the assessment:

7. Within two weeks after the assessment, the assessor must submit a final report to the laboratory. The report should include a copy of the completed AMR Laboratory Scorecard and Laboratory Clinical Interface AMR Assessment Scorecard (and SLIPTA checklist if applicable) as well as the observed nonconformities and recommendations.

The list of recommendations for improvement should be communicated in the form of nonconformities and must be graded as major or minor:

- Major nonconformities are those non-conformities that directly influence the quality of the work performed and therefore require urgent action.
- Minor nonconformities are those that may indirectly compromise quality of the work performed and should be addressed after major nonconformities have been resolved.

Further to this it is advisable to prioritize the recommendations to assist the laboratory with implementing/improving its QMS in a logical and rational way.

The laboratory is responsible for addressing the nonconformities through its own corrective action system. Support to the laboratory to address nonconformities is beyond the scope of the assessment but can be provided in the form of a mentor program.

References

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African Union

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Safeguarding Africa's Health

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