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

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National foreword

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A list of organizations represented on this committee can be obtained on request to its secretary.

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TECHNICAL SPECIFICATION

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

Détermination de la sensibilité aux antibiotiques — Critères d'acceptabilité pour les lots d'agar déshydraté et de bouillon Mueller-Hinton pour déterminer la sensibilité aux antibiotiques

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing Technical Specifications is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

The committee responsible for this document is ISO/TC 212, *Clinical laboratory testing and in vitro diagnostic test systems.*

Introduction

Historically, although various media have been recommended for susceptibility testing, Mueller-Hinton broth (MHB) has been selected as the medium for the reference broth microdilution minimum inhibitory concentration (MIC) method (ISO 20776-1) and Mueller-Hinton agar (MHA) is most widely used for disc diffusion testing of rapidly growing bacteria.

Mueller-Hinton medium provides satisfactory growth of most non-fastidious pathogens, acceptable batch-to-batch reproducibility, low sulfonamide, trimethoprim, and tetracycline inhibitors and a large amount of data has been collected from antimicrobial susceptibility tests with this medium over several decades.

This International Standard is the result of an effort to establish a standard description and protocol by which manufacturers of dehydrated Mueller-Hinton agar (dMHA) and broth (dMHB) may determine its acceptable performance characteristics.

The results of testing conform to defined quality control limit ranges for each combination of antimicrobial agent and quality control strains. Each production lot is tested at least against these combinations of antimicrobial agents and quality control strains.

This Technical Specification has been developed in part based upon the Clinical and Laboratory Standards Institute (CLSI) documents, CLSI M6-A2[1] (protocols for evaluating dehydrated Mueller-Hinton agar) and CLSI M32-P[2] (evaluation of lots of dehydrated Mueller-Hinton broth for antimicrobial susceptibility testing) with permission. Upon publication of ISO 16782, CLSI documents M6-A2[1] and M32-P[2] will no longer be available. Manufacturers can follow ISO 16782 to assess the performance characteristics of their production lots of dMHA and dMHB.

TECHNICAL SPECIFICATION ISO/TS 16782:2016(E)

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

1 Scope

This Technical Specification provides a standard description of the physical properties of dehydrated Mueller-Hinton broth (dMHB) and Mueller-Hinton agar (dMHA) and performance criteria by which manufacturers can assess the performance characteristics of their production lots of dMHA and dMHB. Production lots of broth or agar can then be utilized by all users, including *in vitro* susceptibility testing device manufacturers, as the test medium for performance of antimicrobial susceptibility testing.

This Technical Specification does not address supplements (e.g. blood or blood products) that are added to the medium to support growth of fastidious bacteria[3][4][5][6]. Those additives are provided after the dehydrated medium is prepared in its liquid state as a final product and fall outside of the scope of this Technical Specification. Although dMHA can be used for determination of MICs using the agar dilution method[4][6] or the gradient diffusion method, this Technical Specification only includes performance testing of dMHA using disc diffusion methodology as described by the Clinical and Laboratory Standards Institute (CLSI)[5] and European Committee on Antimicrobial Susceptibility Testing (EUCAST)[3].

2 Normative reference

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 20776-1:2006, *Clinical laboratory testing and in vitro diagnostic test systems — Susceptibility testing of infectious agents and evaluation of performance of antimicrobial susceptibility test devices — Part 1: Reference method for testing the in vitro activity of antimicrobial agents against rapidly growing aerobic bacteria involved in infectious diseases*

CLSI M100, *Performance Standards for Antimicrobial Susceptibility Testing; Informational Supplement*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1
antimicrobial agent
substance of biological, semi-synthetic or synthetic origin that inhibits the growth of or kills bacteria and is thus of potential use in the treatment of infections

Note 1 to entry: Disinfectants, antiseptics and preservatives are not included in this definition.

[SOURCE: ISO 20776-1:2006, 2.1]

3.2
antimicrobial disc
small paper disc containing known amounts of antimicrobial agents used for *in vitro* susceptibility testing

