CLINICAL AND LABORATORY STANDARDS INSTITUTE®

1st Edition

CLSI M67™

Verification of Laboratory Automation in Microbiology

CLSI M67 provides recommendations for verification and implementation of microbiology laboratory automation in medical microbiology laboratories, including modules for specimen processing, plate transport and incubation, and plate imaging, as well as software components associated with digital plate reading and image analysis.

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

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Verification of Laboratory Automation in Microbiology

Kevin Alby, PhD, D(ABMM)
Karissa Culbreath, PhD, D(ABMM)
Esther Babady, PhD, D(ABMM), FIDSA, F(AAM)
Natali Baker, MS, MT(ASCP)SM
Sarah Becket, MS, MLS(ASCP)CM
Kendall Bryant, PhD, D(ABMM)
Mark A. Fisher, PhD, D(ABMM)
Steven Giglio, PhD
Tobin Hellyer, PhD
S. Wesley Long, MD, PhD, D(ABMM)
Erin McElvania, PhD, D(ABMM)
Sunday Ogunkola, MSQA, M(ASCP), CQA, ASQ
Susan Sharp, PhD, D(ABMM), F(AAM)

Abstract

CLSI M67—*Verification of Laboratory Automation in Microbiology* describes recommendations for verification and implementation of various modules associated with microbiology laboratory automation (MLA) systems in medical microbiology laboratories. Guidance is provided on modules for specimen processing, plate transport and incubation, and plate imaging, as well as software components associated with digital plate reading and image analysis, along with issues to consider when implementing MLA in stages or all at once. Guidance is also provided on postverification quality assurance for MLA, including facilities and safety management, management of downtimes, verification after changes, proficiency testing and alternative assessments, and personnel management.

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Foreword

CLSI M67 provides recommendations for verification and implementation of microbiology laboratory automation systems that laboratories may consider while designing their own verification activities. Each laboratory should determine what activities are needed to provide accurate results and meet local regulatory requirements. The number of samples suggested for verification typically represents the minimum number recommended for testing and is based primarily on the experience and expert opinion of the document development committee. Testing additional specimens, especially specimens representing unique populations or unusual situations, should be considered.

NOTE: The content of CLSI M67 is supported by the CLSI consensus process and does not necessarily reflect the views of any single individual or organization.

KEY WORDS

automation
digital plate reading
image analysis algorithms
medical laboratory automation
plate imaging module
plate transport and incubation module
specimen processing module
verification

Chapter 1

Introduction

Verification of Laboratory Automation in Microbiology

1 Introduction

1.1 Scope

CLSI M67 provides recommendations and best practices for the verification and implementation of microbiology laboratory automation (MLA) in medical microbiology laboratories. MLA as described in CLSI M67 includes the various modules associated with MLA systems that can be fully integrated or independently used, including specimen processing modules (SPM), plate transport and incubation modules (PTIM), and plate imaging modules (PIM). Additionally, software components associated with digital plate reading (DPR) and image analysis algorithms (IAA) are included. Guidance is provided on issues to consider when implementing MLA, including the decision to implement in stages or all at once, the number and type of specimens to select for verification, the incorporation of partial or full MLA into existing processes in the laboratory, and recommendations for QC of MLA and postexamination management.

The target audiences for CLSI M67 are medical microbiologists directing, managing, supervising, and/or performing cultures for the recovery and identification of pathogens from clinical specimens submitted for diagnosis at medical laboratories (eg, hospital laboratories, reference laboratories). CLSI M67 provides recommendations for:

- Elements to consider for implementation
- Selection of samples to process with MLA, including Gram stain smear preparation
- Verification testing, including suggested number of samples, medium types, reference methods, discrepant results analysis, and acceptance criteria
- Verification of automated interpretation software
- Verification of results transmission from the MLA to the LIS
- Postverification QA, including managing instrument downtimes

CLSI M67 does not provide recommendations for:

- Verification of automation in the medical microbiology laboratory other than sample processing, incubation, and imaging
- MLA selection and preparation of colonies for downstream applications (out of scope)
- General verification of organism identification and antimicrobial susceptibility testing (AST) (refer to CLSI M52[1])
- Development of artificial intelligence algorithms or applications

1.2 Background

1.2.1 Development of Automation in Medical Microbiology

Automation in medical microbiology is the result of incremental technological and operational advances in specimen collection, including liquid microbiology and digital imaging. One of the largest challenges for automation of microbiology cultures is the complexity and variety of specimen types and containers received for testing in medical laboratories, ranging from liquid specimens that can be received in cups or tubes (eg, urine) to tissues and other specimens collected in a wide variety of containers.[2]

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