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CLINICAL AND LABORATORY STANDARDS INSTITUTE®

July 2014

M56-A

Principles and Procedures for Detection of Anaerobes in Clinical Specimens; Approved Guideline

This document presents standardized, cost-effective, and efficient best practice processes for anaerobe bacteriology to assist clinical laboratories in selecting those methods that lead to improved patient care.

A guideline for global application developed through the Clinical and Laboratory Standards Institute consensus process

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This is a preview of "CLSI M56-A". Click here to purchase the full version from the ANSI store.

ISBN 1-56238-969-6 (Print)
ISBN 1-56238-970-X (Electronic)
ISSN 1558-6502 (Print)
ISSN 2162-2914 (Electronic)

M56-A
Vol. 34 No. 10

Principles and Procedures for Detection of Anaerobes in Clinical Specimens; Approved Guideline

Volume 34 Number 10

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Abstract

Clinical and Laboratory Standards Institute document M56-A—*Principles and Procedures for Detection of Anaerobes in Clinical Specimens; Approved Guideline* provides procedures for performing testing and providing accurate, reliable, and useful results to laboratories with differing levels of expertise in anaerobe bacteriology. Preexamination requirements for specimen selection, collection, transport, timely processing, and examination procedures are discussed. Rapid and complex methods are compared for their ability to provide definitive identifications. Because the delivery of preliminary reports is vital to patient care when complex final reports are delayed, interpretations of direct smears and culture results are presented to help laboratorians confidently issue preliminary reports. Descriptions of anaerobes involved in human disease and a discussion of diagnostic methods for *Clostridium difficile* disease are presented. Guidelines for establishing competency testing to laboratories at their various levels of expertise and complexity are included. Because failures in good practices for preexamination, examination, and postexamination techniques can put patients at risk, a discussion of risk assessment during the design and implementation of anaerobe bacteriology protocols is included.

Clinical and Laboratory Standards Institute (CLSI). *Principles and Procedures for Detection of Anaerobes in Clinical Specimens; Approved Guideline*. CLSI document M56-A (ISBN 1-56238-969-6 [Print] ISBN 1-56238-970-X [Electronic]). Clinical and Laboratory Standards Institute, 950 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2014.

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Suggested Citation

CLSI. *Principles and Procedures for Detection of Anaerobes in Clinical Specimens; Approved Guideline*. CLSI document M56-A. Wayne, PA: Clinical and Laboratory Standards Institute; 2014.

Approved Standard
July 2014

ISBN 1-56238-969-6 (Print)
ISBN 1-56238-970-X (Electronic)
ISSN 1558-6502 (Print)
ISSN 2162-2914 (Electronic)

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Acknowledgment

CLSI, the Consensus Committee on Microbiology, and the Document Development Committee on Detection of Anaerobes in Clinical Specimens gratefully acknowledge the following volunteers for their important contributions to the development of this document:

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Foreword

This document provides information on timely, standardized, and cost-effective methods that constitute best practices for anaerobe bacteriology and has been created to assist clinical laboratories in the selection and use of high-quality, efficient methods to improve patient care.

Anaerobes can be involved in infections of the head and neck, central nervous system, pleuropulmonary sites, intra-abdominal sites, female genital tract, blood, skin, soft tissues, and bones. These infections are known to contribute significantly to patient morbidity and mortality and adequate therapy plays an important role in the outcome. Previously, sites of anaerobe infection and the anaerobic microorganism‘s antimicrobial susceptibilities were thought to be predictable, but this is no longer true. Clinicians are seeing more anaerobe infections in immunocompromised patients and in those patients with complex diseases. Anaerobic isolates that are resistant to antimicrobial agents are encountered more frequently. This changing clinical picture requires an adequate laboratory response.

Anaerobe bacteriology can be challenging. The microorganisms are sensitive to oxygen exposure; thus requiring specialized supplies, equipment, and methods. They are part of the normal human flora often causing infections by penetration of the deeper tissues when physical damage to tissue or structure has occurred. Therefore, the diagnostic process must differentiate between the infecting and noninvolved microorganisms. The isolation and ID of those specific anaerobes involved in infections depend on appropriate methods beginning with specimen selection, collection, transportation, and, finally, ID determinations. New technical microbiology tools now allow IDs to be reported rapidly and to be more extensive and precise. Additional training and collaboration with clinicians will be required to interpret the extensive reports but this can improve patients‘ outcomes, which is the ultimate goal of testing, diagnosis, and treatment.

Key Words

Anaerobe identification, anaerobe taxonomy, anaerobes, anaerobic culture, antimicrobial susceptibility testing, *Clostridium difficile* detection

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1 Scope

This document provides guidance for preexamination, examination, and postexamination procedures associated with the culture of anaerobic bacteria. Because anaerobic bacteria are part of human normal flora and are sensitive to oxygen exposure, good preexamination methods are essential. These recommendations include methods for collecting proper specimens from appropriate clinical sites and for transport procedures that protect anaerobes from oxygen exposure so that all pathogens involved in infections can be detected. The optimal methods needed to provide accurate, timely, and sufficient information for appropriate medical decisions are included, along with a discussion of the use and value of partial and full isolate IDs. Also included in this guideline are recommendations for interpreting results, assistance in understanding the value of rapid preliminary results, and guidance on issues of QC, QA, and competency.

The intended audience includes medical technologists, infectious disease physicians, microbiology laboratory directors, pathologists, and researchers.

Because anaerobe antimicrobial susceptibility testing (AST) methods are presented in CLSI documents M11[1] and M100,[2] this document limits its discussion to the need and indications for AST.

2 Introduction

Institutions allocate varying resources to their laboratories for the development of the expertise and processes needed to work with anaerobic bacteria. The goal of this document is to present procedures that result in accurate and timely anaerobe bacteriology reports at different categories of expertise (refer to Table 1). Users of each laboratory should be aware of the level of expertise and extent of testing provided by that laboratory.

When an institution determines the extent of anaerobe bacteriology that will be provided, it is performing a risk assessment. An extreme risk for potential patient harm is introduced when a hospital decides not to provide resources for detection of anaerobes because of a perception that its patients do not have anaerobe infections or that those types of infections are not important. Other laboratories limit IDs of polymicrobial infections to less than four isolates. Some laboratories even recommend limited workup of specimens such as abdominal abscesses. This recommendation is based on the belief that empiric therapy does not require culture results; but it overlooks the fact that all organisms grown from an abscess were involved in its formation and that some may be antibiotic resistant. Because many anaerobic infections are polymicrobic and the bacterial constituents may act synergistically, ID of all organisms present may provide both prognostic and therapeutic guidance.

Newer techniques may allow the rapid ID of many microorganisms. If a decision is made to conserve resources by limiting the number of isolates identified, each case must be communicated to the clinician so that the risk of incomplete but potentially available information is known, and additional studies can be done if clinically indicated. Without this collaboration between the laboratory and clinician, the risks of arbitrary censure of the data may pose an unacceptable risk. The additional information provided by new technical tools such as 16s ribosomal RNA (rRNA) gene sequencing and matrix-assisted laser desorption/ionization time-of-flight mass spectrometry (MALDI-TOF MS) adds valuable clinical insight regarding the disease process and role of the pathogens. Although it is tempting to restrict the use of these new advances in laboratory medicine because of supposed users‘ unfamiliarity with new taxonomy

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