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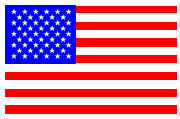
Quality Control for Commercially Prepared Microbiological Culture Media; Approved Standard—Third Edition

This document contains quality assurance procedures for manufacturers and users of prepared, ready-to-use microbiological culture media.

A standard for national application developed through the NCCLS consensus process.



NCCLS...

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Quality Control for Commercially Prepared Microbiological Culture Media; Approved Standard—Third Edition

Karen Krisher, Ph.D., D(ABMM)
Donald R. Callihan, Ph.D.
Ronald N. Jones, M.D.
Dyan C. Luper, B.S., M.T., S.M.(ASCP)(NRM)
J. Michael Miller, Ph.D., D(ABMM)
Susan E. Sharp, Ph.D., D(ABMM)
Roxanne G. Shively, M.S.

Abstract

The M22 standard provides information on quality control of commercially prepared microbiological culture media to users and manufacturers. M22-A3 is a revision of the approved standard, M22-A2, published in December 1996. The standard applies to all commercial media listed in Table 2 regardless of packaging, plate, or tube design. The media included in M22-A3 are from three surveys conducted by the College of American Pathologists. The third survey, conducted in the fall of 2001, was performed in response to the many requests for further expansion of the exempt media list. M22-A3 lists an additional 27 exempt media.

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Committee Membership

Area Committee on Microbiology

Mary Jane Ferraro, Ph.D., M.P.H.
Chairholder
Massachusetts General Hospital
Boston, Massachusetts

James H. Jorgensen, Ph.D.
Vice-Chairholder
University of Texas Health Science Center
San Antonio, Texas

Donald R. Callihan, Ph.D.
BD Diagnostic Systems
Sparks, Maryland

David L. Sewell, Ph.D.
Veterans Affairs Medical Center
Portland, Oregon

Thomas R. Shryock, Ph.D.
Elanco Animal Health
Greenfield, Indiana

Jana M. Swenson, M.M.Sc.
Centers for Disease Control and Prevention
Atlanta, Georgia

Michael L. Wilson, M.D.
Denver Health Medical Center
Denver, Colorado

Advisors

Ellen Jo Baron, Ph.D.
Stanford University Hospital & Medical School
Stanford, California

Lynne S. Garcia, M.S.
LSG and Associates
Santa Monica, California

Richard L. Hodinka, Ph.D.
Children's Hospital of Philadelphia
Philadelphia, Pennsylvania

Michael A. Pfaller, M.D.
University of Iowa College of Medicine
Iowa City, Iowa

Robert P. Rennie, Ph.D.
University of Alberta Hospitals
Edmonton, Canada

Melvin P. Weinstein, M.D.
Robert Wood Johnson Medical School
New Brunswick, New Jersey

Gail L. Woods, M.D.
ARUP Research Institute
Salt Lake City, Utah

Working Group on Quality Control of Culture Media

Karen Krisher, Ph.D., D(ABMM)
Chairholder

Donald R. Callihan, Ph.D.
BD Diagnostic Systems
Sparks, Maryland

Ronald N. Jones, M.D.
The Jones Group/JMI Laboratories
North Liberty, Iowa

Dyan C. Luper, B.S., M.T., S.M.(ASCP), S.M.(NRM)
CHRISTUS Spohn Health System
Corpus Christi, Texas

J. Michael Miller, Ph.D., D(ABMM)
Centers for Disease Control and Prevention
Atlanta, Georgia

Susan E. Sharp, Ph.D., D(ABMM)
Kaiser-Permanente - NW
Portland, Oregon

Roxanne G. Shively, M.S.
FDA Center for Devices/Rad. Health
Rockville, Maryland

Staff

Tracy A. Dooley, M.L.T.(ASCP)
Staff Liaison
NCCLS
Wayne, Pennsylvania

Donna M. Wilhelm
Editor
NCCLS
Wayne, Pennsylvania

Melissa A. Lewis
Assistant Editor
NCCLS
Wayne, Pennsylvania

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Foreword

Quality control of commercially prepared media imposes a substantial financial burden on licensed microbiology laboratories. In response, the College of American Pathologists (CAP) conducted three laboratory surveys to determine the failure rates of commonly used media.[1,2]

The first two surveys provided data that allowed exemption of 24 of 35 assessed media from quality control. The third survey, conducted in 2001, allows the addition of 27 media to the exempt list. The data, however, cause concern. Manufacturers perform quality control on all media sold to customers. Why, then, do certain media repeatedly exhibit failure rates ≥0.3 or 0.5%? Less than optimum storage conditions may contribute to medium failure. Media are shipped, stored, and delivered nonrefrigerated by the manufacturer or distributor. Specialty media that require more fastidious quality control organisms also often exhibit higher failure rates. Separate, limited surveys of different U.S. and Canadian[3,4] clinical microbiology laboratories revealed a lack of standardization in the quality control of media, including processing, storage, and inoculation of quality control organisms. Until resolution of these issues, clinical laboratories must continue to verify the performance of certain medium types.

Karen Krisher, Ph.D., D(ABMM), Chairholder,
Working Group on Quality Assurance for Commercially Prepared Microbiological Culture Media

Key Words

Commercially prepared, ready-to-use culture media; culture media; quality assurance; quality control

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1 Scope

The M22 standard provides information on quality control of commercially prepared microbiological culture media to users and manufacturers. M22-A3 is a revision of the approved standard, M22-A2, published in December 1996.

The basic premise of this standard is that the retesting of commercially prepared microbiological culture media is unnecessary for those media that are of proven reliability. The categorization of media that do not require retesting by the user is based on quality control data collected from surveys of clinical laboratories enrolled in the bacteriology proficiency-testing program conducted by the College of American Pathologists (CAP). The media types listed in the M22 standard are well established for recovery of clinically significant microorganisms. Exemption of certain media from routine quality control by the clinical laboratories assumes that media performance is monitored by an overall quality program that correlates test methods with clinical information, and monitors test procedures and specimen quality. **Media used for antimicrobial susceptibility testing have different quality control recommendations that are detailed in separate NCCLS documents.**

Changes or additions to this newest revision are the following: 1) Designation of the responsibilities of the manufacturer, distributor, and user; 2) clarification of the media included in various categories; 3) simplification of the basic protocols for the maintenance of quality control organisms; 4) incubation conditions for media quality control; 5) recommendations for the quality control of media used for certain fastidious organisms; and 6) expansion of the cutoff for acceptable failure rate from 0.3% to 0.5% and the categorization of an additional 27 media as exempt from user testing.

2 Introduction

The NCCLS Subcommittee on Media Quality Control was formed in 1984 to develop a standard that would specify the requirements for quality control of culture media. The work of this subcommittee resulted in the publication of M22 as a proposed standard in 1985 and an approved standard in 1990. A revision of M22 was published in 1996. In 2001, the document was scheduled for a second revision and the responsibility was assigned to a working group within the original subcommittee. From the inception of M22, the subcommittee has utilized the recommendations of the College of American Pathologists for the categorization of media that require quality control by the user.

CAP evaluated the failure rates of commercially prepared media in three surveys mailed to participants of the CAP Microbiology Proficiency Testing Surveys (see Table 1).[1,2] Failure rates are calculated as a raw percentage score of "total number of lots failing QC/total number of lots tested." An extrapolated failure rate is then determined by calculating what proportion of the raw rate is attributed to some type of failure detected by a QC organism. Only those media with a significant QC experience as defined by >1000 lots or >100 000 items which exhibit QC strain-related failures meet the criteria for calculation of the extrapolated failure rate.

The most recent survey (2001) evaluated 262 968 lots, among which were 32 702 833 plates, tubes, or bottles.[2] Failure rates were calculated for the 38 most commonly used media (97% of the reported lots). Reasons for media failures for all three surveys are listed in Table 1A. The extrapolated failure rate limit was raised from 0.3% to 0.5% based on analysis of the distribution of failures rates from the three surveys. Users are exempt from performing quality control of media with failure rates $\leq$0.5% (see Table 1B). Media with failure rates >0.5% continue to require user quality control.

