



AMR TECHNICAL SCORECARD

VETERINARY General Precedures



Version 1.1 – August 2021

IN PARTNERSHIP WITH





Score

| Section | Sum of | Current Audit | Previous audit | |
|---|---------------------|---------------|----------------|--|
| | maximum | Date: | Date: | |
| | points ¹ | Current audit | Previous audit | |
| | 1 | score | score | |
| 1. Documents and Records | | % | % | |
| 2. Management Reviews | | % | % | |
| 3. Organization and Personnel | | % | % | |
| 4. Client Management and Customer Service | | % | % | |
| 5. Equipment | | % | % | |
| 6. Evaluation and Audits | | % | % | |
| 7. Purchasing and Inventory | | % | % | |
| 8. Process Control and Internal and External Quality Assessment | | % | % | |
| 9. Information Management | | % | % | |
| 10. Corrective Action | | % | % | |
| 11. Occurrence Management and Process Improvement | | % | % | |
| 12. Facilities and Safety | | % | % | |
| General Module Total | | % | % | |
| General Module Stars ² | | | | |

¹ Total number of points of all questions minus points for questions answered with NA.

² No Stars: < 55%

¹ Star: 55% - 64%

² Stars: 65% - 74%

³ Stars: 75% - 84%

⁴ Stars: 85% - 94%

⁵ Stars: ≥95%

A. General Information

| Name of assessor(s) | | | |
|---|--|------|--|
| Title & organization of assessor | | | |
| Name of laboratory being assessed | | | |
| Type of laboratory | National Reference Provincial / 0 District / Subdistrict Zonal Field Other (specified) |)- | Public Private Academic NGO |
| Does the microbiology laboratory meet minimum space and infrastructure requirements? | | | |
| How many farms/counties/villages are in the laboratory catchment area? | | | |
| Location of laboratory being assessed (City/Town, County / District / Sub-district and Country) | | | |
| Details of contact person at laboratory | | | |
| Name | | | |
| Position | | | |
| Qualification | | | |
| Email | | | |
| Phone | | | |
| Is there a veterinary microbiologist and/or veterinarian with experience in microbiology on staff? ³ | | Υ/ | N |
| If "Y", how many years' experience do they have? | | | |
| If, "N", what is the highest qualified member of the laboratory staff? | | | |
| Is the laboratory accredited? | | Υ/ | Ν |
| Name of accrediting body? | | | |
| What tests is the laboratory accredited for? | | | |
| Date of last assessment visit? | Date | Туре | Score |
| Internal | | | |
| External | | | |
| Date of last AMR assessment visit | | | |
| Date of this AMR assessment visit | | | |

³ Someone with a primary veterinary qualification who has specialised in laboratory microbiology at post graduate level.

B. Technical Information

A. What procedures are available for the detection and/or identification of bacterial pathogens?

| | Yes | No | Specify |
|--|-----|----|---------|
| Conventional methods (e.g., Gram stain, | | | |
| biochemical tests) | | | |
| Automated systems ⁴ | | | |
| Kit-based ⁵ / serological methods | | | |
| Anaerobic methods | | | |
| Molecular detection assays | | | |
| (commercial) (please specify) ⁶ | | | |
| Molecular detection assays (non- | | | |
| commercial) (please specify) ⁷ | | | |
| MALDI-TOF Mass Spectrometry (MS) | | | |

B. What methods are available for Antimicrobial Susceptibility Tests (AST) of bacterial pathogens?

| Method | Yes | No | Specify |
|---|-----|----|---------|
| Automated systems | | | |
| Gradient / Disk diffusion | | | |
| Etest | | | |
| Manual broth dilution | | | |
| Molecular AST assays (commercial) | | | |
| (please specify) ⁶ | | | |
| Molecular AST assays (non-commercial | | | |
| / in-house) (please specify) ⁷ | | | |

C. Does the laboratory routinely perform AST on bacterial pathogens? If so, which methods are used for:

| | Automated | Gradient/ Disk Diffusion | Etest | Manual broth dilution | Molecular AST assays (commercial) | Molecular AST assays (non- commercial / in-house) |
|-------------------|-----------|--------------------------------|-------|-----------------------------|---|---|
| S. aureus | | | | | | |
| S. agalactiae | | | | | | |
| S. uberis | | | | | | |
| S. dysgalactiae | | | | | | |
| C. bovis | | | | | | |
| K. pneumoniae | | | | | | |
| E. coli | | | | | | |
| P. aeruginosa | | | | | | |
| Mycoplasma spp. | | | | | | |
| Salmonella sp. | | | | | | |
| Enterococcus sp. | | | | | | |
| Campylobacter sp. | | | | | | |

⁴ E.g. Vitek, Microscan, Phoenix.

⁵ E.g. BioMérieux's API identification and other similar products.

⁶ E.g. Commercial molecular detection platforms for detection and AST including real-time PCR and sequencing. Equipment may include thermocyclers, electrophoresis and gel documentation systems.

⁷ E.g. Non-commercial molecular detection platforms for detection and AST including real-time PCR and sequencing. Equipment may include thermocyclers, electrophoresis and gel documentation systems.

D. Is the following equipment available, and if so, is it functional, monitored, serviced and maintained?

| | Available | Functional ⁸ | Monitored ⁹ | Serviced ¹⁰ | Maintained ¹¹ |
|---|-----------|--------------------------------|------------------------|------------------------|--------------------------|
| Ruler or caliper with millimeter markings | | | | | |
| Bunsen burner or micro-incinerator | | | | | |
| Wire loops for streaking | | | | | |
| Turbidity meter | | | | | |
| Microscope | | | | | |
| Thermometers | | | | | |
| Incubator (Aerobic) | | | | | |
| Incubator (Anaerobic) | | | | | |
| Incubator (CO ₂) | | | | | |
| Refrigerator (2-8°C) | | | | | |
| Freezer (-2080°C) | | | | | |
| Balance / scale | | | | | |
| Autoclave | | | | | |
| Biosafety Cabinet | | | | | |
| MALDI-TOF MS | | | | | |
| Molecular platforms | | | | | |
| Other equipment (please specify) | | | | | |
| • | | | | | |
| • | | | | | |

NA = Not applicable

E. How does the laboratory obtain media for bacterial culture?

| | Feces | Milk |
|---|-------|------|
| Media is prepared on-site (non-commercial) | | |
| Media is prepared off-site (non-commercial) | | |
| Ready-made media is procured from a media supplier (commercial) | | |

F. Which AST interpretation standard (and version) does the laboratory use (check all that apply)?

| Standard ¹² | Yes | No | Version | Clinical / Surveillance |
|--|-----|----|---------|----------------------------|
| Clinical & Laboratory Standards Institute (CLSI) | | | | |
| (https://www.clsi.org) | | | | |
| Clinical & Laboratory Standards Institute (CLSI) Veterinary | | | | |
| Standards (https://clsi.org/standards/products/veterinary- | | | | |
| medicine/) | | | | |
| European Committee on Antimicrobial Susceptibility Testing | | | | |
| (EUCAST) (www.eucast.org/) | | | | |
| Veterinary Committee on Antimicrobial Susceptibility Testing | | | | |
| (VetCAST) | | | | |
| (https://www.eucast.org/ast_of_veterinary_pathogens/) | | | | |
| Other- please specify | | | | |

G. How does the laboratory report results?

| Method | Yes | Νο |
|------------|-----|----|
| Electronic | | |
| Paper | | |

⁸ Is the equipment in working order?

⁹ Is the functionality of equipment regularly checked (e.g. temperature / calibrated)?

¹⁰ Is the equipment regularly serviced by a qualified service technician? Review equipment logbook.

¹¹ Is the equipment regularly maintained according to the manufacturer's recommendations (e.g. cleaning)? Review SOP and equipment logbook

¹² Determine whether the laboratory has constant access, either online or offline.

Section 1: Documents & Records

All generic requirements apply, see SLIPTA Section 1. In addition, assessors should review the following:

| SLIPT | J' | | N | Y | Ρ | Ν | Comments | Score |
|-------|------|--|---|---|---|---|----------|-------|
| Α | | | Α | | | | | |
| | G1.1 | If the laboratory uses automated methods for organism identification and AST (e.g. MS, molecular, Vitek, Microscan, Phoenix): a) Does the documentation provide instructions for preparing the inoculum in the correct medium and at the correct density? b) Does the documentation provide guidance on interpreting results generated by the software? c) Does the documentation provide guidance on how to recognize unacceptable results? d) Does the documentation outline what actions to take when unusual or unexpected AST results are documented from patient samples (e.g., reconfirm relevant QC, repeat testing, notify | | | | | | 3 |
| | | supervisor)? e) Does the documentation describe the defined QC organisms, QC frequency and expected QC results for use with the instrument? | | | | | | |
| 1.5 | G1.2 | If the laboratory uses kit- based methods for organism identification ¹³ : a) Does the | | | | | | 3 |

¹³ E.g. BioMérieux's API identification and other similar products.

| SLIPT A | | | N A | Y | Ρ | Ν | Comments | Score |
|------------|------|--|--------|---|---|---|----------|-------|
| | | documentation provide instructions for preparing the inoculum in the correct medium and at the correct density? | | | | | | |
| | | b) Does the documentation provide guidance on interpreting results? | | | | | | |
| | | c) Does the documentation provide guidance on how to recognize unacceptable results? | | | | | | |
| | | d) Does the documentation outline what actions to take when unusual or unexpected AST results are documented from patient samples (e.g., reconfirm organism ID, reconfirm relevant QC, repeat testing, notify supervisor)? | | | | | | |
| | | e) Does the documentation describe the defined QC organisms, QC frequency and expected QC results for each test? | | | | | | |
| 1.5 | G1.3 | If the laboratory uses conventional methods for organism identification and AST: | | | | | | |
| | | a) Does the documentation provide instructions for preparing the inoculum in the correct medium and at the correct density? | | | | | | 3 |
| | | b) If manual MIC methods are used, does the documentation describe specific criteria for measuring and determining the MIC endpoints? | | | | | | |

| | | | N | Y | Р | N | Commonto | Saara |
|----------------|------------|---|--------|----|---|---|----------|-------|
| SLIPT A | | | N A | Ŷ. | Ρ | Ν | Comments | Score |
| | c) d) | Does the documentation describe criteria for interpretation of the endpoint or zone size? Does the documentation provide guidance on how to recognize unacceptable results? Does the | | | | | | |
| | | documentation outline what actions to take when unusual or unexpected AST results are documented from patient samples (e.g., reconfirm organism ID, reconfirm relevant QC, repeat testing, notify supervisor)? | | | | | | |
| | f) | Does the documentation describe the defined QC organisms, QC frequency and expected QC results for each test? | | | | | | |
| 1.5 G1.4 | res cas | es the laboratory provide strictive (selective or scade) reporting of T ¹⁴ ? | | | | | | 2 |
| Section 1: Doc | umen | nts & Records Subtotal | | | | | | 11 |

¹⁴ In <u>cascade reporting</u>, antimicrobial agents of each class are ranked based on a spectrum of activity, popularity or potential for the over-prescribing risk of drug resistance and cost. Thus, the reported AST should include the most appropriate and least expensive drugs, provided the organism is susceptible. Higher risk agents are only released if alternative options are lacking. In <u>selective reporting</u>, the susceptibilities of broad-spectrum agents and those drugs at risk for over-prescription are deliberately withheld.

Section 2: Management Reviews

All generic requirements apply, see SLIPTA Section 2. In addition, assessors should review the following:

| SLIPT | | N A | Y | Ρ | Ν | Comments | Score |
|-----------------|--|--------|---|---|---|----------|-------|
| 2.2 G2.1 | Does the laboratory have representation on all the following? The AMR surveillance TWG The AMR coordination committee | | | | | | 2 |
| 2.2 G2.2 | Does the laboratory regularly report findings/trends and other related important information regarding bacterial culture and AST results to the oversight committees and the national reference laboratory? | | | | | | 2 |
| 2.2 G2.3 | Does the laboratory report cumulative antibiogram results to oversight committees and the national reference laboratory at least annually? | | | | | | 2 |
| 2.2 G2.4 | Do laboratory management reviews include review of feedback or recommendations from the AMR surveillance team (TWG or AMRCC for example)? | | | | | | 2 |
| Section 2: Mana | agement Reviews Subtota | | | | | | 8 |

Section 3: Organization & Personnel

Section 4: Client Management & Customer Service

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

| SLIPT A | | | N A | Y | Ρ | N | Comments | Score |
|------------|----------|--|--------|--------|-------|-----|----------|-------|
| 4.3 | G4.1 | Does the laboratory provide feedback to veterinarians/ farmers (directly or via oversight committees, see G2.1) regarding: • Sample quality & rejection rates • Identity & frequency of isolated or identified pathogens | | | | | | 2 |
| Section | 4: Clien | it Management & Custome | er Ser | vice S | Subto | tal | • | 2 |

Section 5: Equipment

All generic requirements apply, see SLIPTA Section 5. In addition, assessors should review the following:

| SLIPT A | 0 | | N A | Y | Ρ | Ν | Comments | Score |
|------------|---------|--|--------|---|---|---|----------|-------|
| 5.3 | G5.1 | Does the laboratory use verified/validated methods for isolation/detection/ identification and AST of pathogens ¹⁵ ? | | | | | | 5 |
| 5.1 | G5.2 | Is all equipment for isolation/ detection/identification and AST installed and placed in a suitable environment? | | | | | | 2 |
| 5.11 | G5.3 | Does the laboratory maintain all equipment for isolation/ detection/identification and AST of pathogens? (see question D)? | | | | | | 3 |
| Section | 5: Equi | pment Subtotal | | | | | • | 10 |

¹⁵ Includes all conventional, automated, kit-based, serological, MS and molecular (commercial & non-commercial) methods.

Section 6: Evaluation and Audits

All generic requirements apply, see SLIPTA Section 6. In addition, assessors should review the following:

| SLIPT A | | | N A | Y | Ρ | Ν | Comments | Score |
|--------------|----------|--|--------|---|---|---|----------|-------|
| 6.1 & 1.5 | G6.1 | Evaluations and audits¹⁶: a) Do the laboratory policies require audits to be performed? b) Does the laboratory regularly conduct internal audits? c) Are external audits regularly conducted? d) Are audit recommendations and action plans followed up within the timeframe defined by the laboratory? | | | | | | 5 |
| Section | 6: Evalu | uation and Audits Subtota | | | | | | 5 |

Section 7: Purchasing & Inventory

All generic requirements apply, see SLIPTA Section 7. In addition, assessors should review the following:

| SLIPT | × | | Ν | Y | Р | Ν | Comments | Score |
|---------|---------|---|---|---|---|---|----------|-------|
| Α | | | Α | | | | | |
| 7.2 | G7.1 | Does the laboratory provide specifications for supplies and consumables and are they followed during the procurement process? | | | | | | 2 |
| 7.8 | G7.2 | Are storage areas for reagents and supplies setup, maintained and monitored according to manufacturer's requirements ¹⁷ ? | | | | | | 2 |
| Section | 7: Purc | hasing & Inventory | | | | | | 4 |

¹⁶ It is recommended that internal audits be conducted at least annually. External audits are conducted less frequently-assessors should use the recommendation of local accrediting body to determine the frequency of external audits.

¹⁷ Ensure all supplies/reagents have not expired. Antibiotic packages not in use should be stored in a non-defrosting freezer, unopened and in their original packaging. Once opened, the antibiotic disks must be stored in such a way that the lot number and expiration date of each disk is always traceable. The antibiotic disk cartridges and strips should be stored in a tightly sealed container with active desiccants-the desiccants should be replaced or recharged at least monthly.

Section 8: Process Control

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

| followin | y: | | | | | | | |
|----------------|---------|--|--------|----|---|---|----------|-------|
| SLIPT A | | | N A | Y | Ρ | Ν | Comments | Score |
| SPECIN | | LLECTION | | | | | | |
| 8.2 & 8.3 | G8.1 | Does the Laboratory Request Form require the date and time of sample collection to be recorded? Does the Laboratory Request Form have space for the presumptive diagnosis? | | | | | | 3 |
| BACTE | RIAL DE | TECTION AND/OR IDENTIFIC | CATIC | DN | | | | |
| 8.8 | G8.2 | For automated, kit-based, molecular¹⁸, MS or conventional methods: Is QC performed on every new lot number/shipment of automated test reagents/ID cards/cartridges/conventional media before they are placed into use? Is the lab using inoculation medium appropriate for the procedure being performed? | | | | | | 3 |
| 9.9 & 8.10a | G8.3 | For automated methods only: Is the instrument software up to date? Does the laboratory confirm the detection/ identification result by another method¹⁹? | | | | | | 3 |
| 7.4 & 8.10a | G8.4 | For kit-based methods only: Is the manufacturer's database used for result interpretation up to date? When an ID result does not reach the acceptable threshold, is | | | | | | 3 |

¹⁸ Refer to instructions for use for commercial and non-commercial molecular identification assays.

¹⁹ Follow-up or confirmatory testing should be performed if the software flags a questionable result and if testing is performed using a non-commercial method (or commercial method on a non-validated sample type).

| SLIPT | | | Ν | Y | Ρ | N | Comments | Score |
|---------|---------|---|---|---|---|---|----------|-------|
| А | | | Α | | | | | |
| | | there evidence that appropriate action is taken, such as repeating the test by another method or performing additional biochemical tests? | | | | | | |
| 8.10a | G8.5 | For conventional methods only: When an identification result does not reach the acceptable threshold, is there evidence that appropriate action is taken, such as repeating the test by another method or performing additional biochemical tests? | | | | | | 2 |
| BACTER | RIAL AS | J | | | | | | |
| 8.9 | G8.6 | For automated, kit-based, molecular²⁰ or conventional methods: When performing AST, are fresh isolates (<24 hours old) used? When performing AST, are well-isolated, pure colonies (as evidenced by Gram stain, colony morphology, etc.) used? Has the lab completed a QC conversion plan for all antibiotics in use? When preparing a bacterial inoculum for AST, is a 0.5 McFarland suspension used? After inoculation, are purity plates always made from the remaining suspension? Are control organisms tested with each batch | | | | | | 3 |
| | | of AST performed? | | | | | | |
| Section | 8: Proc | ess Control Subtotal | | | | | | 17 |

²⁰ Refer to instructions for use for commercial and non-commercial molecular AST assays.

Section 9: Information Management

| SLIPT | U. | | Ν | Y | Р | Ν | Comments | Score |
|---|-------|---|---|---|---|---|----------|-------|
| Α | | | Α | | | | | |
| 10.1 | G10.1 | Are all identified nonconforming activities documented adequately? | | | | | | 5 |
| 10.2 | G10.2 | Is root cause analysis performed and corrective action taken for all non-conforming work? | | | | | | 3 |
| Section 10: Identification of Non-conformities, Corrective and Preventive Actions Subtotal | | | | | | | | 8 |

Section 10: Identification of Non-conformities, Corrective and Preventive Actions

All generic requirements apply, see SLIPTA Section 10. In addition, assessors should review the following:

Section 11: Occurrence/Incident Management & Process Improvement

All generic requirements apply, see SLIPTA Section 11. In addition, assessors should review the following:

| SLIPT A | 5 | | N A | Y | Ρ | Ν | Comments | Score |
|----------------|----------|---|--------|-------|--------|------|-----------------|-------|
| 11.4 & 11.5 | G11.1 | Are all reports shared periodically with veterinarians, oversight committees and the national reference laboratory (as applicable)? ²¹ | | | | | | 2 |
| 11.4 & 11.5 | G11.2 | Do reports for veterinarians, oversight committees and the national reference laboratory include at a minimum the number of samples, isolated or identified organisms and AST patterns? | | | | | | 2 |
| Section | 11: Occi | urrence/Incident Manager | nent & | & Pro | cess l | mpro | vement Subtotal | 4 |

²¹ Assessors should review the guidance documents from the AMR surveillance team (TWG or AMRCC for example) and/or veterinary services to determine the frequency that the laboratory should share its reports. If no recommendations exist, this should be at least quarterly.

Section 12: Facilities and Biosafety

All generic requirements apply, see SLIPTA Section 12. In addition, assessors should review the following:

| SLIPT A | | | N A | Y | Р | Ν | Comments | Score |
|------------|----------|---|--------|---|---|---|----------|----------|
| 12.16 | G12.1 | Are the following PPE items used when processing samples? • Gloves | | | | | | 2 |
| | | Laboratory coat | | | | | | |
| 12.4 | G12.2 | Waste management: Does the laboratory handle waste appropriately including disposal media and infectious material generated during testing? Are suitable disinfectants available for use when processing samples, are they freshly prepared, and is there evidence of their use²²? | | | | | | 2 |
| Section | 12: Faci | lities and Biosafety Subto | tal | | | | 1 | 4 |
| 000000 | | | | | | | | <u> </u> |

²² Clinical Microbiology Reviews, Jan. 1999, p. 147–179





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