



CLINICAL AND
LABORATORY
STANDARDS
INSTITUTE

2nd Edition

CLSI VET09™

Understanding Susceptibility Test Data as a Component of Antimicrobial Stewardship in Veterinary Settings

CLSI VET09 provides veterinarians with the information needed to successfully acquire and interpret antimicrobial susceptibility testing (AST) results. It promotes common understanding between the veterinarian and the veterinary microbiology laboratory by providing example culture and susceptibility reports and animal species–specific guidance on applying breakpoints to interpret AST results.

A CLSI report for global application.

Understanding Susceptibility Test Data as a Component of Antimicrobial Stewardship in Veterinary Settings

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Abstract

Clinical and Laboratory Standards Institute VET09—*Understanding Susceptibility Test Data as a Component of Antimicrobial Stewardship in Veterinary Settings* discusses antimicrobial susceptibility testing (AST), which provides important, clinically relevant information to the submitting veterinarian, provided the veterinarian understands how the testing is performed and how the results can be interpreted. CLSI VET09 includes background information on laboratory processes, including how AST is performed, why AST may not be performed, and how AST results are assessed by the laboratory. It also describes the reasons for varying degrees of confidence in applying breakpoints for interpreting AST results, which will inform veterinarians as they make decisions about the use of antimicrobial agents to treat bacterial disease in animals.

CLSI VET09 reviews some of the factors that affect antimicrobial drug selection in animals, including principles of antimicrobial pharmacology, the effect of bacterial species identification on AST results interpretation, and the veterinarian's role in ensuring AST results are accurate and useful. The example AST reports include callout boxes, highlighting important facets of AST reports to help the veterinarian apply the data.

CLSI VET09 has separate chapters for animal species-specific guidance on interpreting AST data for dogs, cats, horses, cattle, pigs, fish, and poultry. It also includes a chapter on guidance and limitations on interpreting AST data for animal species for which there are no approved breakpoints, including sheep, goats, donkeys and mules, camelids, and exotic animals. Uniquely, CLSI VET09 provides evidence-based appraisals of confidence in the AST data reported by laboratories. This guidance can also be used by laboratories to select appropriate breakpoints for assigning interpretive categories and to help client veterinarians interpret their data. CLSI VET09 includes information on the most recent veterinary-specific breakpoints published in CLSI VET01S¹ Tables 2A to 2M.

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Foreword

CLSI VET09 is intended to provide veterinarians and others involved in veterinary diagnostics with key information needed to appropriately interpret antimicrobial susceptibility testing (AST) data and apply them to clinical decision-making. Therefore, CLSI VET09 can be read from beginning to end for a comprehensive overview of AST by animal species, bacterial type, and antimicrobial agents. However, each chapter is also designed to provide stand-alone information, so the reader can find relevant information as needed.

CLSI VET09 includes general guidance on applying pharmacological principles to selection and use of antimicrobial agents and obtaining the most useful information from the laboratory, beginning with submitting an animal specimen for culture and ending with receiving the laboratory report with AST results. CLSI VET09 describes basic components of a laboratory report and provides specific examples of AST reports (including commentary on the information reported). The example reports illustrate different presentations that clinicians may receive from different laboratories. Regulatory and legal considerations for antimicrobial agents are also summarized. Finally, CLSI VET09 includes separate chapters that focus on AST results interpretations applied to different animal species: dogs, cats, horses, cattle, pigs, fish, and poultry. A final chapter explains when breakpoints can be extrapolated for animal species such as sheep and goats, donkeys and mules, camelids, and exotic species, for which there are no approved breakpoints.

Some information in CLSI VET09 is not available elsewhere, including recommendations on extrapolating from:

- One infection site to another
 - For example, whether a breakpoint established for *Escherichia coli* from skin and soft tissue (SST) infections in dogs can be applied to *E. coli* isolated from the lungs
- One bacterial species to another
 - For example, whether a breakpoint established for *E. coli* can be applied to *Klebsiella pneumoniae*
- One animal species to another
 - For example, whether it is reasonable to apply canine breakpoints to bacterial isolates from cats

Overview of Changes

This report replaces CLSI VET09-Ed1, published in 2019. Several changes were made in this edition, including:

- **General:**
 - Updated nomenclature:
 - Reorganized genera formerly included in the family *Enterobacteriaceae* to an order (Enterobacterales) containing seven families: *Budviciaceae*, *Enterobacteriaceae*, *Erwiniaceae*, *Hafniaceae*, *Morganellaceae*, *Pectobacteriaceae*, *Yersiniaceae*²
 - Changed penicillin G “IU/kg” to penicillin G “U/kg”
 - For tables with any updates from the first edition, added **NOTE** on new or modified text.
 - Revised animal chapters (Chapters 5 to 10), including:
 - Added **CAUTION** to each chapter regarding laboratory reports that may look substantially different if a laboratory uses molecular methods (eg, PCR, whole-genome sequencing) to identify resistance genes, instead of using broth dilution, agar dilution, or disk diffusion AST methods as shown in Figure 5B.
 - Updated Tables 7, 12, 17, 22, and 26 to include only the infection site(s) of approved breakpoints and added a paragraph explaining that breakpoints can apply to other sites with listed exceptions

- Updated tables with animal species–specific breakpoints to reflect changes in the 5th, 6th, and 7th editions of CLSI VET01S¹
- Added Subchapters 5.7, 6.7, 7.7, 8.7, and 9.7 for AST for fastidious and/or infrequently isolated bacteria
- Added footnote to tables throughout CLSI VET09, as needed: “Commonly isolated Enterobacterales include *E. coli*, *K. pneumoniae*, and *P. mirabilis*.”
- Added footnote to Tables 9, 14, and 19: “Non-Enterobacterales, nonfermenting gram-negative bacteria include *A. baumannii*, *B. cepacia* complex, and *S. maltophilia*.”
- Added chapters:
 - Chapter 11, for poultry-specific breakpoints and factors affecting AST results interpretations for chickens and turkeys
 - Chapter 12, for factors affecting AST results interpretations for animals without approved, species-specific breakpoints, including:
 - Subchapters 12.3.1 and 12.3.2, for sheep and goats, for which some extrapolations can reasonably be made using antimicrobial agents with bovine-specific breakpoints
 - Subchapter 12.3.3, for donkeys and mules, for which some extrapolations can reasonably be made using antimicrobial agents with equine-specific breakpoints
 - Subchapter 12.4, for animal species for which extrapolations cannot reasonably be made, including camelids, reptiles and amphibians, pet and exotic birds, small mammals, large exotic animals, and mammals without pharmacokinetic or serum concentration data
- Updated all appendixes to include:
 - New animal species–specific breakpoints approved and published in CLSI VET01S¹ since the previous edition of CLSI VET09
 - New **NOTE** referring users to the current edition of CLSI VET01S¹, which is freely available online in nondownloadable format at <http://clsivet.org/Login.aspx>
- **Subchapter 1.1, Scope:**
 - Expanded to include discussion of interpreting AST results for poultry and for animal species for which there are no approved breakpoints (eg, sheep, goats, donkeys and mules, exotic animal species)
- **Chapter 2, Overview of Factors Affecting Antimicrobial Agent Selection in Animals:**
 - Added two subchapters:
 - **Subchapter 2.2, Determination of Antimicrobial Susceptibility: Breakpoint Development**
 - **Subchapter 2.8, Critically Important Antimicrobial Agents**
 - Revised order of subchapters to:
 - **Subchapter 2.1, Pharmacokinetics:**
 - Added details about drug distribution and tissue penetration
 - Revised Figure 1 by replacing “respiratory” with “lung alveoli” under tissues with penetration barriers
 - Expanded Table 2 with additional tissue barriers to drug diffusion after systemic administration

- Added Subchapter 2.1.5, Pharmacokinetics/Pharmacodynamics:
 - Expanded discussion of pharmacokinetics/pharmacodynamics (PK/PD)
 - Added figure to illustrate PK/PD (Figure 2)
 - Expanded Table 3 on PK/PD relationships
 - **Subchapter 2.2, Determination of Antimicrobial Susceptibility: Breakpoint Development:**
 - Revised Subchapter 2.2.1, Protein Binding:
 - Expanded Table 4
 - Revised Subchapter 2.2.2, Dosage Regimens:
 - Expanded discussion of dosage regimens and clarified recommendations for topical antimicrobial agents
 - Revised Subchapter 2.2.4, Drug Formulation:
 - Expanded discussion of drug formulation and route of administration in applying breakpoints
 - Replaced former Figure 2 with Figure 3 comparing plasma concentrations of oxytetracycline (instead of ceftiofur) over time with different formulations and routes of administration
 - Added Subchapter 2.2.5, Reasons for Lack of Breakpoints
 - Revised Subchapter 2.2.6, Bacteria With CLSI-Approved Breakpoints and/or Epidemiological Cutoff Values:
 - Clarified differences between breakpoints and epidemiological cutoff values (ECVs)
 - Discussed interpreting AST results for bacteria with vs without veterinary-specific CLSI-approved breakpoints
 - **Subchapter 2.3, Potential Effects of Disease and Patient Factors on Antimicrobial Agent Efficacy:**
 - Expanded discussion of reasons for decreased patient response to antimicrobial therapy
 - Expanded Table 5
 - **Subchapter 2.4, Bacterial Characteristics to Consider When Interpreting Antimicrobial Susceptibility Testing Data:**
 - Added details on differences among bacterial species in intrinsic and acquired resistance
 - **Subchapter 2.5, Importance of Standardized Antimicrobial Susceptibility Testing Methodology:**
 - Added Subchapter 2.5.1, Broth Dilution, Agar Dilution, and Disk Diffusion Antimicrobial Susceptibility Testing Methods
 - Added Subchapter 2.5.2, Molecular Antimicrobial Susceptibility Testing
 - **Subchapter 2.6, Important Reasons Antimicrobial Susceptibility Testing May Not Be Performed:**
 - Added several circumstances when it is not appropriate to perform AST
 - **Subchapter 2.7, Important Regulatory and Legal Aspects of Antimicrobial Agent Selection in Animals:**
 - Emphasized that veterinarians must consult the laws and regulations in the regions where they are licensed to practice veterinary medicine, which is beyond the scope of CLSI VET09
 - Expanded list of food animals
 - **Subchapter 2.8, Critically Important Antimicrobial Agents:**
 - Added discussion of international and national criteria and classifications of critically important antimicrobials in human medicine and their use in food and/or companion animals, as well as veterinarians' roles in good antimicrobial stewardship
-

• Chapter 3, Antimicrobial Susceptibility Testing Process Overview:

- Added details to Figure 4 (formerly Figure 3), showing process flow chart for veterinarian obtaining AST results
- Divided Figure 5 (formerly Figure 4), showing process flow chart for laboratory AST, into two parts:
 - Figure 5A, showing laboratory processes from specimen receipt through culture and determining whether AST is appropriate
 - Figure 5B, showing laboratory AST processes, including added process step for saving bacterial isolates for short-term or long-term storage and some reasons isolates might be saved
- **Deleted** former Table 7, Antimicrobial Agents Used for Primary AST and Reporting, because the information is included in greater detail in each of the animal species chapters
- Added separate subchapters for selecting antimicrobial agents for testing (Subchapter 3.2.1, Reasons for Including or Excluding Antimicrobial Agents in Testing) vs for reporting (Subchapter 3.2.2, Reasons for Including or Excluding Antimicrobial Agents in Reports)
- Combined former Tables 8 and 9 into one table (Table 6), with examples of bacterial groups with intrinsic resistance

• Chapter 4, Typical Antimicrobial Susceptibility Testing Reports:

- Revised Subchapter 4.1, Basic Information Documented in Laboratory Antimicrobial Susceptibility Testing Reports:
 - Added separate subchapters for basic information documented in laboratory AST reports for individual animals (Subchapter 4.1.1, Basic Information Documented in Laboratory Reports for Individual Animals) vs herds (Subchapter 4.1.2, Basic Information Documented in Laboratory Reports for Herd Testing)
 - Added figure with basic laboratory, specimen, and animal information reported for herd testing (Figure 10)
 - Added figure with basic culture, AST, breakpoint, and interpretive information reported for herd testing (Figure 11)
- Revised Subchapter 4.2, Example Laboratory Antimicrobial Susceptibility Testing Reports:
 - Added separate subchapters for example laboratory AST reports for individual animals (Subchapter 4.2.1, Example Laboratory Reports for Individual Animal Culture and Antimicrobial Susceptibility Testing Results) vs for herds (Subchapter 4.2.2, Example Laboratory Reports for Herd Culture and Antimicrobial Susceptibility Testing Results)
 - Added descriptive details to figure headings for example AST reports for individual animals (Figures 12 to 17 [formerly Figures 9 to 14])
 - Added example AST reports for individual animals:
 - Figure 18, Example Laboratory Report With AST Results for *Flavobacterium psychrophilum* From Fish
 - Figure 19, Example Laboratory Report With AST Results for Animals for Which There Are No Approved Breakpoints
 - Added example AST reports for herd testing (Figures 20 and 21)
- Added Subchapter 4.3, Basic Information in Cumulative Antimicrobial Susceptibility Testing Reports and Example Antibiograms or Population Susceptibility Reports:
 - Added figure showing the basic format for a cumulative AST report (Figure 22)
 - Added example antibiograms (Figures 23 to 25)

• **Chapter 5, Canine-Specific and Other Breakpoints and Factors Affecting Antimicrobial Susceptibility Testing Results Interpretations for Dogs:**

- Revised Table 7 (formerly Table 10):
 - Added antimicrobial agent dosage regimens used to establish new or revised canine-specific breakpoints and applicable tissue, body site for:
 - Ampicillin for serious *Enterococcus* spp. infections in SST body sites
 - Ceftazidime for Enterobacterales and *Pseudomonas aeruginosa* infections in SST body sites
 - Chloramphenicol for respiratory and SST body sites
 - Levofloxacin for respiratory, SST, and urinary tract body sites
 - Enrofloxacin to include dosage regimens for new susceptible-dose dependent (SDD) breakpoints
 - Marbofloxacin to include dosage regimen for new SDD breakpoints
 - Piperacillin-tazobactam to include 350 mg/kg intravenous every 6 hours
- Added **NOTE** stating that susceptibility to fluoroquinolones should not be used to predict susceptibility to ciprofloxacin because PK/PD analysis does not support its use in dogs.
- Revised Table 8 (formerly Table 11):
 - Revised footnote a regarding predicting resistance to doxycycline or minocycline
 - Indicated that clindamycin does not predict susceptibility to other antimicrobial agents used in dogs
 - **Deleted** cephalothin, gentamicin, minocycline, and piperacillin-tazobactam
- Revised Table 9 (formerly Table 12):
 - Added that *E. coli* breakpoints may not be extrapolated to *Pseudomonas* spp. or *Pasteurellaceae* or gram-negative bacteria with known intrinsic resistance
 - Added that (new) *Enterococcus* spp. breakpoints may not be extrapolated to other gram-positive cocci (eg, *Staphylococcus* spp., *Streptococcus* spp.)
- Revised Table 10 (formerly Table 13):
 - **Deleted** cefotaxime, ceftazidime, chloramphenicol, erythromycin, and penicillin
- Revised Table 11 (formerly Table 14):
 - **Deleted** *Enterococcus* spp., for which canine-specific breakpoints have been approved

• **Chapter 6, Feline-Specific and Other Breakpoints and Factors Affecting Antimicrobial Susceptibility Testing Results Interpretations for Cats:**

- Revised Table 12 (formerly Table 15):
 - Revised amoxicillin dose in the dosage regimen used to establish feline-specific breakpoints
- Added **NOTE** stating that susceptibility to fluoroquinolones should not be used to predict susceptibility to ciprofloxacin because PK/PD analysis does not support its use in cats.
- Revised Table 13 (formerly Table 16):
 - **Deleted** clindamycin, which does not predict susceptibility to other antimicrobial agents used in cats

- Revised Table 14 (formerly Table 17):
 - Added that *E. coli* breakpoints may not be extrapolated to *Pseudomonas* spp. or *Pasteurellaceae* or gram-negative bacteria with known intrinsic resistance
 - Added that (new) *Enterococcus* spp. breakpoints may not be extrapolated to other gram-positive cocci (eg, *Staphylococcus* spp., *Streptococcus* spp.)
- Revised Table 15 (formerly Table 18):
 - Added oxacillin
 - **Deleted** cefotaxime and penicillin
- Revised Table 16 (formerly Table 19):
 - **Deleted** *Enterococcus* spp., for which feline-specific breakpoints have been approved
- **Chapter 7, Equine-Specific and Other Breakpoints and Factors Affecting Antimicrobial Susceptibility Testing Results Interpretations for Horses:**
 - Revised Table 18 (formerly Table 21):
 - Revised footnote a regarding predicting resistance to doxycycline or minocycline
 - **Deleted** gentamicin, which does not predict susceptibility to other antimicrobial agents used in horses
 - Revised Table 19 (formerly Table 22):
 - Added that *E. coli* breakpoints may not be extrapolated to *Pseudomonas* spp. or *Pasteurellaceae* or gram-negative bacteria with known intrinsic resistance
 - Added the exception of ceftiofur for gram-positive bacteria
 - Revised Table 20 (formerly Table 23):
 - **Deleted** chloramphenicol and rifampin
- **Chapter 8, Bovine-Specific and Other Breakpoints and Factors Affecting Antimicrobial Susceptibility Testing Results Interpretations for Cattle:**
 - Revised Table 22 (formerly Table 25):
 - Added antimicrobial agent dosage regimens used to establish new bovine-specific breakpoints and applicable tissue, body site for:
 - Cefoperazone for mammary gland body site
 - Kanamycin-cephalexin for mammary gland body site
 - Pradofloxacin for respiratory body sites
 - Ceftiofur to include 125 mg intramammary (ceftiofur hydrochloride intramammary formulation) twice 24 hours apart
 - Danofloxacin to include 8 mg/kg subcutaneous once
 - Added footnote regarding SST bovine breakpoints, which refers to the ampicillin breakpoint set for metritis isolates
 - Revised Table 23 (formerly Table 26) entries for ampicillin and penicillin G predicting susceptibility to other antimicrobial agents

- Revised Table 24 (formerly Table 27):
 - Added that *E. coli* breakpoints may not be extrapolated to *Pseudomonas* spp. or *Pasteurellaceae* or gram-negative bacteria with known intrinsic resistance
 - Added the exception of ceftiofur for gram-positive bacteria
- Revised Table 25 (formerly Table 28):
 - Added *Listeria monocytogenes*
 - **Deleted** *Mycobacterium* spp.
- **Chapter 9, Porcine-Specific and Other Breakpoints and Factors Affecting Antimicrobial Susceptibility Testing Results Interpretations for Pigs:**
 - Revised Table 26 (formerly Table 29):
 - Added pradofloxacin dosage regimen used to establish new porcine-specific breakpoints for respiratory body sites
 - Revised Table 27 (formerly Table 30) entry for ampicillin, which predicts only amoxicillin susceptibility
 - Revised Table 28 (formerly Table 31):
 - Added that *Salmonella enterica* subsp. *enterica* serovar Choleraesuis breakpoints may not be extrapolated to *Pasteurellaceae* or gram-negative bacteria with known intrinsic resistance
 - Added the exception of ceftiofur for gram-positive bacteria
 - **Deleted** *Bordetella bronchiseptica*
 - **Deleted** statement that breakpoints for *Actinobacillus pleuropneumoniae* and *Pasteurella multocida* are not applicable to central nervous system infections
- **Chapter 10, Fish-Specific Breakpoints, Epidemiological Cutoff Values, and Factors Affecting Antimicrobial Susceptibility Testing Results Interpretations for Fish:**
 - Revised Table 31 (formerly Table 34):
 - Added availability of zone diameter and/or minimal inhibitory concentration ECVs for *Aeromonas hydrophila*, *Flavobacterium columnare*, and *Flavobacterium psychrophilum*
 - Added ampicillin, enrofloxacin, and flumequine

NOTE: The content of CLSI VET09 is supported by the CLSI consensus process and does not necessarily reflect the views of any single individual or organization.

KEY WORDS

antimicrobial stewardship

antimicrobial susceptibility testing

breakpoints

interpretive categories

laboratory

reporting

species-specific breakpoints

veterinary

Chapter 1

Introduction

Sample

Understanding Susceptibility Test Data as a Component of Antimicrobial Stewardship in Veterinary Settings

1 Introduction

1.1 Scope

CLSI VET09 is designed to facilitate common understanding among veterinarians, microbiologists, and laboratorians of how antimicrobial susceptibility testing (AST) is performed and how the results can be interpreted and applied to clinical decision-making. The intended audience includes veterinarians, microbiologists, laboratorians conducting *in vitro* testing, veterinary educators, pharmacists, and students.

CLSI VET09 provides information that may be used in conjunction with other efforts and activities to support antimicrobial stewardship, such as those advocated by professional associations³ or regulatory agencies.^{4,5}

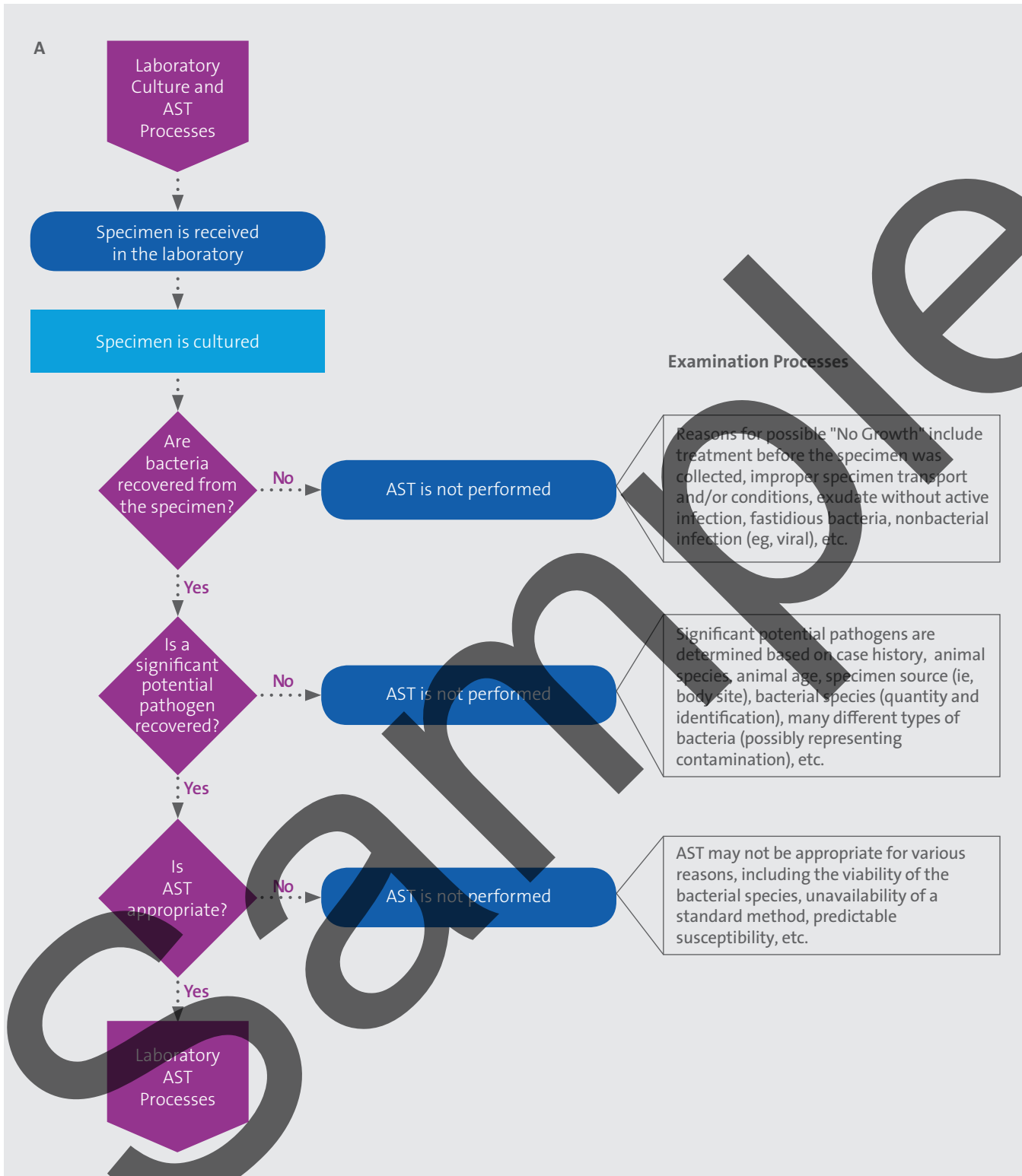
CLSI VET09 provides an overview of factors affecting antimicrobial agent selection, including pharmacokinetics (PK) and pharmacokinetics/pharmacodynamics (PK/PD), breakpoint development, effects of disease and patient factors on antimicrobial agent efficacy, characteristics of bacteria relevant to AST, regulatory and legal aspects, and the public health significance of antimicrobial agent selection. Example AST reports are included, in which common questions are answered and misconceptions are clarified. CLSI VET09 also provides animal species-specific guidance on applying AST results; reasonable extrapolations that can be made across bacterial species, infection sites, or antimicrobial agents; and the expected degree of confidence in these extrapolations. Also included are excerpts from other CLSI documents relevant to interpreting AST reports.

Based on available expertise and perceived need, CLSI VET09 covers dogs, cats, horses, cattle, pigs, fish, and poultry. These animal species represent all the veterinary breakpoints that have been approved to date by the CLSI Subcommittee on Veterinary Antimicrobial Susceptibility Testing (VAST). CLSI VET09 also covers interpretation of AST results for animal species for which there are no approved breakpoints, eg, sheep, goats, donkeys and mules, and exotic animal species.

Clinical decision-making about antimicrobial agents is complicated, and AST data account for only part of the information needed to successfully manage bacterial disease in animals. CLSI VET09 does not include guidance on diagnosis or treatment of bacterial disease in animals, prescribing information, or dosing recommendations. Dosage regimens used to set breakpoints are included only to aid in AST results interpretation. CLSI VET09 is not intended to produce standards for antimicrobial agent prescribing, to affect or supersede current regulatory restrictions on antimicrobial agent use, or to endorse any particular product for antimicrobial use. Additional factors veterinarians consider when prescribing antimicrobial agents include disease factors (eg, severity and duration), patient factors (eg, potential for adverse effects or selection for antimicrobial resistance), and legal restrictions on drug use, as well as their own experience. However, these factors are not discussed in depth in CLSI VET09.

1.2 Background

The standards and AST procedures covered in CLSI VET09 are commonly followed by diagnostic laboratories and clinical microbiologists performing AST at the request of veterinarians and others involved in animal health. The standards most relevant to CLSI VET09 have been developed by the Subcommittee on VAST and its working groups. Currently, veterinary-specific breakpoints are not set by regulatory organizations. Rather, they have been developed and approved solely by the Subcommittee on VAST.



Sample



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