



AMR VETERINARY

Laboratory Scorecard

USER GUIDE

Building AMR Testing and
Management Capacity Utilizing

VERSION 1.1 – SEPTEMBER 2021

IN PARTNERSHIP WITH



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Acronyms & Abbreviations

AMR	Antimicrobial Resistance
AMR CC	AMR Coordination Committee
AMU	Antimicrobial Use
ASLM	African Society for Laboratory Medicine
AST	Antimicrobial Susceptibility Testing
ATLASS	Assessment Tool for Laboratories and AMR Surveillance Systems
CCDA	Charcoal-Cefoperazone-Deoxycholate Agar
CDC	Centers for Disease Control and Prevention
CFU	Colony Forming Units
CLSI	Clinical and Laboratory Standards Institute
DCA	Deoxycholate Citrate Agar
EQA	External Quality Assessment
ESBL	Extended Spectrum Beta-Lactamase
EUCAST	European Committee on Antimicrobial Susceptibility Testing
FAO	Food and Agriculture Organization of the United States
FIND	FIND, the global alliance for diagnostics
GLASS	Global Antimicrobial Resistance Surveillance System
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
MAC	MacConkey agar
MHA	Mueller Hinton Agar
MIC	Minimal Inhibitory Concentration
MRSA	Methicillin-Resistant Staphylococcus aureus
MS	Mass Spectrometry
MSA	Mannitol Salt Agar
NA	Not applicable
NCCLS	See CLSI
OIE	World Organisation for Animal Health
PCR	Polymerase Chain Reaction
PPE	Personal Protective Equipment
PT	Proficiency Testing
PYR	Pyrrolidonyl Arylamidase
QC	Quality Control
SLIPTA	Stepwise Laboratory Quality Improvement Process Towards Accreditation
SLMTA	Strengthening Laboratory Management Toward Accreditation
SOP	Standard Operating Procedure
SS agar	Salmonella Shigella agar
TAT	Turnaround Time
TSB	Tris-Buffered Saline
TWG	Technical Working Group
VetCAST	EUCAST Veterinary Subcommittee on AST
WHO	World Health Organization
WHO-AFRO	World Health Organization Regional Office for Africa
XLD agar	Xylose Lysine Deoxycholate Agar

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The AMR Veterinary Lab 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-Building quality-assured tuberculosis testing and management capacity utilizing SLIPTA methodology.

1. Guidance to readers

This user guide instructs assessors on how to use the AMR Veterinary Laboratory Scorecard (AMR Vet Lab Scorecard) for antimicrobial resistance (AMR) assessment of veterinary laboratories. Chapter 2 starts with an explanation of the structure and contents of the AMR Vet Lab Scorecards. 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 Vet Lab Scorecard. The chapter ends with instructions on how to report assessment findings.

Important: We assume that assessors are laboratory experts with experience in veterinary AMR testing and 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, or references to technical information is also provided in the scorecards themselves. It is assumed that assessors using the AMR Vet Lab 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 reduced efficacy of antimicrobial-based disease treatment options. It is estimated to account for more than 700,000 deaths per year worldwide [2]. The antimicrobial use (and misuse) in the human, animal, and environmental sectors, along with the global-scale spread of the resistance mechanisms within and between these sectors are identified as the major AMR driving forces [3,4].

Recent reviews of AMR data from Africa have found a high level of resistance to commonly used antibiotics in the region [2,5,6]. Most of the antimicrobial classes employed in the treatment of human infections are shared with the veterinary sector. Misuse of antimicrobials can result in an increased, cumulative selective pressure exerted to microorganisms which in turn can lead to resistance and, hence, reduced efficacy of the antimicrobial-based treatments [4,7]. Subsequent spread of resistance in both human, veterinary and environmental fields can occur through direct or indirect contact through food, water, and animal waste application to farm fields [8].

The O'Neill report highlights global gaps in surveillance, standardized procedures, and data management [2]. Concerning is the lack of quality AMR data from many low- and middle-income countries (LMICs). A functional surveillance system is essential for monitoring trends in antimicrobial susceptibility patterns to inform high-level decisions on national AMR policy

[9]. To successfully monitor the antimicrobial susceptibility of bacterial pathogens, it is vital that veterinary diagnostic laboratories are incorporated into surveillance activities [10].

Veterinary laboratories fulfil an essential role in the delivery of veterinary services by providing data and information for animal disease detection, control and prevention [11]. Usual purposes for which laboratory testing is conducted include [12]:

- Demonstration of freedom from infection in defined animal populations
- Certification of freedom from infection in individual animals or products for trade/movement purposes
- Contributions to the elimination of infection from defined populations
- Confirmation of diagnosis of suspect or clinical cases
- Estimation of prevalence of infection or exposure
- Determination of the immune status of individual animals or populations.

From a public health perspective, well-functioning veterinary laboratories are indispensable for monitoring AMR among animal populations. Antimicrobial susceptibility testing (AST) is an important component of prudent antimicrobial use guidelines in animal husbandry worldwide and veterinarians in all countries should have these data available for informed decision-making [9,13]. The ability to reliably isolate and identify bacterial pathogens and conduct AST would enable selection of appropriate treatment leading to better outcomes, reduced cost and reduced antimicrobial pressure for generation of AMR [14]. Data from such testing would also 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) [15].

Apart from the delivery of diagnostic and surveillance services, a veterinary laboratory is held accountable for a range of other issues which include health and safety, biosecurity, animal welfare and ethics, environmental contamination, genetic manipulations and quality assurance. It is therefore essential that processes are established for the proper management and reporting of these issues [12]. However, implementing quality veterinary microbiology services faces numerous challenges, including infrastructure, equipment and supplies, technical and quality assurance [9]. In human health, 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. The World Organisation for Animal Health has developed standards and guidance for quality management in veterinary laboratories and AST [16]. Similarly, the Food and Agriculture Organization (FAO) action plan on AMR 2016-2020 highlights strengthening of surveillance systems in the veterinary and environmental fields as a priority. Key activities focus on improving laboratory capacity on AMR and antimicrobial residue monitoring through laboratory mapping and assessment of existing capacities at national levels, supporting revision and uptake of guidelines for AMR monitoring and surveillance programmes, and providing assistance to countries on preparing and implementing national plans to improve integrated surveillance and monitoring of AMR

and antimicrobial use (AMU) [17]. However, initiatives similar to SLIPTA and SLMTA specifically focused on assisting veterinary laboratories to meet international standards for quality and competence in a stepwise fashion do not yet exist.

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 veterinary microbiology laboratories to reliably isolate and identify priority bacterial pathogens and conduct AST in fecal and milk samples, and (2) to provide a tool to assess the effective use of laboratory data in antimicrobial stewardship practices and management of AMR and AMR outbreaks in animal populations.

Target audience

The AMR Vet Lab Scorecard is intended to inform Ministry of Environment and Food officials, veterinarians and veterinary laboratory managers, donors, implementing partners, quality assurance personnel, program managers and supervisory staff at national, regional and facility levels on requirements for delivering quality-assured veterinary laboratory testing for AMR and ensuring effective use of laboratory resources as well as data for animal disease management and surveillance in LMIC.

2. Overview

The collection, analysis and decimation of laboratory data to inform decision making and impact clinical care and surveillance capacity is a fundamental premise undergirding the use of the AMR Vet Lab Scorecard. The scorecard supports the DIKW framework [18], 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 Vet Lab Scorecard focuses on the priority specimens and priority pathogens, including those listed in GLASS [15]. It consists of the following components:

1. The User Guide
2. The AMR Vet Lab 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 fecal samples
Contains questions specific to testing for Salmonella sp., E. coli, Enterococcus sp., Campylobacter sp. and other isolates on fecal samples, only applicable to laboratories that perform this type of testing.
 - c. Bacterial culture, detection, identification and AST of milk samples
Contains questions specific to testing for S. aureus, S. agalactiae, S. uberis, C. bovis, K. pneumoniae, E. coli, P. aeruginosa, Mycoplasma spp. and other isolates on milk samples, only applicable to laboratories that perform this type of testing.

The scorecards are available as hardcopy and in electronic format (referred to as the eTool).
3. The SLIPTA checklist
The SLIPTA checklist is primarily based on ISO 15189:2012, the international standard for quality and competence of medical laboratories. Veterinary laboratories generally aim to implement a quality management system based on ISO 17025, the international standard for quality and competence of test and calibration laboratories. However, both standards, being based on the ISO 9001 standard with more generic requirements for a quality management system, are for a large part similar¹. In absence of a similar tool for

¹ Whereas the outlines of previous versions of the ISO 17025 standard were comparable, the outline and approach to quality management system establishment of the latest version of ISO 17025 published in 2017 is different from the latest

this standard, the use of the SLIPTA checklist by veterinary laboratories is recommended to assess implementation and functioning of basic quality management system elements.

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.

Additional resources

- WHO SLIPTA Checklist Version 2:2015

version of ISO 15189 published in 2012. However, the next version of ISO 15189 is expected in 2021 and will again be similar to ISO 17025:2017 in terms of both outline and approach.

3. User Guide

This chapter explains how to schedule and perform assessments using the AMR Vet Lab 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 Vet Lab 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 Vet Lab 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 Vet Lab 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 Vet Lab 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.

² Full 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.

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 aspects of the laboratory.
8. Laboratories should be requested to provide key quality indicator data (number of fecal and milk 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. 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 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 (messengers, drivers, cleaners and IT) and representation on oversight committees such as the AMR surveillance TWG and the AMR coordinating committee³.

3.3 The SLIPTA checklist

The AMR Vet Lab Scorecard is designed to be used in conjunction 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 <https://apps.who.int/iris/handle/10665/204423>. Although the SLIPTA checklist was developed for human health laboratories and based on ISO 15189, the questions are also relevant for QMS implementation in veterinary laboratories based on ISO 17025 (see Chapter 1).

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 (<https://aslm.org/what-we-do/#slipta>).

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

3.4 The AMR Vet Lab Scorecard

The AMR Vet Lab Scorecard is available in hard-copy and electronic (eTool) formats. The eTool also contains a digital version of the SLIPTA checklist, whereby the AMR Vet Lab Scorecard is merged with the SLIPTA checklist to enable calculation of one, overall, AMR-SLIPTA score for the laboratory.

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 Vet Lab Scorecard can be used in two ways when using the eTool:

1. One can use the AMR Vet Lab Scorecard as a stand-alone scorecard to assess the quality of testing for culture, identification and AST from fecal and milk samples.
2. One could use the AMR Vet Lab Scorecard 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 used for the assessment.

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

3.4.2 Scoring

The AMR Vet Lab 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. It is therefore recommended to 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 G1.1 (of the General Procedures scorecard) is related to the conduct of automated methods for organism identification and AST. If the laboratory doesn't have automated methods this question should be answered with 'NA'. The total number of points that can be scored with this question is 3. The total number of points that can be scored in the General Procedures module is 73. But because this question is answered with 'NA', the three points for this question should be subtracted from the total number of points that can be scored in the General Procedures module, which, hence, becomes 70.

The scoring of the AMR technical modules is integrated into the SLIPTA scoring.

3.4.3 Information on the scorecard structure

The scorecards are used for assessing veterinary microbiology laboratories that analyze fecal and milk samples.

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

Scorecard structure

All scorecards 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:

- No stars: < 55%
- 1 star: 55% - 64%
- 2 stars: 65% - 74%
- 3 stars: 75% - 84%
- 4 stars: 85% - 94%
- 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 veterinary microbiology laboratory and provides the assessor the context for performing the assessment. Assessor can select multiple options if these apply (e.g. National **and** Reference). The veterinary microbiologist(s) is someone with a primary veterinary qualification who has specialized in laboratory microbiology at post graduate level. 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.

Assessors should note that veterinary microbiology laboratory may use human and veterinary AST interpretation standards (F). A number of options are available for selection, and if multiple methods (e.g. EUCAST SBP & EUCAST ECOFF), these should be indicated in the space provided.

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 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 or technical working groups. These may be known by different names. Assessors should note that the relationship between the laboratory and the oversight/coordination 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 covering instructions for collection of samples and feedback to clients after testing. Instruction documents such as the Client Handbook can be requested and reviewed beforehand, feedback to clients can be discussed with the Laboratory Manager or Microbiologist and proof should be requested.

Evidence that the laboratory has provided clients (veterinarians/farmers/etc.) with information on fecal and milk 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.

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.

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 analysis⁵ 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.

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).

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.

Question(s)	Technical information
F1.1 + F1.3 / M1.1 + M1.3	Refer to OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals sections 1.1 and 2.1 for additional information on the various processes listed by these questions. https://www.oie.int/en/standard-setting/terrestrial-manual/access-online/
G1.1-G1.4 + section 8 in all scorecard modules	Refer to OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals chapter 2.1.1 for information on bacterial antimicrobial susceptibility testing: https://www.oie.int/fileadmin/Home/eng/Health_standards/tahm/2.01.01_ANTIMICROBIAL.pdf
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.
F3.1-F3.2 / M3.1-M3.2	Refer to OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals chapter 1.1.1 for general information on management of veterinary diagnostic laboratories: https://www.oie.int/fileadmin/Home/eng/Health_standards/tahm/1.01.01_MANAGING_VET_LABS.pdf
G5.1	<p>The main objective of validation and verification of methods is to demonstrate that an examination procedure is fit-for-purpose (J Lab 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:</p> <ul style="list-style-type: none"> • 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? <p>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).</p>

Section 8 in all scorecards	<p>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 G.F), and the laboratory's SOPs (F1.1/M1.1).</p>
F8.1 / M8.1	<p>Refer to OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals chapter 1.1.3 for information on transport of biological materials:</p> <p>https://www.oie.int/fileadmin/Home/eng/Health_standards/tahm/1.01.03_TRANSPORT.pdf</p>
M8.3 / F8.3	<p>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 subculture (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.</p> <p>Refer to the CLSI standards (https://clsi.org/standards/products/microbiology/) or the EUCAST document on routine and extended internal quality control for MIC determination and disk diffusion for recommended strains for routine quality control: https://www.eucast.org/ast_of_bacteria/quality_control/.</p>
G8.6	<p>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.</p> <p>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).</p> <p>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</p>

	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.
G8.6 / F8.13-F8.22 / M8.13- M8.26	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 (F1.1/M1.1).
F8.9	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 is 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.
F8.21 / M8.25	<p>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 F9.2 / U9.2 / B9.2). 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.</p> <p>Finally, assessors should determine whether the laboratory uses both positive and negative control organisms to QC for the ESBL test in use. A commonly used ESBL positive strain is <i>Klebsiella pneumoniae</i> ATCC 700603 (also see F8.3 / U8.5 / B8.3).</p>
F8.22 / M8.26	<p>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.</p> <p>Finally, assessors should determine whether the laboratory uses both positive and</p>

	negative control organisms to QC for the carbapenemase test in use. Commonly used carbapenemase positive strains include <i>Klebsiella pneumoniae</i> ATCC BAA-170S, CCUG I 56233, and NCTC13438 (also see F8.3 / M8.3).
F8.23-F8.25 / M8.27-M8.29	Assessors should request interlaboratory, 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).
Section 12 (both feces and milk scorecard modules)	Refer to OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals chapters 1.1.4 and 2.1.3 for information on biosafety and biorisk management in the veterinary laboratory: https://www.oie.int/fileadmin/Home/eng/Health_standards/tahm/1.01.04_BIOSAFETY_BIOSECURITY.pdf https://www.oie.int/fileadmin/Home/eng/Health_standards/tahm/2.01.03_BIOL_AGENT_SPECIF_RA.pdf

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 VetCAST/EUCAST or CLSI guidelines for veterinary AST.

A list of background information is provided below:

Resource	Description
GAP, GLASS and partners	
Global Action Plan on AMR	Adopted in 2015 and aimed at ensuring our long-term capability to treat infectious diseases with effective and high-quality antimicrobials.
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.
OIE AMR landing page	Landing page of OIE with links to OIE resources related to AMR.
OIE Standards to control AMR	Links to OIE codes and manuals on AMR and AMU.
FAO AMR landing page	Landing page of FAO with links to FAO resources related to AMR.
FAO Assessment Tool for Laboratories and AMR	FAO-ATLASS is a tool for assessing and defining targets to improve national AMR surveillance systems in the food and

Surveillance Systems (FAO-ATLASS)	agriculture sectors. It is composed of two modules: the surveillance module, and the laboratory module. Each module includes two standardized questionnaires, which are completed by the assessors.
CLSI and EUCAST	
CLSI guidelines for veterinary AST	Landing page to obtain veterinary antimicrobial susceptibility testing standards with guidance on quality control and testing methods.
CLSI Microbiology standards	Landing page to obtain other 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.
VetCAST	VetCAST is a EUCAST subcommittee formed in 2015. It deals with all aspects of antimicrobial susceptibility testing of bacterial pathogens of animal origin and animal bacteria with zoonotic potential.
EUCAST clinical breakpoints and guidance (version 2020)	Links to PDF and Excel files with clinical breakpoints and guidance on how to use them.
OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals – section on laboratory methodologies for bacterial antimicrobial susceptibility testing	Provides information on laboratory methodologies for bacterial AST.
Laboratory Quality Management	
OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals – section on quality management in veterinary testing laboratories	Outlines the important issues and considerations a veterinary laboratory should address in the design and maintenance of its quality management system, whether or not it has been formally accredited. ⁶
OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals – section on management of veterinary diagnostic laboratories	Gives an introduction to the components of governance and management of veterinary laboratories that are necessary for the effective delivery of diagnostic services, and highlights the critical elements that should be established as minimum requirements. ⁵
FAO manual: Quality assurance for microbiology in feed analysis laboratories	Contains information on the quality management system in a microbiology laboratory, SOP templates for general laboratory procedures, and SOP templates for microbiology procedures.
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	

⁶ Various other sections of the Manual of Diagnostic Tests and Vaccines for Terrestrial Animals are also relevant/related to laboratory quality management and biosafety. Moreover, this manual also contains information on specific pathogens. It is therefore **strongly recommended** to scrutinize [the overall outline of this manual](#) for other relevant sections.

OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals – section on biosafety and biosecurity	Standard for managing biological risks in the veterinary laboratory and animal facilities. ⁵
WHO Laboratory Biosafety Manual	This manual provides information and explanation on biosafety requirements for medical laboratories.
Other	
OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals - outline	Though specific sections in this manual are linked above, the manual contains more information relevant to veterinary laboratory practice.
Overview of the phenotypic, genotypic, and emerging techniques for AST	Publication by Khan et al., (2019) <i>Diagnostics (Basel)</i> , 9(2):49
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
FAO information sheet on strengthening regional veterinary laboratory networks in Africa	Presents general information on FAO activities to strengthen regional veterinary laboratory networks in Africa and provides information on FAO global initiatives and tools to support veterinary laboratories.

3.5 Reporting the assessment

During the assessment:

1. Fill in the General Procedures scorecard and the scorecards for all materials on which AST is performed in the laboratory. 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 Vet Lab 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 Vet Lab 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 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 Vet Lab 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 Vet Lab 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.


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