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Procedure for Confirming the Acceptability of Mueller-Hinton Agar Sources for Subsequent Use in CLSI and/or EUCAST Studies to Establish Disk Diffusion Quality Control Ranges

This document describes the necessary technical steps for confirming the acceptability of Mueller-Hinton agar sources for subsequent use in CLSI and/or EUCAST studies to establish disk diffusion quality control ranges.

A CLSI supplement for global application.

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Procedure for Confirming the Acceptability of Mueller-Hinton Agar Sources for Subsequent Use in CLSI and/or EUCAST Studies to Establish Disk Diffusion Quality Control Ranges

Janet A. Hindler, MCLS, MT(ASCP), F(AAM)
Erika Matuschek, PhD
Mandy Wootton, PhD
Mariana Castanheira, PhD
Sharon K. Cullen, BS, RAC
Dana C. Dressel, BS, MT(ASCP)
Christian G. Giske, MD, PhD
Katy Jeannot, MD, PhD
Gunnar Kahlmeter, MD, PhD
Laura M. Koeth, BS, MT(ASCP)
Ian Morrissey, BSc, MBA, PhD, FRSM
Chris Pillar, PhD
John D. Turnidge, MD, BS, FRACP, FASM, FRCPA

Abstract

Clinical and Laboratory Standards Institute document M23S3—*Procedure for Confirming the Acceptability of Mueller-Hinton Agar Sources for Subsequent Use in CLSI and/or EUCAST Studies to Establish Disk Diffusion Quality Control Ranges* describes the necessary technical steps for confirming the acceptability of Mueller-Hinton agar sources for subsequent use in CLSI and/or European Committee on Antimicrobial Susceptibility Testing (EUCAST) studies to establish disk diffusion QC ranges.

Clinical and Laboratory Standards Institute (CLSI). *Procedure for Confirming the Acceptability of Mueller-Hinton Agar Sources for Subsequent Use in CLSI and/or EUCAST Studies to Establish Disk Diffusion Quality Control Ranges*. 1st ed. CLSI supplement M23S3 (ISBN 978-1-68440-191-8). Clinical and Laboratory Standards Institute, USA, 2023.

NOTE: The content in this document is identical to the content in "European Committee on Antimicrobial Susceptibility Testing. Procedure for Confirming the Acceptability of Mueller-Hinton Agar Sources for Subsequent Use in CLSI and/or EUCAST Studies to Establish Disk Diffusion QC Ranges. EUCAST SOP 13.0, 2023. http://www.eucast.org."

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Foreword

The CLSI and European Committee on Antimicrobial Susceptibility Testing (EUCAST) disk diffusion methods are based on reproducible and reliable separation between isolates belonging to different interpretive categories as determined by reference minimal inhibitory concentration methodology. Determining the optimal disk content (potency) is an important part of achieving a reproducible disk diffusion method.

Mueller-Hinton agar (MHA), which is the primary medium used for disk diffusion testing, is available from several commercial manufacturers with various brands available in different parts of the world. Disks are usually available from several commercial manufacturers as well. CLSI and EUCAST QC ranges are established using disks and media from several manufacturers to accommodate reasonable variation between materials from different manufacturers. To achieve a reproducible and reliable disk diffusion test, the variation in zone diameters obtained from different disk and medium sources should be minimal. Variability in the composition of MHA is the most common cause of systematic variation in disk diffusion testing results.

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

CLSI
www.clsi.org

EUCAST
www.EUCAST.org

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

KEY WORDS

disk content **disk diffusion** **disk potency**

Chapter 1

Introduction

Procedure for Confirming the Acceptability of Mueller-Hinton Agar Sources for Subsequent Use in CLSI and/or EUCAST Studies to Establish Disk Diffusion Quality Control Ranges

1 Introduction

1.1 Scope

The procedure presented in this document is intended to confirm that Mueller-Hinton agar (MHA) sources will perform reliably when a full QC study is performed, thereby avoiding media-related problems when QC ranges are established. This procedure is performed after a disk content (potency) has been selected according to CLSI document M23S[1] or EUCAST SOP 11.0[2] and before a study to establish QC ranges per CLSI document M23[3] and/or EUCAST SOP 9.3[4] is performed.

NOTE: This procedure is not mandatory for any CLSI or European Committee on Antimicrobial Susceptibility Testing (EUCAST) QC or other study that requires the use of MHA. However, it is strongly advised as a supplemental quality check of a reagent component that may significantly affect test results.

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.[5] 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 document M29.[6]

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 B1. Acceptable Results for Three of Four Medium Sources. In this example, three of four media show acceptable results with four test strains.

In Table B1:

- Green highlights = medium with mean or median zone diameters within ± 1 mm for test agent
- Orange highlights = medium with mean or median zone diameters not within ± 1 mm for test agent

Escherichia coli ATCC® 25922	Test Agent Manufacturer 1				Test Agent Manufacturer 2				Control Agent			
	Medium 1	Medium 2	Medium 3	Medium 4	Medium 1	Medium 2	Medium 3	Medium 4	Medium 1	Medium 2	Medium 3	Medium 4
Date test 1:	26	27	28	24	27	27	28	24	23	23	24	20
Date test 2:	26	26	27	25	26	27	28	23	24	23	24	21
Date test 3:	27	27	27	24	27	27	27	24	23	24	25	21
Mean value	26	27	27	24	27	27	28	24	23	23	24	21
Median value	26	27	27	24	27	27	28	24	23	23	24	21
Standard deviation	0.6	0.6	0.6	0.6	0.6	0.0	0.6	0.6	0.6	0.6	0.6	0.6
Minimum value	26	26	27	24	26	27	27	23	23	23	24	20
Maximum value	27	27	28	25	27	27	28	24	24	24	25	21

Pseudomonas aeruginosa ATCC® 27853	Test Agent Manufacturer 1				Test Agent Manufacturer 2				Control Agent			
	Medium 1	Medium 2	Medium 3	Medium 4	Medium 1	Medium 2	Medium 3	Medium 4	Medium 1	Medium 2	Medium 3	Medium 4
Date test 1:	20	20	21	17	20	20	21	17	18	17	17	16
Date test 2:	21	20	20	18	21	20	21	18	17	17	18	17
Date test 3:	20	19	21	17	21	21	20	18	17	18	19	16
Mean value	20	20	21	17	21	20	21	18	17	17	18	16
Median value	20	20	21	17	21	20	21	18	17	17	18	16
Standard deviation	0.6	0.6	0.6	0.6	0.6	0.6	0.6	0.6	0.6	0.6	1.0	0.6
Minimum value	20	19	20	17	20	20	20	17	17	17	17	16
Maximum value	21	20	21	18	21	21	21	18	18	18	19	17

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