CLINICAL AND LABORATORY STANDARDS INSTITUTE®

1st Edition

CLSI M64™

Implementation of Taxonomy Nomenclature Changes

CLSI M64 includes recommendations for implementing nomenclature changes for medically important bacteria and fungi that are identified and reported from clinical specimens, especially when testing for antimicrobial susceptibility.

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

Clinical and Laboratory Standards Institute

Setting the standard for quality in medical laboratory testing around the world.

The Clinical and Laboratory Standards Institute (CLSI) is a not-for-profit membership organization that brings together the varied perspectives and expertise of the worldwide laboratory community for the advancement of a common cause: to foster excellence in laboratory medicine by developing and implementing medical laboratory standards and guidelines that help laboratories fulfill their responsibilities with efficiency, effectiveness, and global applicability.

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For additional information on committee participation or to submit comments, contact CLSI.

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Implementation of Taxonomy Nomenclature Changes

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Abstract

Clinical and Laboratory Standards Institute M64—*Implementation of Taxonomy Nomenclature Changes* provides background and historic information related to the process of microbial taxon discovery, publication, and acceptance by recognized professional committees and societies. Additional nuances within these topics exist in the field of medical mycology. CLSI M64 reflects collaborative discussions from experts in the fields of medical bacteriology, medical mycology, veterinary diagnostic microbiology, antimicrobial susceptibility testing, and diagnostics manufacturing. Recommendations are provided for the implementation of novel and revised taxonomy in human and veterinary microbiology laboratories. A two- to three-year timeline is presented for laboratories to enact these changes; changes that may more profoundly affect patient care can be acted upon more expediently. Communication with clinical and public health stakeholders is imperative to the successful implementation of taxonomic changes.

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Committee Membership

Consensus Council

The Consensus Council sets priorities for CLSI standards development and votes on Final Draft documents to confirm that process requirements have been met. Consensus Council members are listed on the CLSI website: https://clsi.org/standards-development/consensus-council/

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Expert panel volunteers support the development of CLSI documents by providing technical expertise in specialty areas. Expert panel members are listed by area of expertise on the CLSI website: https://clsi.org/standards-development/expert-panels/

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Contents

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Foreword

Advancements in molecular, proteomic, and phylogenetic technology in both the clinical and research setting have resulted in a plethora of novel bacterial and fungal taxa, as well as revisions to the nomenclature of currently existing microbes. CLSI M64 has been developed to provide laboratorians with practical guidance on how to assimilate novel and revised taxonomy into the medical and veterinary microbiology laboratories. To provide the medical laboratorian a more complete understanding of this topic, CLSI M64 provides several foundational summaries, including:

- A brief history of microbial systematics
- Contemporary attempts at nomenclature standardization
- General processes (including phenotypic and genotypic investigations) involved in the discovery, initial characterization, and effective publication of novel taxa
- Analogous processes that result in taxonomic revisions
- Criteria for official acceptance of novel and/or revised taxonomy
- Effect of the ever-changing field of microbial taxonomy on other scientific and medical disciplines

New taxonomy often comes with controversies, including determining the clinical relevance of these revised or novel taxa. CLSI M64 elaborates on these issues in an unbiased manner, using the expertise of scientists in the fields of infectious diseases, infection control and prevention, medical microbiology, medical mycology, veterinary diagnostic microbiology, antimicrobial and fungal susceptibility testing and pharmacology, and diagnostics manufacturing. While the bacterial taxonomy field has an ultimate adjudication authority, the medical mycology field has no authoritative organization for taxonomy. The ultimate deliverables within CLSI M64 are two sets of recommendations for implementing bacterial and fungal nomenclature revisions in medical and veterinary microbiology laboratories, along with a rationale for these recommendations. Final implementation may necessitate raising awareness of taxonomic revisions, performing various validation procedures, interacting with commercial diagnostics manufacturers, and communicating with important stakeholders.

NOTE: The content of CLSI M64 is supported by the CLSI consensus process and does not necessarily reflect the views of any single individual or organization.

KEY WORDS

anamorph

International Code of Nomenclature of Prokaryotes

International Committee on Systematics of Prokaryotes

novel species taxonomy

systematics

taxonomy revision

teleomorph

Validation Lists

Chapter 1

Introduction

Implementation of Taxonomy Nomenclature Changes

1 Introduction

1.1 Scope

CLSI M64 focuses on nomenclature changes for medically important bacteria and fungi that are included in CLSI documents, especially CLSI antimicrobial susceptibility testing (AST) standards and guidelines, as well as documents that cover molecular techniques that apply to bacteria and fungi. Veterinary pathogens are also included. CLSI M64 is intended for use by human and veterinary microbiology laboratory personnel, as well as primary and consulting care clinicians, pharmacists, and infection preventionists.

CLSI M64 discusses how and why changes to the nomenclature are made. It includes guidelines for assessing the effect of a nomenclature change on clinical care (eg, factors to consider). It includes tables with examples of changes proposed in the literature, a brief summary of why the changes are proposed, recommendations for reporting in a medical laboratory, and statements on the clinical effects of the recommendations. CLSI M64 does not include nomenclature changes for parasites and viruses causing disease in humans and animals.

1.2 Standard Precautions

Because it is often impossible to know what isolates or specimens might be infectious, all patient and laboratory specimens are treated as infectious and handled according to "standard precautions." Standard precautions are guidelines that combine the major features of "universal precautions and body substance isolation" practices. Standard precautions cover the transmission of all known infectious agents and thus are more comprehensive than universal precautions, which are intended to apply only to transmission of bloodborne pathogens. Published guidelines are available that discuss the daily operations of diagnostic medicine in humans and animals while encouraging a culture of safety in the laboratory.[1] For specific precautions for preventing the laboratory transmission of all known infectious agents from laboratory instruments and materials and for recommendations for the management of exposure to all known infectious diseases, refer to CLSI M29.[2]

1.3 Terminology

CLSI, as a global leader in standardization, is firmly committed to achieving global harmonization whenever possible. Harmonization is a process of recognizing, understanding, and explaining differences while taking steps to achieve worldwide uniformity. CLSI recognizes that medical conventions in the global metrological community have evolved differently in different countries and regions and that legally required use of terms, regional usage, and different consensus timelines are all important considerations in the harmonization process. CLSI recognizes its important role in these efforts, and its consensus process focuses on harmonization of terms to facilitate the global application of standards and guidelines. Table 1 is provided to clarify the intended interpretations of common terms.