

QMS02

Quality Management System: Development and Management of Laboratory Documents, 6th Edition

This document provides guidance on the processes needed for document management, including creating, controlling, changing, and retiring a laboratory's policy, process, procedure, and form documents in both paper and electronic environments.

.....

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

Clinical and Laboratory Standards Institute

Setting the standard for quality in medical 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 medical 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 managed according to the consensus process by a committee of experts.

Appeals Process

When it is believed that an objection has not been adequately considered and responded to, the process for appeals, documented in the CLSI Standards Development Policies and Processes, is followed.

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 additional 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: +1.610.688.0100
F: +1.610.688.0700
www.clsi.org
standard@clsi.org

ISBN 1-56238-869-X (Print)
ISBN 1-56238-870-3 (Electronic)
ISSN 1558-6502 (Print)
ISSN 2162-2914 (Electronic)

QMS02-A6
Vol. 33 No. 3
Replaces GP02-A5
Vol. 26 No. 12

Quality Management System: Development and Management of Laboratory Documents; Approved Guideline—Sixth Edition

Volume 33 Number 3

Lucia M. Berte, MA, MT(ASCP)SBB, DLM; CQA(ASQ)CMQOE
Linda A. Chambers, MD
Joan M. Carlson, MLT(CMLTA), BSc(MLS), MT(ASCP)
Heidi Dillenbeck, BS, MT
Mark F. Gendron, MBA, MT(ASCP)
Heather Meyer, MT(ASCP), (ASQ)CQE
Jane Marshall Norris, MT(ASCP)SBB, CQA(ASQ)
Kareena D. Parris
Jasmyn Ray, BSc, MLS, MLT
Doreen M. Ryan, MT(ASCP)
Melissa Singer, MT(ASCP)
Elaine Van Oyen, MLT, ART

Abstract

Clinical and Laboratory Standards Institute document QMS02-A6—*Quality Management System: Development and Management of Laboratory Documents; Approved Guideline—Sixth Edition* presents the important components of creating, evaluating, approving, controlling, changing, and retiring documents used in the laboratory environment. This guideline describes the processes needed in a document management system, whether paper-based or electronic. Key features of electronic document management systems are described. Several examples of process and procedure documents for preexamination, examination, and postexamination laboratory activities are included.

Clinical and Laboratory Standards Institute (CLSI). *Quality Management System: Development and Management of Laboratory Documents; Approved Guideline—Sixth Edition*. CLSI document QMS02-A6 (ISBN 1-56238-869-X [Print]; ISBN 1-56238-870-3 [Electronic]). Clinical and Laboratory Standards Institute, 950 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2013.

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. If 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; Website: www.clsi.org



CLINICAL AND
LABORATORY
STANDARDS
INSTITUTE®

Copyright ©2013 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.

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.

Suggested Citation

CLSI. *Quality Management System: Development and Management of Laboratory Documents; Approved Guideline—Sixth Edition*. CLSI document QMS02-A6. Wayne, PA: Clinical and Laboratory Standards Institute; 2013.

Previous Editions:

May 1980, June 1981, February 1984, July 1992, December 1996, April 2002, March 2006

Reaffirmed:

January 2018

ISBN 1-56238-869-X (Print)
ISBN 1-56238-870-3 (Electronic)
ISSN 1558-6502 (Print)
ISSN 2162-2914 (Electronic)

Contents

Abstract.....	i
Committee Membership.....	iii
Foreword.....	ix
1 Scope.....	1
2 Introduction.....	1
3 Terminology.....	3
3.1 A Note on Terminology	3
3.2 Definitions	3
3.3 Abbreviations and Acronyms	4
4 Need for New Document	5
4.1 International Influence	5
4.2 The Quality Management System and Documentation Management.....	5
4.3 Documentation Hierarchy	5
4.4 Documentation Categories.....	6
5 Document Type Is Determined	7
5.1 Policies.....	8
5.2 Processes: Quality and Operations.....	8
5.3 Procedures and Job Aids: Quality and Operations.....	12
5.4 Form Identification	13
5.5 Putting It All Together.....	13
6 Document Is Drafted.....	14
6.1 Use of Document Templates.....	14
6.2 Template Types and the Document Hierarchy	16
6.3 Contents of Template Types	16
6.4 Sources of Information for Content for the Different Document Template Types.....	17
6.5 Composing the Draft Using the Selected Template.....	18
7 Draft Is Evaluated, Edited as Needed, and Verified	27
7.1 Selection of Document Reviewers.....	28
7.2 Reviewing Documents for Format and Content	28
7.3 Performing Electronic and Paper-based Reviews.....	29
7.4 Verifying That Documents Are Correct	29
8 Approval	29
9 Training Requirements Determined and Training Verified	31
10 Document Is Distributed and Implemented	32
11 Document Maintenance	32
11.1 Document Maintenance	32
11.2 Changing Documents.....	33
11.3 Retiring Documents	34
11.4 Master File	34
11.5 Document Archiving, Storage, and Retention	35
12 Control of Reference Documents.....	35

Contents (Continued)

13	Procedures Manuals	36
14	Key Features of Electronic Document Management System	37
14.1	Draft	38
14.2	Evaluation	38
14.3	Approval	39
14.4	Record of Acknowledgment	40
14.5	Publishing	40
14.6	Maintenance.....	41
14.7	Procedures Manuals.....	42
15	How to Get Started.....	43
16	Conclusion	43
	References.....	44
	Appendix A. Sample Policy: “Quality System Essential Facilities and Safety Policy”	45
	Appendix B. Sample Policy: “Quality System Essential Nonconforming Event Management Policy”	47
	Appendix C. Sample Quality Process for Quality System Essential Assessments: “Unannounced Inspection Day Process”	49
	Appendix D. Sample Preexamination Process: “Blood Sample Collection Process”	51
	Appendix E1. Sample Examination Process: “Analyzer Setup and Run Process”	52
	Appendix E2. Sample Examination Process: “Surgical Pathology Process”	53
	Appendix F. Sample Postexamination Process: “Critical Value Handling Process”	54
	Appendix G1. Sample Quality Procedure: “Correcting a Laboratory Paper Record Procedure”	55
	Appendix G2. Sample Preexamination Procedure: “Identifying the Patient for Sample Collection Procedure”	56
	Appendix G3. Sample Microbiology Examination Procedure: “Urine Culture: Reading and Interpreting Procedure”	58
	Appendix G4. Sample Transfusion Medicine Examination Procedure: “Weak D (D ^u) Determination Procedure”	61
	Appendix G5. Sample Histology Examination Procedure: “Hematoxylin and Eosin Staining Procedure: Manual Method”	63
	Appendix G6. Sample Postexamination Procedure: “Critical Values Reporting Procedure”	65
	Appendix H1. Sample Job Aid: “Shared Testing Job Aid”	66
	Appendix H2. Sample Job Aid: “Draw Tubes and Minimum Fill”	67
	Appendix I1. Sample Form: “Document Management Form”	68
	Appendix I2. Sample Form: “ABO/Rh Discrepancy Worksheet”	69
	Appendix J. Suggested Contents of Templates for Laboratory Documents	71
	Appendix K1. How to Construct a Process Flow Chart.....	72
	Appendix K2. Sample Process Flow Chart: “Laboratory Sample Receiving Process”	75
	Appendix K3. Sample Process Flow Chart: “Bacteriology Culture Process”	76

Contents (Continued)

Appendix K4. Table Format for the Document Management Process	77
Appendix L1. Sample Attributes for a Single Analyte on a Single Analyzer.....	78
Appendix L2. Attributes for Multiple Analytes on a Single Analyzer	79
Appendix L3. Attributes for a Single Analyte on Multiple Analyzers	80
Appendix M. Sample Checklist: Document Review Checklist	81
Appendix N. Sample Form: “Group Training Record”	83
Appendix O1. Sample Procedures Manual Table of Contents: “Transfusion Reaction Investigation Process”	84
Appendix O2. Sample Procedures Manual Table of Contents: “Automated Analyzer Operations Process”	85
Appendix P. Ten Rules for Laboratory Document Management.....	86
The Quality Management System Approach.....	88
Related CLSI Reference Materials	89

SAMPLE

Foreword

Control of documents and records (DR) is critical to optimizing the effectiveness of a QMS and sustaining quality. This guideline encourages using an organized process-based approach for implementing and managing a program to develop and control the medical laboratory's many documents. In an environment of document management, only approved versions of paper-based or electronic documents are available for use by staff in all locations where they are needed.

DR is one of the 12 quality system essentials (QSEs) in CLSI document GP26,¹ which describes a structured approach to organizing, creating, and maintaining the necessary information for the QSEs. The QMS model depicted in Figure 1 demonstrates how each QSE, such as DR, is a building block to quality that is necessary to support any laboratory's path of workflow (POW) from preexamination to examination to postexamination. This document is designed to guide the user in the development and implementation of a document management system.

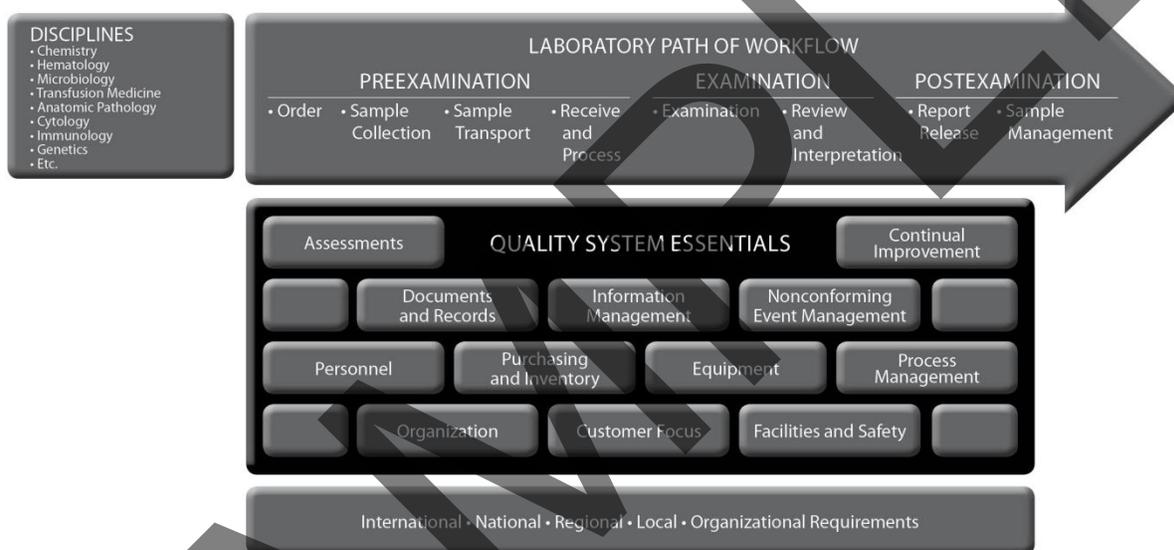


Figure 1. The Quality Management System Model (see CLSI document GP26)¹

If a QSE is missing or not well implemented, problems may occur in any or all preexamination, examination, and postexamination laboratory activities, as well as laboratory management activities. For example, when the laboratory lacks defined processes for properly installing, calibrating, and maintaining its instruments so they work effectively, problems will occur in examination processes.

The requirements for QSE DR can be summarized as:

- Development and maintenance of a document management system
- Development and maintenance of a record management system

The current edition of QMS02 will focus only on the processes within a document management system.

Overview of Changes From GP02-A5

Previous editions of QMS02 have focused on essential elements to include in laboratory examination procedures.

Quality Management System: Development and Management of Laboratory Documents; Approved Guideline—Sixth Edition

1 Scope

This guideline presents evidence-based suggestions for preparing different types of laboratory documents. In addition, a process is described for how laboratory documents can be managed and controlled from the time a need is recognized for a new or revised document, through the document's use and control, until the time it is retired.

This guideline is applicable to documents used by medical laboratories of any size, complexity, or specialty, including point-of-care testing.

QMS02 is intended for use by the following:

- Administrative and technical personnel who develop laboratory documents
- Manufacturers
- Educators
- Regulatory and accreditation organizations

QMS02 is a *guideline* for how to implement requirements established in international standards, and by regulatory and accrediting organizations for laboratory documents and procedures manuals. ***QMS02 is not a standard***; that is, this guideline does not set requirements for laboratory documents and procedures. **Instead, this guideline describes what laboratories need to do to meet published regulations, accreditation requirements, and international standards²⁻¹³ for documents and document management, and provides suggestions and examples for fulfilling the requirements.**

2 Introduction

All work happens in processes—that is, sequences of activities that a laboratory needs to perform in a specific order, and correctly, to transform a given input into the desired output. Laboratories need to communicate both the sequence of activities (ie, process) as well as the instructions for how to perform a given process activity (ie, procedure). Documented processes and procedures provide essential information for both new and experienced employees about how to perform all of their job tasks—including tasks not related to directly performing examinations, such as training, competence assessment, collecting blood samples, and using the laboratory's computer system.

To provide structure for the document management system described in this guideline, a process for how a laboratory can manage and control its documents is introduced. The flow chart starts with awareness of a need for a new document and proceeds through the lifespan of a document from development, evaluation, approval, distribution, review, change, and finally retirement. Figure 2 shows the activities and decisions in an effective document management process. Each main activity in the process is shown in a box; decisions made regarding documents are shown in a diamond as a question with a yes/no answer. Each activity, with its respective decisions and actions, is discussed in a separate section of this guideline; section numbers are shown to the left of the respective activities. Additional information to assist with developing a document management system is found in later sections.

This guideline provides several examples of common laboratory processes and procedures. Laboratories are encouraged to use these examples as starting points for documenting their own processes and procedures. Although there are specified international standard, regulatory, and accreditation requirements for needed contents of laboratory procedures manuals, *there are no specific requirements*

for the formats of laboratory documents. Therefore, this guideline presents evidence-based suggestions for document formats that effectively communicate management’s message to staff about how to do the laboratory’s work.¹⁴

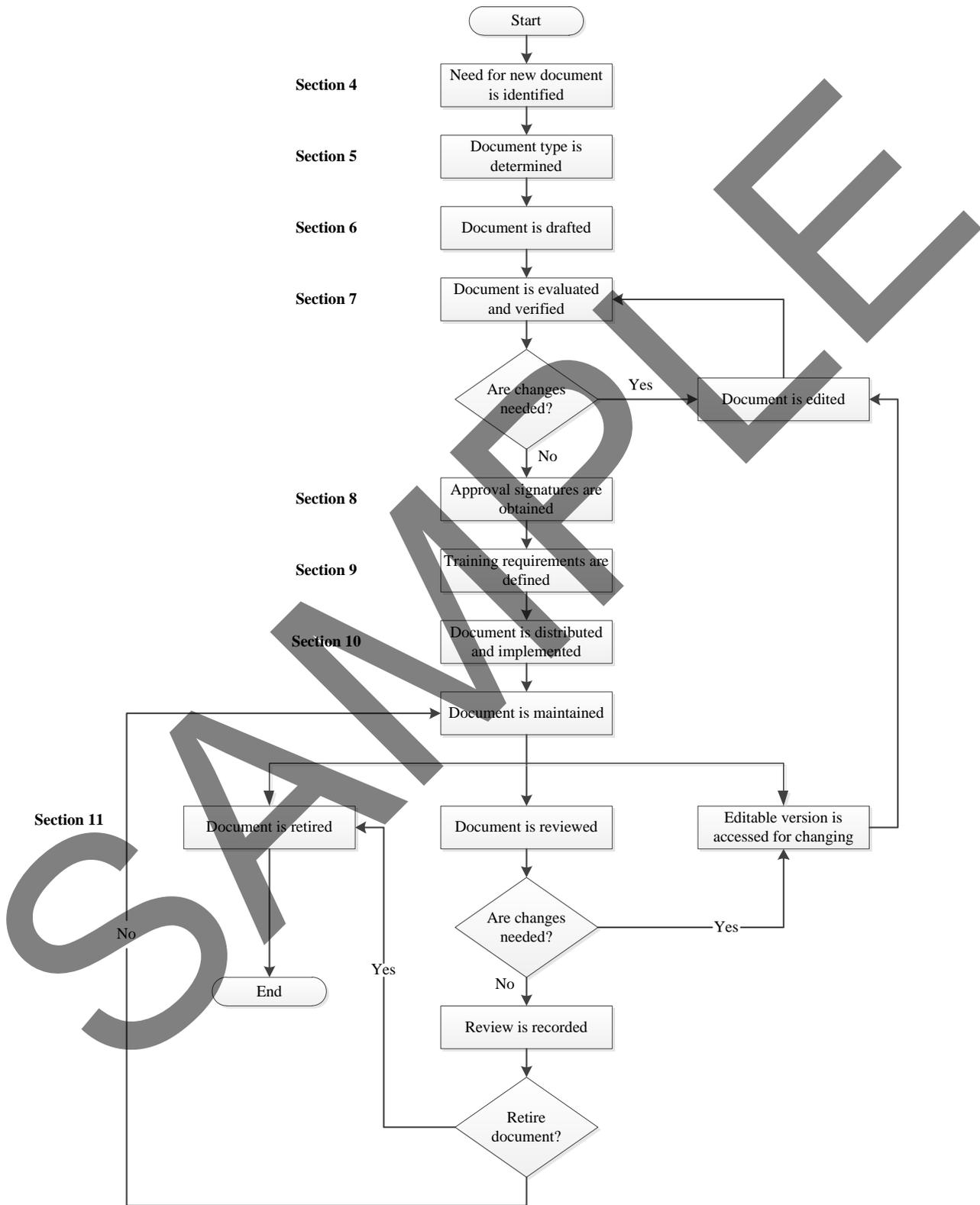


Figure 2. Document Management Process. This process shows the activities performed and decisions made throughout the lifespan of a document.

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

QMS02-A6 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 on the following page.

Organization	Customer Focus	Facilities and Safety	Personnel	Purchasing and Inventory	Equipment	Process Management	Documents and Records	Information Management	Nonconforming Event Management	Assessments	Continual Improvement
GP26	GP26	GP26 H03	GP21 GP26	GP26 H03	GP26	GP26 H01 H03	X GP26	GP26	GP26	GP26	GP26

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.

QMS02-A6 does not address any of the clinical laboratory path of workflow steps. For a description of the documents listed in the grid, please refer to the Related CLSI Reference Materials 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
GP26 H03	GP26 H01 H03	GP26 H03	GP26 H03	GP26 H03	GP26 H03	GP26	GP26	GP26

Related CLSI Reference Materials*

- GP21-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.
- GP26-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.
- H01-A6** **Tubes and Additives for Venous and Capillary Blood Specimen Collection; Approved Standard—Sixth Edition (2010).** This standard contains requirements for the materials, manufacturing, and labeling of venous and capillary blood collection devices.
- H03-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.

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

Explore the Latest Offerings From CLSI!

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



By becoming a CLSI member, your laboratory will join 1,600+ other influential organizations all working together to further CLSI's efforts to improve health care outcomes. You can play an active role in raising global laboratory testing standards—in your laboratory, and around the world.

Find out which membership option is best for you at www.clsi.org/membership.



Find what your laboratory needs to succeed! CLSI U provides convenient, cost-effective continuing education and training resources to help you advance your professional development. We have a variety of easy-to-use, online educational resources that make eLearning stress-free and convenient for you and your staff.

See our current educational offerings at www.clsi.org/education.



When laboratory testing quality is critical, standards are needed and there is no time to waste. eCLIPSE™ Ultimate Access, our cloud-based online portal of the complete library of CLSI standards, makes it easy to quickly find the CLSI resources you need.

Learn more and purchase eCLIPSE at clsi.org/eCLIPSE.

For more information, visit 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 www.clsi.org

PRINT ISBN 1-56238-869-X
ELECTRONIC ISBN 1-56238-870-3