September 1999

Methods for Determining Bactericidal Activity of Antimicrobial Agents; Approved Guideline

This document provides procedures for determining the lethal activity of antimicrobial agents.

AB C

# NCCLS...

# Serving the World's Medical Science Community Through Voluntary Consensus

NCCLS is an international, interdisciplinary, nonprofit, standards-developing, and educational organization that promotes the development and use of voluntary consensus standards and guidelines within the healthcare community. It is recognized worldwide for the application of its unique consensus process in the development of standards and guidelines for patient testing and related healthcare issues. NCCLS is based on the principle that consensus is an effective and cost-effective way to improve patient testing and healthcare services.

In addition to developing and promoting the use of voluntary consensus standards and guidelines, NCCLS provides an open and unbiased forum to address critical issues affecting the quality of patient testing and health care.

#### **PUBLICATIONS**

An NCCLS document is published as a standard, guideline, or committee report.

**Standard** A document developed through the consensus process that clearly identifies specific, essential requirements for materials, methods, or practices for use in an unmodified form. A standard may, in addition, contain discretionary elements, which are clearly identified.

**Guideline** A document developed through the consensus process describing criteria for a general operating practice, procedure, or material for voluntary use. A guideline may be used as written or modified by the user to fit specific needs.

**Report** A document that has not been subjected to consensus review and is released by the Board of Directors.

#### **CONSENSUS PROCESS**

The NCCLS voluntary consensus process is a protocol establishing formal criteria for:

- the authorization of a project
- the development and open review of documents
- the revision of documents in response to comments by users
- the acceptance of a document as a consensus standard or guideline.

Most NCCLS documents are subject to two levels of consensus- "proposed" and "approved." Depending on the need for field evaluation or data collection, documents may also be made available for review at an intermediate (i.e., "tentative") consensus level.

**Proposed** An NCCLS consensus document undergoes the first stage of review by the healthcare community as a proposed standard or guideline. The document should

receive a wide and thorough technical review, including an overall review of its scope, approach, and utility, and a line-by-line review of its technical and editorial content.

**Tentative** A tentative standard or guideline is made available for review and comment only when a recommended method has a well-defined need for a field evaluation or when a recommended protocol requires that specific data be collected. It should be reviewed to ensure its utility.

Approved An approved standard or guideline has achieved consensus within the healthcare community. It should be reviewed to assess the utility of the final document, to ensure attainment of consensus (i.e., that comments on earlier versions have been satisfactorily addressed), and to identify the need for additional consensus documents.

NCCLS standards and guidelines represent a consensus opinion on good practices and reflect the substantial agreement by materially affected, competent, and interested parties obtained by following NCCLS's established consensus procedures. Provisions in NCCLS standards and guidelines may be more or less stringent than applicable regulations. Consequently, conformance to this voluntary consensus document does not relieve the user of responsibility for compliance with applicable regulations.

#### **COMMENTS**

The comments of users are essential to the consensus process. Anyone may submit a comment, and all comments are addressed, according to the consensus process, by the NCCLS committee that wrote the document. All comments, including those that result in a change to the document when published at the next consensus level and those that do not result in a change, are responded to by the committee in an appendix to the document. Readers are strongly encouraged to comment in any form and at any time on any NCCLS document. Address comments to the NCCLS Executive Offices, 940 West Valley Road, Suite 1400, Wayne, PA 19087, USA.

### **VOLUNTEER PARTICIPATION**

Healthcare professionals in all specialties are urged to volunteer for participation in NCCLS projects. Please contact the NCCLS Executive Offices for additional information on committee participation.

Vol. 19 No. 18 M26-A

# Methods for Determining Bactericidal Activity of Antimicrobial Agents; Approved Guideline

# **Abstract**

Established laboratory methods that can assess the bactericidal activity of an antimicrobial agent are needed, both because of the increase in the number of patients who do not have completely normal host immune defenses and because of the new classes of antimicrobial agents that have been introduced. Clinical cure depends largely upon host factors. Bactericidal tests can provide a rough prediction of bacterial eradication. It should be noted, however, that other factors (e.g., postantibiotic effect and the growth-inhibitory effects of sub-MIC concentrations of antibiotics) may also impact bacteriologic response of patients. The special susceptibility tests that assess lethal activity are not routinely applied to all microorganisms, but are applied in unusual situations; e.g., endocarditis. Uniform test procedures are thus needed to permit comparison of different datasets.

The methods for bactericidal testing are now evolving, but more work is needed with the methodological aspects and clinical correlations. The techniques described in this document are intended primarily for testing aerobic bacteria that grow after incubation in adjusted Mueller-Hinton broth or adjusted Mueller-Hinton broth supplemented with human serum or an ultrafiltrate thereof.

(NCCLS. *Methods for Determining Bactericidal Activity of Antimicrobial Agents; Approved Guideline*. NCCLS document M26-A [ISBN 1-56238-384-1]. NCCLS, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087 USA, 1999.)

THE NCCLS consensus process, which is the mechanism for moving a document through two or more levels of review by the healthcare community, is an ongoing process. Users should expect revised editions of any given document. Because rapid changes in technology may affect the procedures, methods, and protocols in a standard or guideline, users should replace outdated editions with the current editions of NCCLS documents. Current editions are listed in the NCCLS Catalog, which is distributed to member organizations, and to nonmembers on request. If your organization is not a member and would like to become one, and to request a copy of the NCCLS Catalog, contact the NCCLS Executive Offices. Telephone: 610.688.0100; Fax: 610.688.0700; E-Mail: exoffice@nccls.org

i

September 1999 NCCLS

September 1999

# Methods for Determining Bactericidal Activity of Antimicrobial Agents; Approved Guideline

# Volume 19 Number 18

Arthur L. Barry, Ph.D.
William A. Craig, M.D.
Harriette Nadler, Ph.D.
L. Barth Reller, M.D.
Christine C. Sanders, Ph.D.
Jana M. Swenson, M.M.Sc.

AB C

September 1999 NCCLS

This publication is protected by copyright. No part of it may be reproduced, stored in a retrieval system, or transmitted in any form or by any means (electronic, mechanical, photocopying, recording, or otherwise) without written permission from NCCLS, except as stated below.

NCCLS hereby grants permission to reproduce limited portions of this publication for use in laboratory procedure manuals at a single site, for interlibrary loan, or for use in educational programs provided that multiple copies of such reproduction shall include the following notice, be distributed without charge, and, in no event, contain more than 20% of the document's text.

Reproduced with permission, from NCCLS publication M26-A—*Methods for Determining Bactericidal Activity of Antimicrobial Agents; Approved Guideline*. Copies of the current edition may be obtained from NCCLS, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087 USA.

Permission to reproduce or otherwise use the text of this document to an extent that exceeds the exemptions granted here or under the Copyright Law must be obtained from NCCLS by written request. To request such permission, address inquiries to the Executive Director, NCCLS, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087 USA.

Copyright ©1999. The National Committee for Clinical Laboratory Standards.

# **Suggested Citation**

(NCCLS. *Methods for Determining Bactericidal Activity of Antimicrobial Agents; Approved Guideline*. NCCLS document M26-A [ISBN 1-56238-384-1]. NCCLS, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087 USA, 1999.)

### **Proposed Guideline**

September 1986

## **Tentative Guideline**

September 1992

#### Approved Guideline

September 1999

ISBN 1-56238-384-1 ISSN 0273-3099