VET03/VET04-S2
Performance Standards for Antimicrobial Susceptibility Testing of Bacteria Isolated From Aquatic Animals; Second Informational Supplement

This document provides updated tables for the Clinical and Laboratory Standards Institute antimicrobial susceptibility testing guidelines VET03-A and VET04-A2.

An informational supplement for global application developed through the Clinical and Laboratory Standards Institute consensus process.
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For further information on committee participation or to submit comments, contact CLSI.

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Abstract

The supplemental information presented in this document is intended for use with the antimicrobial susceptibility testing procedures published in the following Clinical and Laboratory Standards Institute (CLSI)–approved documents: VET03-A—Methods for Antimicrobial Disk Susceptibility Testing of Bacteria Isolated From Aquatic Animals; Approved Guideline; and VET04-A2—Methods for Broth Dilution Susceptibility Testing of Bacteria Isolated From Aquatic Animals; Approved Guideline—Second Edition. The guidelines contain information about both disk (VET03-A) and dilution (VET04-A2) test procedures for bacteria isolated from aquatic animals.

The clinical importance of antimicrobial susceptibility test results requires that these tests be conducted under optimal conditions and that laboratories have the capability to interpret results.

The tabular information presented here represents the most current information for interpretation of antimicrobial susceptibility test results using the procedures standardized in VET03-A and VET04-A2. Users should consider the interpretive criteria presented in these tables specific only to isolates of *Aeromonas salmonicida*, and not to any other genus or species. Fish disease diagnostic laboratories that typically conduct susceptibility tests less than once per week should consult this supplement for revised guidance for frequency of quality control.


The data in the interpretive tables in this supplement are valid only if the methodologies in VET03-A—Methods for Antimicrobial Disk Susceptibility Testing of Bacteria Isolated From Aquatic Animals; Approved Guideline; and VET04-A2—Methods for Broth Dilution Susceptibility Testing of Bacteria Isolated From Aquatic Animals; Approved Guideline—Second Edition are followed.
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Foreword

It is important for users of VET03-A, VET04-A2, and this informational supplement to recognize that the standard methods described in CLSI documents are reference methods. These methods may be used for routine antimicrobial susceptibility testing of bacteria isolated from aquatic animals. The Working Group on Aquaculture envisions adding more aquaculture pathogens and antimicrobial agents to these interpretive criteria (clinical breakpoint) and epidemiological cutoff tables as the data become available. Data needed to develop more clinical breakpoints could include, for example, a clinical effectiveness report that may be correlated with minimal inhibitory concentrations and/or zone diameters for a suspected pathogen obtained using standard methods. If such data are available, individuals are strongly encouraged to contact any member of the Working Group on Aquaculture.

In this revision of the VET03/VET04 supplement, all tables were moved out of VET04-A2 and into this supplement.

Clinical breakpoints established by CLSI may differ from those approved by various regulatory authorities for many reasons, including the following: different databases, differences in data interpretation, and different public health policies. Differences also exist because CLSI proactively evaluates the need for changing clinical breakpoints. The reasons why veterinary breakpoints may change and the manner in which CLSI evaluates data and determines veterinary breakpoints are outlined in CLSI document VET02-A3—Development of In Vitro Susceptibility Testing Criteria and Quality Control Parameters for Veterinary Antimicrobial Agents; Approved Guideline—Third Edition.

Following a decision by CLSI to change an existing clinical breakpoint, regulatory authorities may also review data to determine how changing a breakpoint may affect the safety and effectiveness of the antimicrobial agent for the approved indications. If the regulatory authority changes a breakpoint, commercial device manufacturers may have to conduct a clinical laboratory trial, submit the data to the regulatory authority, and await review and approval. For these reasons, a delay of more than the suggested CLSI “tentative” period of one year may be required if a breakpoint change is to be implemented by a device manufacturer.

Ron A. Miller, PhD, Chairholder
Working Group on Aquaculture

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*See the Related CLSI Reference Materials section for more information.*
The Quality Management System Approach

Clinical and Laboratory Standards Institute (CLSI) subscribes to a quality management system approach in the development of standards and guidelines, which facilitates project management; defines a document structure via a template; and provides a process to identify needed documents. The quality management system approach applies a core set of “quality system essentials” (QSEs), basic to any organization, to all operations in any health care service’s path of workflow (i.e., operational aspects that define how a particular product or service is provided). The QSEs provide the framework for delivery of any type of product or service, serving as a manager’s guide. The QSEs are as follows:

- Organization
- Customer Focus
- Facilities and Safety
- Personnel
- Purchasing and Inventory
- Equipment
- Process Management
- Documents and Records
- Information Management
- Nonconforming Event Management
- Assessments
- Continual Improvement

VET03/VET04-S2 does not address any of the QSEs. For a description of the documents listed in the grid, please refer to the Related CLSI Reference Materials section on the following page.

Path of Workflow

A path of workflow is the description of the necessary processes to deliver the particular product or service that the organization or entity provides. A laboratory path of workflow consists of the sequential processes: preexamination, examination, and postexamination and their respective sequential subprocesses. All laboratories follow these processes to deliver the laboratory’s services, namely quality laboratory information.

VET03/VET04-S2 addresses the clinical laboratory path of workflow steps indicated by an “X.” For a description of the other documents listed in the grid, please refer to the Related CLSI Reference Materials section on the following page.
Related CLSI Reference Materials*

**M24-A2**  
Susceptibility Testing of Mycobacteria, Nocardiae, and Other Aerobic Actinomycetes; Approved Standard—Second Edition (2011). This standard provides protocols and related quality control parameters and interpretive criteria for the susceptibility testing of mycobacteria, Nocardia spp., and other aerobic actinomycetes.

**M100-S24**  

**VET01-A4**  
Performance Standards for Antimicrobial Disk and Dilution Susceptibility Tests for Bacteria Isolated From Animals; Approved Standard—Fourth Edition (2013). This document provides the currently recommended techniques for antimicrobial agent and disk and dilution susceptibility testing, criteria for quality control testing, and interpretive criteria for veterinary use.

**VET01-S2**  
Performance Standards for Antimicrobial Disk and Dilution Susceptibility Tests for Bacteria Isolated From Animals; Second Informational Supplement (2013). This document provides updated tables for the CLSI antimicrobial susceptibility testing standard VET01.

**VET02-A3**  
Development of In Vitro Susceptibility Testing Criteria and Quality Control Parameters for Veterinary Antimicrobial Agents; Approved Guideline—Third Edition (2008). This document addresses the required and recommended data needed for selection of appropriate interpretive standards and quality control guidance for new veterinary antimicrobial agents.

**VET03-A**  
Methods for Antimicrobial Disk Susceptibility Testing of Bacteria Isolated From Aquatic Animals; Approved Guideline (2006). This document provides the most up-to-date techniques for disk diffusion susceptibility testing of aquatic species isolates, and criteria for quality control testing.

**VET04-A2**  
Methods for Broth Dilution Susceptibility Testing of Bacteria Isolated From Aquatic Animals; Approved Guideline—Second Edition (2014). This document provides the most up-to-date techniques for the determination of minimal inhibitory concentrations of aquatic bacteria by broth micro- and macrodilution, and criteria for quality control testing.

* CLSI documents are continually reviewed and revised through the CLSI consensus process; therefore, readers should refer to the most current editions.
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