CLINICAL AND LABORATORY STANDARDS INSTITUTE®

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M47-A

Principles and Procedures for Blood Cultures; Approved Guideline

This document provides recommendations for the collection, transport, and processing of blood cultures as well as guidance for the recovery of pathogens from blood specimens taken from patients who are suspected of having bacteremia or fungemia.

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

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For further information on committee participation or to submit comments, contact CLSI.

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Principles and Procedures for Blood Cultures; Approved Guideline

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Abstract

Clinical and Laboratory Standards Institute document M47-A—*Principles and Procedures for Blood Cultures; Approved Guideline* addresses the laboratory detection of bacteremia and fungemia by use of blood cultures. Included in this guideline are recommendations for the: 1) clinical importance of blood cultures; 2) specimen collection and transportation; 3) critical factors in the recovery of pathogens from blood specimens; 4) special topics, including pediatric blood cultures, catheter-related bloodstream infections, infective endocarditis, patients receiving antimicrobial therapy, rare and fastidious pathogens, and test of cure; 5) reporting results; 6) interpreting blood culture results; 7) safety issues; and 8) quality assurance.

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Foreword

The incidence of sepsis continues to increase in the United States: the most recent published data indicate that as many as 660,000 cases occur annually.[1] Because the morbidity and mortality attributable to sepsis is high, the prompt and accurate detection of bacteremia and fungemia is important for improving patient care. The laboratory test that is used to detect the presence of bacteria (bacteremia) or fungi (fungemia) in the blood is the blood culture.

During the past 30 years, a number of studies have been conducted to: 1) define the clinical significance of blood cultures; 2) define the critical factors in the recovery of pathogens from the blood; 3) establish the best medium formulations and other laboratory practices; 4) evaluate and compare commercial blood culture systems; and 5) develop interpretive criteria. Because of the clinical importance of bacteremia and fungemia, and therefore the importance of blood cultures, guidelines are needed so that laboratories and providers use optimal laboratory methods and interpret the results correctly. To date there has not been a single document that incorporates these data into consensus guidelines. Such guidelines are also needed to help control healthcare costs, as the costs attributable to the recovery of contaminants from blood cultures are high.

Key Words

Bacteremia, bacteria, blood culture, bloodstream infection, fungemia, fungi, mycobacteria, sepsis

Principles and Procedures for Blood Cultures; Approved Guideline

1 Scope

The laboratory detection of bacteremia and fungemia remains one of the most important functions of clinical microbiology laboratories. During the past 30 years, a number of studies have defined the critical factors in the recovery of pathogens from blood and the optimal laboratory methods for recovering specific pathogens, and have established the performance characteristics of blood culture systems. Despite this information, there remains a need for guidelines for the collection, processing, and interpretation of blood cultures.

Several *in vitro* blood culture devices are cleared by the United States Food and Drug Administration (FDA) for use in the United States. These devices typically are available for use in other countries.

This guideline is intended to provide guidance to clinical microbiologists and other laboratorians (e.g., pathologists, laboratory supervisors, laboratory managers) for the recovery of pathogens from blood specimens taken from patients who are suspected of having bacteremia or fungemia. Specific recommendations will be offered for the collection, transport, and processing of blood cultures. The existing blood culture technology will be reviewed and the relative benefits of these technologies will be compared. Procedures for the identification of pathogens will not be addressed. Antimicrobial susceptibility testing of bacteria is addressed in CLSI documents M2—*Performance Standards for Antimicrobial Disk Susceptibility Tests,*[2] M7—*Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria That Grow Aerobically,*[3] and M11—*Methods for Antimicrobial Susceptibility Testing of Anaerobic Bacteria*.[4] Antimicrobial susceptibility testing of fungi is covered in CLSI/NCCLS documents M27—*Reference Method for Broth Dilution Antifungal Susceptibility Testing of Yeasts*[5] and M38—*Reference Method for Broth Dilution Antifungal Susceptibility Testing of Filamentous Fungi*.[6]

2 Standard Precautions

Because it is often impossible to know what isolates or specimens might be infectious, all patient and laboratory specimens are treated as infectious and handled according to "standard precautions." Standard precautions are guidelines that combine the major features of "universal precautions and body substance isolation" practices. Standard precautions cover the transmission of all infectious agents and thus are more comprehensive than universal precautions which are intended to apply only to transmission of blood-borne pathogens. Standard and universal precaution guidelines are available from the US Centers for Disease Control and Prevention.[7] For specific precautions for preventing the laboratory transmission of all infectious agents from laboratory instruments and materials and for recommendations for the management of exposure to all infectious disease, refer to the most current edition of CLSI document M29—*Protection of Laboratory Workers From Occupationally Acquired Infections*.[8]

3 Definitions

antiseptic - a substance that inhibits the growth and development of microorganisms without necessarily killing them.[9]

automated blood culture system - a blood culture system that uses mechanical systems to incubate, agitate, and/or monitor blood culture bottles for microbial growth.

bacteremia – the presence of bacteria in the bloodstream; **NOTE:** Bacteria isolated from blood may be the cause of sepsis, indeterminate as a cause of sepsis, or contaminants.[10]

biphasic blood culture system - a blood culture system in which a single container (vial) has separate chambers for solid- and liquid-based media; **NOTE:** Most biphasic systems are designed so that the solid medium can be irrigated with the liquid medium.

blind subcultures – subcultures performed as a routine laboratory procedure irrespective of any objective evidence of microbial growth.[10]

blood culture – a specimen of blood that is submitted for bacterial or fungal culture; **NOTE:** This is irrespective of the number of bottles or tubes into which the specimen is divided or distributed.[10]

blood culture series – a group of temporally related blood cultures that are collected to determine whether a patient has bacteremia or fungemia.[10]

blood culture set – the combination of blood culture bottles or tubes into which a single blood specimen is inoculated.[10]

bloodstream infection – an infection associated with bacteremia or fungemia.

breakthrough bacteremia – bacteremia that persists while a patient is receiving antimicrobial therapy for an episode of bacteremia; **NOTE 1:** Breakthrough bacteremia that occurs early usually is the result of inappropriate or inadequate antimicrobial chemotherapy; **NOTE 2:** Breakthrough bacteremia that occurs late usually is the result of a focus of infection (e.g., an abscess) that has not been drained adequately.[10]

chlorhexidine gluconate – the digluconate salt of chlorhexidine[9]; **NOTE:** It is used as a topical agent for cleansing and disinfecting the skin.

contaminant – a microorganism isolated from a blood culture that was introduced into the culture during specimen collection or processing and that was not pathogenic for the patient from whom blood was collected[10] (i.e., the isolates were not present in the patient's blood when the blood was sampled for culture).

conventional (manual) blood culture system – a blood culture system that processes bottles without the use of mechanical systems (i.e., manually).

culture – **1)** the intentional growing of microorganisms, such as bacteria or fungi, in a controlled environment, for purposes of identification or other scientific study, or for commercial and/or medicinal use; **2)** the product resulting from the intentional growth of microorganisms.

culture medium – a substance or preparation used for the cultivation and growth of microorganisms.

disinfectant – a substance used to reduce the concentration of bacteria, fungi, or viruses on a surface.

false positive – a positive test result for a disease or condition when the disease or condition is not present; **NOTE:** *For blood cultures,* **1)** a culture that yields a microbial isolate(s) that is determined not to be the cause of sepsis, or **2)** a culture with objective evidence of microbial growth (i.e., an instrument signal that indicates microbial growth) but for which subcultures and stains are negative.

fungemia – the presence of fungi (yeasts or molds) in the bloodstream.[10]

inadequate blood volume – a blood culture bottle containing less than 80% of the recommended minimum volume indicated on the bottle label.

indeterminate isolates – a microorganism of undetermined clinical importance.[10]

The Quality Management System Approach

Clinical and Laboratory Standards Institute (CLSI) subscribes to a quality management system approach in the development of standards and guidelines, which facilitates project management; defines a document structure via a template; and provides a process to identify needed documents. The approach is based on the model presented in the most current edition of CLSI/NCCLS document HS1—*A Quality Management System Model for Health Care.* The quality management system approach applies a core set of "quality system essentials" (QSEs), basic to any organization, to all operations in any healthcare service's path of workflow (i.e., operational aspects that define how a particular product or service is provided). The QSEs provide the framework for delivery of any type of product or service, serving as a manager's guide. The quality system essentials (QSEs) are:

Documents & Records	Equipment	Information Management	Process Improvement
Organization	Purchasing & Inventory	Occurrence Management	Customer Service
Personnel	Process Control	Assessments—External and Internal	Facilities & Safety

M47-A addresses the quality system essentials (QSEs) indicated by an "X." For a description of the other documents listed in the grid, please refer to the Related CLSI/NCCLS Publications section on the following page.

Documents & Records	Organization	Personnel	Equipment	Purchasing & Inventory	Process Control	Information Management	Occurrence Management	Assessment	Process Improvement	Service & Satisfaction	Facilities & Safety
					X						

Adapted from CLSI/NCCLS document HS1—*A Quality Management System Model for Health Care*.

Path of Workflow

A path of workflow is the description of the necessary steps to deliver the particular product or service that the organization or entity provides. For example, CLSI/NCCLS document GP26—*Application of a Quality Management System Model for Laboratory Services* defines a clinical laboratory path of workflow which consists of three sequential processes: preexamination, examination, and postexamination. All clinical laboratories follow these processes to deliver the laboratory's services, namely quality laboratory information.

M47-A addresses the clinical laboratory path of workflow steps indicated by an "X." For a description of the other documents listed in the grid, please refer to the Related CLSI/NCCLS Publications section on the following page.

Preexamination				**Examination**			**Postexamination**	
Examination ordering	Sample collection	Sample transport	Sample receipt/processing	Examination	Results review and follow-up	Interpretation	Results reporting and archiving	Sample management
	X	X	X	X	X		X	

Adapted from CLSI/NCCLS document HS1—*A Quality Management System Model for Health Care*.

Related CLSI/NCCLS Publications*

GP2-A5 **Laboratory Documents: Development and Control; Approved Guideline— Fifth Edition (2006).** This document provides guidance on development, review, approval, management, and use of policy, process, and procedure documents in the medical laboratory community.

GP17-A2 **Clinical Laboratory Safety; Approved Guideline—Second Edition (2004).** This document contains general guidelines for implementing a high-quality laboratory safety program. The framework is adaptable to any laboratory. An NCCLS-CAP joint project.

H3-A5 **Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture; Approved Standard—Fifth Edition (2003).** This document provides procedures for the collection of diagnostic specimens by venipuncture, including line draws, blood culture collection, and venipuncture in children. It also includes recommendations on order of draw.

HS1-A2 **A Quality Management System Model for Health Care; Approved Guideline—Second Edition (2004).** This document provides a model for healthcare service providers that will assist with implementation and maintenance of effective quality systems.

M22-A3 **Quality Control for Commercially Prepared Microbiological Culture Media; Approved Standard—Third Edition (2004).** This standard contains quality assurance procedures for manufacturers and users of prepared, ready-to-use microbiological culture media.

M29-A3 **Protection of Laboratory Workers From Occupationally Acquired Infections; Approved Guideline—Third Edition (2005).** Based on US regulations, this document provides guidance on the risk of transmission of infectious agents by aerosols, droplets, blood, and body substances in a laboratory setting; specific precautions for preventing the laboratory transmission of microbial infection from laboratory instruments and materials; and recommendations for the management of exposure to infectious agents.

X3-R **Implementing a Needlestick and Sharps Injury Prevention Program in the Clinical Laboratory; A Report (2002).** This report presents a step-by-step approach for implementing safer medical devices that reduce or eliminate sharps injuries to laboratory personnel. X3-R is written in an expanded checklist format, outlines a process that goes beyond general recommendations, and specifically addresses the needs of professionals performing specimen collection and clinical laboratory procedures.

* Proposed-level documents are being advanced through the Clinical and Laboratory Standards Institute consensus process; therefore, readers should refer to the most recent editions.

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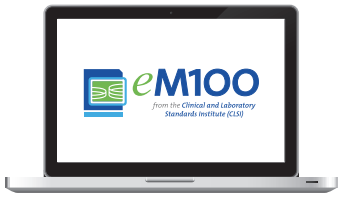

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