

# M29-A4

## Protection of Laboratory Workers From Occupationally Acquired Infections; Approved Guideline—Fourth Edition

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.

---

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

# Clinical and Laboratory Standards Institute

*Setting the standard for quality in clinical laboratory testing around the world.*

The Clinical and Laboratory Standards Institute (CLSI) is a not-for-profit membership organization that brings together the varied perspectives and expertise of the worldwide laboratory community for the advancement of a common cause: to foster excellence in laboratory medicine by developing and implementing clinical laboratory standards and guidelines that help laboratories fulfill their responsibilities with efficiency, effectiveness, and global applicability.

## Consensus Process

Consensus—the substantial agreement by materially affected, competent, and interested parties—is core to the development of all CLSI documents. It does not always connote unanimous agreement, but does mean that the participants in the development of a consensus document have considered and resolved all relevant objections and accept the resulting agreement.

## Commenting on Documents

CLSI documents undergo periodic evaluation and modification to keep pace with advancements in technologies, procedures, methods, and protocols affecting the laboratory or health care.

CLSI's consensus process depends on experts who volunteer to serve as contributing authors and/or as participants in the reviewing and commenting process. At the end of each comment period, the committee that developed the document is obligated to review all comments, respond in writing to all substantive comments, and revise the draft document as appropriate.

Comments on published CLSI documents are equally essential, and may be submitted by anyone, at any time, on any document. All comments are addressed according to the consensus process by a committee of experts.

## Appeals Process

If it is believed that an objection has not been adequately addressed, the process for appeals is documented in the CLSI Standards Development Policies and Process document.

All comments and responses submitted on draft and published documents are retained on file at CLSI and are available upon request.

## Get Involved—Volunteer!

Do you use CLSI documents in your workplace? Do you see room for improvement? Would you like to get involved in the revision process? Or maybe you see a need to develop a new document for an emerging technology? CLSI wants to hear from you. We are always looking for volunteers. By donating your time and talents to improve the standards that affect your own work, you will play an active role in improving public health across the globe.

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

Clinical and Laboratory Standards Institute  
950 West Valley Road, Suite 2500  
Wayne, PA 19087 USA  
P: 610.688.0100  
F: 610.688.0700  
[www.clsi.org](http://www.clsi.org)  
[standard@clsi.org](mailto:standard@clsi.org)

ISBN 1-56238-961-0 (Print)  
ISBN 1-56238-962-9 (Electronic)  
ISSN 1558-6502 (Print)  
ISSN 2162-2914 (Electronic)

M29-A4  
Vol. 34 No. 8  
Replaces M29-A3  
Vol. 25 No. 10

---

## Protection of Laboratory Workers From Occupationally Acquired Infections; Approved Guideline—Fourth Edition

Volume 34 Number 8

Donald R. Callihan, PhD, D(ABMM)  
Terry Jo Gile, MT(ASCP), MA Ed  
Kathleen G. Beavis, MD  
Mary L. Cipriano, MBA, RBP, CBSP  
Barry D. Cohen, MPH, CBSP  
Mary DeMartino, BS, MT, SM(ASCP)  
Gerald A. Denys, PhD, D(ABMM)

Marcia Finucane, MS, CBSP, MT(ASCP)  
Larry D. Gray, PhD  
William E. Homovec, CBSP, MPH  
Steven J. LaCroix, MS, CBSP  
Marcia Pindling-Watkins, MS, MT, M(ASCP)  
Jonathan Richmond  
Elizabeth G. Weirich, MS, SM(NRCM), CBSP

### Abstract

Clinical and Laboratory Standards Institute document M29-A4—*Protection of Laboratory Workers From Occupationally Acquired Infections; Approved Guideline—Fourth Edition* is intended to be a practical tool to aid in the development of an effective biosafety program for laboratory workers. It promotes best laboratory practices to protect workers from exposure to infectious diseases encountered in the clinical laboratory and to minimize the potential transfer of infectious organisms outside of the laboratory. These practices include but are not limited to use of standard precautions, good laboratory practices (eg, disinfection of contaminated work surfaces), safety devices, personal protective equipment, and appropriate decontamination and disposal of biological hazards. It emphasizes that specific policies and procedures, along with appropriate training of personnel on consistent application of laboratory precautions during the performance of work tasks, are essential administrative controls for the prevention of laboratory-acquired infections. Information is provided on safe transport of infectious substances, laboratory equipment hazards, occupational health and incident response, planning for public health emergencies, and best practices for biosafety training and competency assessment. Guidelines for the development of an effective biological risk assessment are also provided.

Clinical and Laboratory Standards Institute (CLSI). *Protection of Laboratory Workers From Occupationally Acquired Infections; Approved Guideline—Fourth Edition*. CLSI document M29-A4 (ISBN 1-56238-961-0 [Print]; ISBN 1-56238-962-9 [Electronic]). Clinical and Laboratory Standards Institute, 950 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2014.

The Clinical and Laboratory Standards Institute consensus process, which is the mechanism for moving a document through two or more levels of review by the health care 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 CLSI documents. Current editions are listed in the CLSI catalog and posted on our website at [www.clsi.org](http://www.clsi.org). If you or your organization is not a member and would like to become one, and to request a copy of the catalog, contact us at: Telephone: 610.688.0100; Fax: 610.688.0700; E-Mail: [customerservice@clsi.org](mailto:customerservice@clsi.org); Website: [www.clsi.org](http://www.clsi.org).



CLINICAL AND  
LABORATORY  
STANDARDS  
INSTITUTE®



Copyright ©2014 Clinical and Laboratory Standards Institute. Except as stated below, any reproduction of content from a CLSI copyrighted standard, guideline, companion product, or other material requires express written consent from CLSI. All rights reserved. Interested parties may send permission requests to [permissions@clsi.org](mailto:permissions@clsi.org).

CLSI hereby grants permission to each individual member or purchaser to make a single reproduction of this publication for use in its laboratory procedure manual at a single site. To request permission to use this publication in any other manner, e-mail [permissions@clsi.org](mailto:permissions@clsi.org).

### **Suggested Citation**

CLSI. *Protection of Laboratory Workers From Occupationally Acquired Infections; Approved Guideline—Fourth Edition*. CLSI document M29-A4. Wayne, PA: Clinical and Laboratory Standards Institute; 2014.

### **Proposed Standard**

November 1987

### **Approved Standard—Second Edition**

December 2001

### **Tentative Standard**

January 1989

### **Approved Guideline—Third Edition**

March 2005

### **Tentative Standard—Second Edition**

September 1991

### **Approved Guideline—Fourth Edition**

May 2014

### **Approved Standard**

December 1997

ISBN 1-56238-961-0 (Print)  
ISBN 1-56238-962-9 (Electronic)  
ISSN 1558-6502 (Print)  
ISSN 2162-2914 (Electronic)

## Contents

Abstract.....	i
Committee Membership.....	iii
Foreword.....	ix
1 Scope.....	1
2 Introduction.....	1
3 Standard Precautions.....	2
4 Terminology.....	3
4.1 A Note on Terminology.....	3
4.2 Definitions.....	3
4.3 Abbreviations and Acronyms.....	8
5 Essential Elements for Managing an Effective Biosafety Program.....	9
5.1 Responsibilities for Managing Laboratory Safety.....	10
5.2 Laboratory Safety Policies, Procedures, and Instructions.....	11
5.3 Biosafety Manual for Clinical Laboratories.....	11
5.4 Biosafety Training.....	12
5.5 Biosafety Program Implementation and Continuous Improvement.....	12
6 Biological Risk Assessment.....	13
6.1 Introduction.....	13
6.2 Performing a Biological Risk Assessment.....	14
7 Standard Laboratory Precautions.....	20
7.1 Components of Standard Laboratory Precautions.....	20
7.2 Warning Labels.....	23
7.3 Biological Safety Levels.....	24
7.4 Safe Work Practices.....	27
7.5 Personal Protective Equipment.....	33
8 Specimen- and Organism-Specific Guidelines.....	37
8.1 Guidelines and Algorithms for Handling Unusual Isolates.....	37
8.2 <i>Mycobacterium tuberculosis</i> .....	38
8.3 <i>Neisseria meningitidis</i> .....	38
8.4 Enteric Pathogens.....	39
8.5 Proteinaceous Infectious Particles.....	39
8.6 Potential Biological Threat Agents (Select Agents).....	40
9 Engineering Controls.....	42
9.1 Principles of Containment.....	43
9.2 Primary Containment (Biological Safety Cabinets and Centrifuges).....	43
9.3 Secondary Containment.....	45
10 Cleanup and Good Housekeeping Practices.....	48
10.1 Disinfectants and Sterilants.....	48
10.2 Procedures and Products.....	50
11 Safe Collection, Handling, Storage, and Transport of Potentially Infectious Substances.....	51
11.1 Collecting, Handling, and Storing Specimens.....	51

**Contents (Continued)**

11.2	Transport of Infectious Substances .....	54
12	Management of Medical Waste .....	58
12.1	Applicable Standards of Care .....	58
12.2	Types of Medical Waste .....	58
12.3	Collection and Management of Medical Waste .....	59
12.4	Mixed Medical Waste .....	60
12.5	Special Medical Waste – Proteinaceous Infectious Particles.....	60
13	Laboratory Equipment Hazards (Risk Mitigation) .....	60
13.1	Manufacturer’s Operations Manual .....	61
13.2	Laboratory Instrument or Diagnostic Device Contamination Concerns .....	62
13.3	Cleaning and Disinfection Basics for Equipment .....	63
13.4	Decontamination Procedures .....	63
13.5	Facilities Receiving Potentially Contaminated Devices for Repair or Refurbishing ..	67
13.6	Selected Device Biohazards.....	67
13.7	Other Laboratory Equipment .....	69
13.8	Policies for General Use Equipment.....	71
13.9	Equipment Maintenance .....	71
14	Management of Biological Releases, Exposure Incidents, or Accidents.....	72
14.1	Biohazard Spill Cleanup .....	72
14.2	Postexposure Actions.....	73
14.3	Corrective Actions .....	75
15	Occupational Health.....	75
15.1	Medical Surveillance .....	75
15.2	Workers for Whom Infection May Pose Increased Risk .....	80
15.3	Serum Banking Issues.....	80
16	Preparedness Planning for Worker Safety During Public Health Emergencies.....	81
16.1	Role of Clinical Laboratories During Public Health Emergencies (eg, Pandemic Influenza, Bioterrorism, Infectious Disease Outbreaks, Natural Disasters, Weather Emergencies, Power Outages).....	81
16.2	Employee Health and Safety.....	81
17	Biosafety Training and Competency Assessment.....	83
17.1	General Training Practices.....	83
17.2	Regulated Training for Laboratory Workers .....	86
17.3	Core Curriculum, Core Competencies, and Their Development .....	88
17.4	Competence, Training, and Awareness .....	92
17.5	Documentation and Recordkeeping .....	92
17.6	Monitoring and Enforcement of Compliance .....	93
17.7	Training Exercises .....	93
	References.....	95
	Appendix A. Safe Practices for the Autopsy Room.....	103
	Appendix B. Biological Risk Assessment Template .....	110
	Appendix C. General Characteristics to Consider for Early Recognition of Select Agents Associated With Bioterrorism and Potential Laboratory-Acquired Infections .....	126

**Contents (Continued)**

Appendix D. Model Decontamination Checklist for Laboratory Equipment ..... 128  
The Quality Management System Approach ..... 130  
Related CLSI Reference Materials ..... 132

SAMPLE

## Foreword

Upsurges in global population, together with the free movement of goods and people across national borders, have increased the likelihood for rapid worldwide transmission of infectious agents. This potential for the rapid transmission of novel agents also increases the risk of laboratory workers acquiring infections as a result of their occupational exposure to potentially infectious patient material. The recognition of new infectious agents, the worldwide emergence of antimicrobial resistance, the introduction of new diagnostic and treatment methods, and the potential for acts of bioterrorism have focused attention on the risk of infection to all health care workers—including laboratorians.

The risk to these workers increases with the heightened exposure to these potentially infectious materials and is present during all three phases of the laboratory path of workflow. In the preexamination phase, there is an increased risk of percutaneous injury during blood specimen collection through exposure to infectious aerosols or through direct contact with patients or specimens during transport. In the examination phase, specimen and culture manipulations expose the laboratory worker to numerous risks, including laboratory accidents and equipment. Management of biohazardous waste presents the primary risk associated with the postexamination phase.

Laboratory workers, who are routinely exposed to potentially infectious materials, have long been recognized as a high-risk group for occupationally related infections. Experience has demonstrated that implementing practices that decrease the worker's exposure to potentially infectious materials can minimize the risk of infection. These practices include designing facilities appropriately, effective training and consistent application of safe laboratory practices, following standard precautions, using personal protective equipment and safety devices, and the appropriate handling and disposal of biohazardous waste.

Because they pose a risk that is common and grave, diseases transmitted by blood and body substances (primarily hepatitis B virus [HBV], hepatitis C virus [HCV], and HIV) have been the focus of previous editions of M29. Many other infectious agents may be transmitted in blood; however, the consistent use of standard precautions recommended for HBV, HCV, and HIV has proven to be an effective means to protect workers from exposure to any bloodborne pathogen.

A single source of current, authoritative, practical recommendations addressing all laboratory areas (eg, clinical, anatomical pathology, and veterinary diagnostic laboratories; point-of-care testing sites; medical clinics; physician offices), M29 has been developed to provide a useful guide to best practices for the protection of laboratory workers, the local community, and the surrounding environment from exposure. This guideline is intended as a reference document for managers and supervisors of laboratory workers who have the potential for exposure to infectious materials.

The recommendations in this guideline are based on current knowledge and can be used to assist in the establishment of local institutional policy. However, each institution should be aware of and follow the laws and regulations applicable to its location.

Although this document draws heavily from the recommended and mandated guidelines and regulations applicable to the United States, the material contained in this document may be useful for improving laboratory safety throughout the world. Changes in regulations and recommendations occur rapidly, and it is advised that users consult authoritative publications and websites for the most current information. Although M29 may be a useful resource for a wider audience, it is intended primarily to help the US user navigate through US regulations. Because occupational exposure practices are heavily regulated and widely country specific, it has been determined that development of a comparable guideline intended for global application may not be feasible. It is anticipated that development of such a guideline may be possible in the future as part of a long-term effort to harmonize regulations and practices.



The unique tagline on the cover and the imprint of the US flag on the Abstract page and throughout the document footers call attention to M29's national focus and differentiate it from CLSI's global consensus documents.

### Overview of Changes From M29-A3

- The entire document was reorganized and updated with the focus on providing those responsible for providing a safe workplace with best practices for designing, implementing, and continuously improving the biosafety program for a clinical laboratory.
- Information on safe practices for the autopsy suite is no longer within the scope of M29. For reference purposes, the text from the previous edition was moved to Appendix A but was not revised. The most current guidelines for autopsy/necropsy and surgical pathology are contained in *Guidelines for Safe Work Practices in Human and Animal Medical Diagnostic Laboratories*.<sup>1</sup>
- Information on standard laboratory practices that all clinical laboratories should follow when working with materials that could contain infectious agents, including bloodborne pathogens, was consolidated into a single section. Additional precautions to follow when working with agents known or suspected to cause laboratory-acquired infections (LAIs) are provided.
- Discussion of engineering controls and good housekeeping practices applicable to all clinical laboratories was updated.
- The section on shipping biohazardous material was updated to reflect current national and international regulations and has been supplemented with guidance on safe transport between laboratory sections as well as between laboratory facilities within a single institution.
- Current information on safe handling of material that might contain proteinaceous infectious particles was added to the section on medical waste management (see Section 12).
- Information on mitigating risks posed by laboratory equipment that may be exposed to biological agents was added, including recommendations for routine cleaning and decontamination. Best practices for preparing equipment for onsite repair and for return to the manufacturer for repair, refurbishing, or disposal were updated.
- The section on incident response to release, exposure, or injury involving potentially infectious materials was updated. Information on best practices for occupational health programs and their role in preventing and treating LAIs was updated. A new section on preparedness for public health emergencies was added.
- The section on biosafety training was extensively rewritten. Additional information was included on design and implementation of a biosafety training program based on recent guidance from the Centers for Disease Control and Prevention and Association of Public Health Laboratories on biosafety laboratory competencies.

### Key Words

Aerosols, airborne transmission, biological risk assessment, biological safety cabinet, biosafety levels, bloodborne pathogens, exposure control, health care workers, infectious disease, instrument biohazards, laboratory biosafety, laboratory biosecurity, laboratory workers, medical waste, personal protective equipment, standard precautions, universal precautions

# Protection of Laboratory Workers From Occupationally Acquired Infections; Approved Guideline—Fourth Edition

## 1 Scope

This guideline is intended to describe best laboratory practices for the protection of clinical laboratory workers from exposure to infectious pathogens. M29 was revised to provide guidance for clinical laboratory directors, managers, and supervisors in developing an effective laboratory-specific biosafety program according to the risks associated within the scope of services offered by the laboratory. The focus of this document is to provide guidance for laboratory management on the integration of appropriate biosafety practices within the overall laboratory safety program. The implementation of effective administrative controls as described herein is intended to provide the safest possible laboratory workplace where potentially infectious materials are present.

This guideline directly addresses issues concerning the biological risks present in clinical laboratories, in hospitals, and in other patient care settings. The same risk mitigation and exposure avoidance practices are also appropriate for many other diagnostic laboratory settings such as physician's office laboratories; reference laboratories; or local, regional, or state public health laboratories. Even workers in a clinical veterinary diagnostic laboratory are at risk for exposure to many common and uncommon infectious agents present in their patients' specimens. Although this document does not specifically address medical or animal research laboratories, information may be applicable to research settings in which specimens containing potentially infectious materials are tested.

## 2 Introduction

Clinical laboratory workers as well as pathologists and other health care workers (HCWs) who handle tissue, body fluids, and other specimens from infected patients are at high risk for work-related exposures to infectious material. The laboratory-associated hazards of working with microorganisms have been well documented by Pike from 1952 to 1979.<sup>2</sup> Accidental or unrecognized exposure to specimens or cultures of highly transmissible microorganisms, notably *Brucella* species, *Clostridium difficile*, *Coccidioides immitis/posadasii*, *Francisella tularensis*, *Mycobacterium tuberculosis*, *Neisseria meningitidis*, *Salmonella*, *Shigella*, and Shiga toxin-producing *Escherichia coli* has resulted in either life-threatening infection or death of clinical laboratory workers. For some of these organisms, laboratory workers are at greater risk of acquiring such infections than the general population (see Table 1).<sup>3</sup> Laboratory-acquired infections (LAIs) may occur through inhalation; ingestion; direct contact of the eye, nose, mouth, or skin; or parenteral inoculation.

Prevention of exposure to bloodborne pathogens such as hepatitis B virus (HBV), hepatitis C virus (HCV), and HIV has been regulated by the Occupational Safety and Health Administration's (OSHA's) Bloodborne Pathogens Standard since the final rule was published in 1991.<sup>4</sup> CLSI has been on the forefront of providing guidance for laboratory workers since publication of the proposed-level edition of M29 in 1987. Exposure includes accidental needlesticks; cuts from contaminated sharp instruments; and contact of the eye, nose, mouth, and skin with infected patients' blood, body substances, or other potentially infectious materials (OPIM). Although most known exposures do not result in infection, the risk of HCWs acquiring HBV, HCV, or HIV following needlesticks or cuts via percutaneous exposure (the most frequently cited mode of percutaneous transmission) is estimated to be 6% to 30%, 1.8%, and 0.3%, respectively.<sup>5</sup> Transmission of at least 20 different pathogens by needlestick and sharps injuries has been reported.<sup>6</sup> In each year from 1985 to 1995 in the United States, an estimated 100 to 200 health care personnel have died from occupationally acquired HBV infection.<sup>7</sup> From 1978 to 2002, 57 HCWs acquired HIV through occupational exposure, with additional cases documented as probable cases of occupationally acquired HIV infection among HCWs in the United States (see Table 2).

Laboratory workers provide important services that are necessary to diagnose and treat infectious diseases in individuals. The intent of this guideline is to protect those workers, their communities, and the general public from acquiring infections that could result from unintended exposure in the laboratory workplace.

**Table 1. Risk of an LAI in Microbiologists vs the General Population of the Same Relative Age.** (Reprinted from *Diagnostic Microbiology and Infectious Disease*, Vol. 60 / No. 3, Baron EJ, Miller JM, Bacterial and fungal infections among diagnostic laboratory workers: evaluating the risks, pp. 241-246, 2008, with permission from Elsevier.<sup>3)</sup>)

Organism	Risk per 100 000 Microbiologists	Risk per 100 000 General Population
<i>Brucella</i> species	641	0.08
<i>C. immitis/posadasii</i>	13.7	12
<i>C. difficile</i>	0.2	8
<i>E. coli</i> O157:H7	8.3	0.96
<i>N. meningitidis</i>	25.3	0.62
<i>Salmonella</i> spp.	1.5	17.9
<i>Shigella</i> spp.	6.6	6.6

**Table 2. Epidemiological Statistics for Occupationally Acquired Bloodborne Infections in HCWs Compared With the General US Population, 1978 to 2002.** (Data for HBV and HCV provided by CDC, Division of Viral Hepatitis and National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention [NCHHSTP]. <http://www.cdc.gov/hepatitis/>; Data for HIV provided by CDC, Division of HIV/AIDS Prevention and NCHHSTP: <http://www.cdc.gov/nchhstp/default.htm>).

Group at Risk	Statistics*	HBV	HCV	HIV
HCWs (8–9 million)	New cases per year <sup>8,9</sup>	< 100	< 100	0
	Deaths per year <sup>9,10</sup>	< 100	1 400	Unknown
	Total infected <sup>9,11,12</sup>	200 000	128 000–144 000	57
US Population in General (250–300 million)	New cases per year <sup>8,13</sup>	38 000	16 000	48 100
	Deaths per year <sup>10,14</sup>	2 000	40 000–50 000	16 000
	Total infected <sup>11,12,15</sup>	550 000–940 000	3 200 000	1 178 350

\*The references listed in each row in the Statistics column apply to the data listed in each of the columns for HBV, HCV, and HIV.

Abbreviations: HBV, hepatitis B virus; HCV, hepatitis C virus; HCW, health care worker; HIV, human immunodeficiency virus.

### 3 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 known infectious agents and thus are more comprehensive than universal precautions, which are intended to apply only to transmission of bloodborne pathogens. The Centers for Disease Control and Prevention (CDC) address this topic in published guidelines that address the daily operations of diagnostic medicine in human and animal medicine while encouraging a culture of safety in the laboratory.<sup>1</sup>

## 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 quality management system approach applies a core set of “quality system essentials” (QSEs), basic to any organization, to all operations in any health care service’s path of workflow (ie, 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 QSEs are as follows:

- Organization
- Customer Focus
- Facilities and Safety
- Personnel
- Purchasing and Inventory
- Equipment
- Process Management
- Documents and Records
- Information Management
- Nonconforming Event Management
- Assessments
- Continual Improvement

M29-A4 addresses the QSE indicated by an “X.” For a description of the other documents listed in the grid, please refer to the Related CLSI Reference Materials section, beginning on page 130.

Organization	Customer Focus	Facilities and Safety	Personnel	Purchasing and Inventory	Equipment	Process Management	Documents and Records	Information Management	Nonconforming Event Management	Assessments	Continual Improvement
		X				C49					
		GP05				GP16					
		GP17				GP23					
		GP41		GP41	GP31	GP41					
		GP43	GP43		GP43	GP42	GP43				GP43
		M48				GP43					
						H56					
						M47					
						M48					
						MM13					
						NBS01					
QMS01	QMS01	QMS01	QMS01	QMS01	QMS01	QMS01	QMS01	QMS01	QMS01	QMS01	QMS01
		QMS04	QMS03								

**Path of Workflow**

A path of workflow is the description of the necessary processes to deliver the particular product or service that the organization or entity provides. A laboratory path of workflow consists of the sequential processes: preexamination, examination, and postexamination and their respective sequential subprocesses. All laboratories follow these processes to deliver the laboratory’s services, namely quality laboratory information.

M29-A4 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 Reference Materials section on the following page.

Examination ordering	Preexamination			Examination			Postexamination	
	Sample collection	Sample transport	Sample receipt/processing	Examination	Results review and follow-up	Interpretation	Results reporting and archiving	Sample management
GP20	GP16	GP16	GP16	GP16	GP16			
GP23	GP20	GP20	GP20					
GP41	GP23	GP23	GP23					
	GP41	GP41	GP41	GP41	GP41			
GP43	GP42							
	GP43	GP43	GP43					
	GP44	GP44	GP44					
	H56	H56	H56	H56			H56	
	M47	M47	M47	M47	M47	M47	M47	
	M48	M48	M48	M48	M48	M48	M48	M48
NBS01	MM13	MM13	MM13	NBS01				MM13
QMS01	NBS01	NBS01	NBS01	NBS01				NBS01
	QMS01	QMS01	QMS01	QMS01	QMS01	QMS01	QMS01	QMS01

## Related CLSI Reference Materials\*

- C49-A**      **Analysis of Body Fluids in Clinical Chemistry; Approved Guideline (2007).** This document provides guidance for the application of widely available measurement procedures for testing body fluids and for reporting and interpreting those results. It emphasizes defining the common clinical situations for this use; acceptable practice for measuring analytes without extended method verification for abnormal body fluid; influence of biologic and analytic variation on interpretation of results; and variability in comparing results between different instrument manufacturers. This document does not consider serum, plasma, whole blood, or fluids for which assays typically have performance claims in the measurement procedure documentation. A CLSI-IFCC joint project.
- GP05-A3**    **Clinical Laboratory Waste Management; Approved Guideline—Third Edition (2011).** Based on US regulations, this document provides guidance on the safe handling and disposal of chemical, infectious, radioactive, and multihazardous wastes generated in the clinical laboratory. Although this document is a valuable resource for a wider audience, it is intended for use primarily in the United States.
- GP16-A3**    **Urinalysis; Approved Guideline—Third Edition (2009).** This document addresses procedures for testing urine, including materials and equipment; macroscopic/physical evaluation; chemical analysis; and microscopic analysis.
- GP17-A3**    **Clinical Laboratory Safety; Approved Guideline—Third Edition (2012).** This document contains general guidelines for implementing a high-quality laboratory safety program, which are provided in a framework that is adaptable within any laboratory.
- GP20-A2**    **Fine Needle Aspiration Biopsy (FNAB) Techniques; Approved Guideline—Second Edition (2003).** This document contains recommended procedures for performing fine needle aspiration biopsies of superficial (palpable) and deep-seated (nonpalpable) lesions/masses, from patient preparation through staining the smear.
- GP23-A**      **Nongynecologic Cytologic Specimens: Collection and Cytopreparatory Techniques; Approved Guideline (1999).** This document provides recommended procedures for the collection, handling, transport, and processing of cytologic specimens from nongynecologic sources.
- GP31-A**      **Laboratory Instrument Implementation, Verification, and Maintenance; Approved Guideline (2009).** This guideline provides information about assessing instrument performance and function from the time of instrument purchase to the routine performance of clinical testing.
- GP41-A6**    **Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture; Approved Standard—Sixth Edition (2007).** This document provides procedures for the collection of diagnostic specimens by venipuncture, including line draws, blood culture collection, and venipuncture in children.
- GP42-A6**    **Procedures and Devices for the Collection of Diagnostic Capillary Blood Specimens; Approved Standard—Sixth Edition (2008).** This document provides a technique for the collection of diagnostic capillary blood specimens, including recommendations for collection sites and specimen handling and identification. Specifications for disposable devices used to collect, process, and transfer diagnostic capillary blood specimens are also included.
- GP43-A4**    **Procedures for the Collection of Arterial Blood Specimens; Approved Standard—Fourth Edition (2004).** This document provides principles for collecting, handling, and transporting arterial blood specimens to assist with reducing collection hazards and ensuring the integrity of the arterial specimen.
- GP44-A4**    **Procedures for the Handling and Processing of Blood Specimens for Common Laboratory Tests; Approved Guideline—Fourth Edition (2010).** This document includes criteria for preparing an optimal serum or plasma sample and for the devices used to process blood specimens.
- H56-A**      **Body Fluid Analysis for Cellular Composition; Approved Guideline (2006).** This guideline provides users with recommendations for collection and transport of body fluids, numeration and identification of cellular components, and guidance for qualitative and quantitative assessment of body fluid. A CLSI-IFCC joint project.

---

\* CLSI documents are continually reviewed and revised through the CLSI consensus process; therefore, readers should refer to the most current editions.

**Related CLSI Reference Materials (Continued)**

- M47-A**      **Principles and Procedures for Blood Cultures; Approved Guideline (2007).** 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.
- M48-A**      **Laboratory Detection and Identification of Mycobacteria; Approved Guideline (2008).** This document provides guidance to clinical mycobacteriology laboratories on the most optimum approach for the diagnosis of mycobacterial infections.
- MM13-A**     **Collection, Transport, Preparation, and Storage of Specimens for Molecular Methods; Approved Guideline (2005).** This document provides guidance related to proper and safe biological specimen collection and nucleic acid isolation and purification. These topics include methods of collection, recommended storage and transport conditions, and available nucleic acid purification technologies for each specimen/nucleic acid type. A CLSI-IFCC joint project.
- NBS01-A6**   **Blood Collection on Filter Paper for Newborn Screening Programs; Approved Standard—Sixth Edition (2013).** This document highlights specimen collection methods, discusses acceptable techniques for applying blood drops or aliquots to the filter paper segment of the specimen collection device, and provides instructions on proper specimen handling and transport to ensure quality specimens are consistently obtained for newborn screening analysis.
- QMS01-A4**   **Quality Management System: A Model for Laboratory Services; Approved Guideline—Fourth Edition (2011).** This document provides a model for medical laboratories that will assist with implementation and maintenance of an effective quality management system.
- QMS03-A3**   **Training and Competence Assessment; Approved Guideline—Third Edition (2009).** This document provides background information and recommended processes for the development of training and competence assessment programs that meet quality and regulatory objectives.
- QMS04-A2**   **Laboratory Design; Approved Guideline—Second Edition (2007).** This document provides a foundation of information about laboratory design elements and guidance to help define the issues to be considered when designing a clinical laboratory.



# Explore the Latest Offerings from CLSI!

As we continue to set the global standard for quality in laboratory testing, we're adding initiatives to bring even more value to our members and customers.



## Shop Our Online Products

Including eM100, the interactive searchable database for drug selection, interpretation, and quality control procedures within M100.



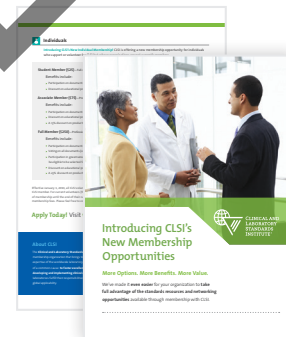
## Visit the CLSI U Education Center

Where we provide the convenient and cost-effective education resources that laboratories need to put CLSI standards into practice, including webinars, workshops, and more.



## Shop Our Online Products

Including eCLIPSE Ultimate Access™, CLSI's cloud-based, online portal that makes it easy to access our standards and guidelines—*anytime, anywhere.*



## Find Membership Opportunities

See the options that make it even easier for your organization to take full advantage of CLSI benefits and our unique membership value.

For more information, visit [www.clsi.org](http://www.clsi.org) today.



SAMPLE



CLINICAL AND  
LABORATORY  
STANDARDS  
INSTITUTE®

950 West Valley Road, Suite 2500, Wayne, PA 19087 USA

P: 610.688.0100 Toll Free (US): 877.447.1888 F: 610.688.0700

E: [customerservice@clsi.org](mailto:customerservice@clsi.org) [www.clsi.org](http://www.clsi.org)

PRINT ISBN 1-56238-961-0

ELECTRONIC ISBN 1-56238-962-9