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# NATIONAL STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA



# GB/T 40672-2021

# Clinical laboratory testing - Criteria for acceptable lots of dehydrated Mueller-Hinton agar and broth for antimicrobial susceptibility testing

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## Foreword

This document is in accordance with the provisions of GB/T 1.1-2020 "Guidelines for Standardization Work Part 1.Structure and Drafting Rules of Standardization Documents"

Drafting.

This document is equivalent to using ISO /T S16782.2016 "Clinical laboratory test antimicrobial agent sensitivity test dehydrated MH agar and broth can be

Acceptance of batch standards.

## Introduction

Historically, although various media have been recommended for antimicrobial sensitivity tests, MH broth (MHB) was selected as the broth micro-dilution

The minimum inhibitory concentration (MIC) reference method (ISO 20776-1) is the medium, and MH agar (MHA) is widely used for rapid growth of cells.

The paper disc diffusion test of bacteria.

MH medium can provide satisfactory growth conditions for most non-fastidious pathogens, with acceptable batch-to-batch reproducibility and low content

Inhibitors of sulfa, trimethoprim and tetracycline, and a large number of antimicrobial agent sensitivity tests have accumulated from this medium for decades

data.

This document aims to establish a standard description and protocol, based on which dehydrated MH agar (dMHA) and dehydrated MH broth (dMHB) are prepared

The manufacturer can determine its acceptable performance characteristics.

The test results must meet the quality control limit range specified for each combination of antimicrobial agents and quality control strains. Each production batch should at least deal with this

Combinations of these antibacterial agents and quality control strains were tested.

This document is based in part on the previous two documents of the Clinical and Laboratory Standards Institute (CLSI) under license. CLSI

M6-A2[1] (Dehydrated MH agar evaluation program) and CLSIM32-P[2] (Batch evaluation of dehydrated MH broth for antimicrobial susceptibility test). manufacture

Traders can use this document to evaluate the performance characteristics of their dehydrated MH agar (dMHA) and dehydrated MH broth (dMHB) production batches.

Clinical laboratory test

Antimicrobial sensitivity test dehydrated MH agar and broth

Acceptable batch standard

## 1 Scope

This document gives the standard description and performance standards of the physical properties of dehydrated MH broth (dMHB) and dehydrated MH agar (dMHA).

In this way, manufacturers can evaluate the performance characteristics of their dMHB and

dMHA production batches. Batches of broth or agar can then be used by all users

(Including the manufacturer of in vitro susceptibility testing equipment) as a medium for conducting antimicrobial susceptibility testing.

This document does not describe additives (such as blood or blood products) that are added to the culture medium to support the growth of fastidious bacteria (CLSI method

Method)[3][4][5][6]. These additives are added as a final product when the dehydrated medium is prepared as a liquid, which is beyond the scope of this document. Although

dMHA can be used for the agar dilution method[4][6] or gradient diffusion method to determine MIC. This document only contains in accordance with the American Association for Clinical and Laboratory Standards

(CLSI) [5] and European Committee for Antimicrobial Susceptibility Testing (EUCAST) [3] performance test using the paper diffusion method.



## 2 Normative references

The content of the following documents constitutes an indispensable clause of this document through normative references in the text. Among them, dated quotations

Only the version corresponding to the date is applicable to this document; for undated reference documents, the latest version (including all amendments) is applicable to

This document.

YY/T 0688.1-2008 Clinical laboratory testing and in vitro diagnostic system infection pathogen susceptibility test and antimicrobial susceptibility

Performance evaluation of test equipment. Part 1.Reference for the in vitro activity detection of antibacterial agents for rapid-growing aerobic bacteria related to infectious diseases

Method (ISO 20776-1.2006, MOD)

Note. There is no technical difference between the quoted content of YY/T 0688.1-2008 and the quoted content of ISO 20776-1.2006.

ISO 20776-1 Infectious pathogen susceptibility test and performance evaluation of antibacterial agent susceptibility test equipment Part 1.Antibacterial agent pair

The broth microdilution reference method for the in vitro activity detection of rapidly growing aerobic bacteria related to infectious diseases (Susceptibility testing of

infectiousagentsandevaluationofperformanceofantimicrobialsusceptibilitytestdevices-Part 1.

Brothmicro-dilutionreferencemethodfortestingtheinvitroactivityofantimicrobialagentsagainst

rapidlygrowingaerobicbacteriainvolvedininfectiousdiseases)

CLSIM100 Antimicrobial Agent Sensitivity Test Implementation Standard; Informational Supplement (Performance Standards for Antimicrobial

SusceptibilityTesting;InformationalSupplement)

## 3 Terms and definitions

The following terms and definitions apply to this document.

3.1

Antimicrobial agent

A general term for biologically derived, synthetic or semi-synthetic substances that can inhibit or kill microorganisms and may be used for anti-infective treatment.

Note. Disinfectants, sterilants and preservatives are not within the scope of this definition.

[Source. YY/T 0688.1-2008,2.1]