CLINICAL AND LABORATORY STANDARDS INSTITUTE®

1st Edition

M52

Verification of Commercial Microbial Identification and Antimicrobial Susceptibility Testing Systems

This guideline includes recommendations for verification of commercial US Food and Drug Administration–cleared microbial identification and antimicrobial susceptibility testing systems by clinical laboratory professionals to fulfill regulatory or quality assurance requirements for the use of these systems for diagnostic testing.

A guideline for US application developed through the Clinical and Laboratory Standards Institute consensus process.

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Verification of Commercial Microbial Identification and Antimicrobial Susceptibility Testing Systems

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Abstract

Clinical and Laboratory Standards Institute document M52—*Verification of Commercial Microbial Identification and Antimicrobial Susceptibility Testing Systems* provides recommendations for verification of commercial US Food and Drug Administration–cleared antimicrobial susceptibility testing (AST) and microbial identification (ID) systems by clinical laboratory professionals to fulfill regulatory or QA requirements for the use of these systems for diagnostic testing. This guideline focuses on instrument-based systems commonly used in clinical laboratories and may also be applicable to manual methods for ID and AST.

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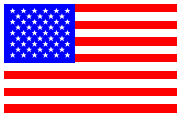

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Contents (Continued)

Foreword

M52 provides recommendations that laboratories may consider while designing their own verification activities. Each laboratory needs to determine what activities are needed to provide accurate results and meet local regulatory requirements. The number of isolates suggested for verification represent the minimum number recommended for testing. Testing additional isolates, especially isolates with unusual identifications and resistance patterns, should be considered. Because antimicrobial resistance continues to evolve, laboratories need to continually review and evaluate patient results as part of their QA activities.

This guideline is based on US regulations and may also serve as a useful resource for a wider audience. The unique tagline on the cover and the imprint of the US flag on the Abstract page and throughout the document footers call attention to M52's national focus and differentiate it from CLSI's global consensus documents. M52 is expected to be used extensively in the United States and globally to guide users on verification of microbial identification and antimicrobial susceptibility testing systems.

In order to clarify and emphasize the difference between a standard and a guideline, the CLSI definitions for standard and guideline documents are provided.

standard – a CLSI document developed through the consensus process, clearly identifying specific, essential requirements for materials, methods, or practices for voluntary use in an unmodified form. A CLSI standard may, in addition, contain discretionary elements. These discretionary elements are clearly identified.

guideline – a CLSI document developed through the consensus process describing criteria for a general operating practice, method, or material for voluntary use. A guideline can be used as written or modified by the user to fit specific needs. Mandates (ie, "must" or "shall") are occasionally allowed in guidelines, in cases in which the document development committee feels strongly that a particular action is either required or prohibited, or when a guideline addresses provisions based on regulations.

NOTE 1: Mandates are occasionally allowed in CLSI guidelines, in cases in which the document development committee feels strongly that a particular action is either required or prohibited, or when a guideline addresses provisions based on regulations. Throughout M52, the use of the term "must" was evaluated by the document development committee and deemed appropriate because the uses are either 1) based on a requirement or 2) indicative of a necessary step to ensure patient safety or proper fulfillment of a procedure.

NOTE 2: The findings and conclusions in this document are those of the authors and do not necessarily represent the views of the organizations they represent.

Key Words

Antimicrobial susceptibility testing, antimicrobial susceptibility testing system, microbial identification testing, microbial identification testing system, verification

Verification of Commercial Microbial Identification and Antimicrobial Susceptibility Testing Systems

Chapter 1: Introduction

This chapter includes:

- Document scope and applicable exclusions
- Background information
- Standard precautions information
- "Note on Terminology" that highlights particular use and/or variation in use of terms and/or definitions
- Terms and definitions used in the document
- Abbreviations and acronyms used in the document

1.1 Scope

This guideline provides recommendations for clinical laboratory professionals for verification of commercial microbial identification systems (MIS) and US Food and Drug Administration (FDA)–cleared antimicrobial susceptibility testing systems (ASTS) to fulfill regulatory or QA requirements for use in diagnostic testing. Recommendations for postverification QA are also included. This guideline focuses on instrument-based systems commonly used in clinical laboratories, but the recommendations may also be applicable to manual methods for microbial identification (ID) and antimicrobial susceptibility testing (AST), including disk diffusion and gradient diffusion strips.

This guideline is not intended to provide guidance to manufacturers of *in vitro* diagnostic devices. A manufacturer must perform many studies during the research and development phases and the manufacturing validation phase that are unique to the design of the test system and the manufacturing processes. These studies go beyond the scope of this document. See Appendix A for a description of the FDA requirements for MIS and ASTS clearance.

This document does not address verification of chromogenic media, laboratory-developed methods, or systems using nucleic acid detection methods.

Appendix B addresses studies that may be used to implement alternative interpretive criteria (breakpoints) for ASTS.

1.2 Background

1.2.1 Verification

In this guideline, the term "verification" is used to describe the processes and studies performed when a system is first introduced into a laboratory or when that system is updated by the introduction of new identification substrates, antimicrobial agents, updated databases, software, or hardware.