CLINICAL AND LABORATORY STANDARDS INSTITUTE®

2nd Edition

# CLSI M23S2™

## Process to Submit Disk Content (Potency) Data for Joint CLSI-EUCAST Working Group Review and Approval



CLSI M23S2 describes the process to submit disk content (potency) data to the joint CLSI-EUCAST working group for review and approval.

A CLSI supplement for global application.

CLSI M23S2-Ed2
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Replaces CLSI M23S2-Ed1

# Process to Submit Disk Content (Potency) Data for Joint CLSI-EUCAST Working Group Review and Approval

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## Abstract

Clinical and Laboratory Standards Institute M23S2—*Process to Submit Disk Content (Potency) Data for Joint CLSI-EUCAST Working Group Review and Approval* describes the process to submit disk content (potency) data to the joint CLSI-EUCAST working group for review and approval.

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**NOTE:** The content in CLSI M23S2 is identical to the content in "Process to Submit Disk Content (Potency) Data for Joint CLSI-EUCAST Working Group Review and Approval. EUCAST SOP 12.1, 2024. http://www.eucast.org."





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# Foreword

The disk diffusion antimicrobial susceptibility test has been widely used around the world for decades and was first standardized in 1966.[1] In the 1970s, CLSI (then the National Committee for Clinical Laboratory Standards) published additional guidance for disk diffusion testing. In Europe, different variants of the disk diffusion method were used in different countries until 2009, when the European Committee on Antimicrobial Susceptibility Testing (EUCAST) provided a standardized disk diffusion method calibrated to the harmonized European minimal inhibitory concentration breakpoints. The disk diffusion test is based on incorporating a standard amount of an antimicrobial agent into a filter paper disk. Because it is relatively easy to perform and uses standard microbiology laboratory equipment, the disk diffusion test is used in many types of laboratories, including those in low-resource settings.

The disk content (potency) recommended for new antimicrobial agents has sometimes varied among organizations that set criteria (eg, breakpoints) for interpreting results of disk diffusion testing. Subsequently, pharmaceutical manufacturers have performed testing with two different disk contents (potencies) for generating data to present to breakpoint-setting organizations. This burdensome situation was caused in part by a lack of harmonized recommendations for selecting optimal disk contents (potencies). To correct this issue and improve efficiency for pharmaceutical manufacturers, disk manufacturers, researchers, and other organizations, CLSI and EUCAST initiated a joint venture to develop standardized recommendations for disk content (potency) selection. Their recommendations are presented in CLSI M23S2, in CLSI M23S,[2] and in EUCAST SOP 11.1.[3] (The content in CLSI M23S[2] and EUCAST SOP 11.1[3] is identical.)

**Contact information:** clsi.org/m23-supplement-question

CLSI
www.clsi.org

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## Overview of Changes

CLSI M23S2-Ed2 replaces CLSI M23S2-Ed1, published in 2021. The sole change made in this edition is updating the process to indicate sponsors should interact with the Joint CLSI-EUCAST working group before initiating a disk content study (see Chapter 2).

**NOTE:** The content of CLSI M23S2 is supported by the CLSI consensus process and does not necessarily reflect the views of any single individual or organization.

**KEY WORDS**

**data submission** **disk content** **disk potency**

# Chapter 1

# Introduction

# Process to Submit Disk Content (Potency) Data for Joint CLSI-EUCAST Working Group Review and Approval

## 1 Introduction

### 1.1 Scope

CLSI M23S2 is intended for pharmaceutical manufacturers involved in the development of antimicrobial agents and tests to support evaluation of antimicrobial agent activity for testing of bacteria. It is also intended for manufacturers of antimicrobial disks and any independent laboratory that supports the development of these disks. CLSI M23S2 describes the process to submit disk content (potency) data to the joint CLSI-EUCAST working group (WG) for review and approval. It does not explain the steps needed to perform the standardized disk diffusion test, nor does it define the criteria (breakpoints) used to interpret zone diameters of inhibition into interpretive categories. These steps are described elsewhere (see CLSI M02[4] and CLSI M07[5]).[6,7] The process for selecting the optimal content (potency) of antimicrobial agent to be added to filter paper disks to obtain reliable results with the standardized disk diffusion test is covered in CLSI M23S.[2] In some cases, the breakpoints defined by breakpoint-setting organizations for a single agent may differ even when the same disk content (potency) is used.

### 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.[8] 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.[9]

### 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.

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