CLINICAL AND LABORATORY STANDARDS INSTITUTE®

December 2010

POCT08-A

Quality Practices in Noninstrumented Point-of-Care Testing: An Instructional Manual and Resources for Health Care Workers; Approved Guideline

This instructional guideline delivers laboratory science concepts and activities with the goal of increasing knowledge and quality of laboratory testing for testing personnel with no laboratory background.

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

POCT08-A
Vol. 30 No. 23
ISBN 1-56238-737-5 Replaces POCT08-P
ISSN 0273-3099 Vol. 29 No. 23

Quality Practices in Noninstrumented Point-of-Care Testing: An Instructional Manual and Resources for Health Care Workers; Approved Guideline

Volume 30 Number 23

Sheldon M. Campbell, MD, PhD, FCAP
Sharon E. Granade, MPH, MT(ASCP)
Jeanniline Koehler, MT(ASCP)SBB CLS(NCA)
Peggy Mann, MS, MT(ASCP)
Valerie L. Ng, PhD, MD
Sharon K. Norman, MBA, MT(ASCP)
Joan E. Paulson, MLS(ASCP)^{CM}
Gregory P. Payne, RAC
Halcyon St. Hill, EdD, MS, MT(ASCP)
Kathy Scruggs, MT(ASCP)
Patricia White, BS, MT(ASCP)
Lou Ann Wyer, MS, MT(ASCP)

Abstract

The goal of Clinical and Laboratory Standards Institute document POCT08-A—*Quality Practices in Noninstrumented Point-of-Care Testing: An Instructional Manual and Resources for Health Care Workers; Approved Guideline* is to improve the quality of noninstrumented point-of-care testing by generating a deep understanding of the testing process while eliciting commitment of testing personnel to quality and patient care. The guideline uses a simplified instructional approach to present scientific concepts, highlight the areas where quality can be compromised, and provide methods to avoid errors.

Clinical and Laboratory Standards Institute (CLSI). *Quality Practices in Noninstrumented Point-of-Care Testing: An Instructional Manual and Resources for Health Care Workers; Approved Guideline*. CLSI document POCT08-A (ISBN 1-56238-737-5). Clinical and Laboratory Standards Institute, 950 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2010.

Suggested Citation

CLSI. *Quality Practices in Noninstrumented Point-of-Care Testing: An Instructional Manual and Resources for Health Care Workers; Approved Guideline*. CLSI document POCT08-A. Wayne, PA: Clinical and Laboratory Standards Institute; 2010.

Previous Edition:
October 2009

Reaffirmed:
January 2017

ISBN 1-56238-737-5
ISSN 0273-3099

Contents

Contents (Continued)

Foreword

Arguably, the simplest form of laboratory testing is noninstrumented point-of-care testing (POCT). Designed to be used near the patient, noninstrumented tests are simple devices such as urine dipsticks, fecal occult blood test cards, and rapid flu tests that are read by eye, without a reader or other test instrument. This testing is typically performed by health care workers whose duties include a variety of nontesting-related duties, rather than by laboratory specialists in a dedicated laboratory. Sites and disciplines employing noninstrumented POCT include, but are not limited to, physician offices, schools, sports organizations, community service and outreach programs, home care, and telemedicine. POCT needs to be simple to use, but that simplicity can be deceptive. Complicated technology is required for a simple test, and even simple tests are used to make important medical decisions.

Advances in technology, including the development of microtechniques and portable testing methodologies, have made it possible to move some testing closer to the patient. POCT is intended to provide test results more rapidly and conveniently than a centralized, possibly off-site laboratory. This is particularly important in intensive care units, emergency rooms, skilled nursing facilities, outpatient clinics, and similar settings where either the urgency of the clinical problems or the problems of follow-up make near-patient testing clinically valuable and economically feasible. POCT can also expedite treatment decisions and provide convenience for the patient/client, which is particularly significant in ambulatory outpatient settings (eg, physician offices, clinics, outreach programs), where POCT has become widespread.

Laboratory test results are required for many medical decisions. The drive to shorten patient encounters and provide care during a single visit makes POCT an important and attractive patient assessment tool. In addition, POCT can provide access to testing for populations that otherwise may not be tested.

Noninstrumented technologies may lack the robust fail-check mechanisms of tests performed by automated instruments, making the quality and accuracy of results more dependent both on the operator and on manual quality checks. The expanding menu of POCT makes it desirable to improve access to testing, quality of patient care, and convenience for clinical care providers but can also lead to risks to patients and providers, especially when specialized laboratory oversight is unavailable or not used.

This document aims to provide guidance and resources for facilities and personnel who may not be familiar with the principles of standard laboratory practices, as well as tools for laboratorians working with them. Our objective is to translate the essentials of good laboratory practice into terms usable by general medical professionals, to enable them to produce reliable, clinically useful results using noninstrumented POCT, and ultimately improve patient care. Responsibility for test quality lies along the entire continuum that stretches from the manufacturer, to the management of the testing organization, to the providers who order tests, to the persons who perform them, and to the providers who use and act on the results. A commitment to quality testing, knowledge of the essentials of good testing practice, and systems for monitoring and maintaining quality are required to ensure that these tests best serve patients. Although future technological innovations and automated readers may minimize the potential for operator error and the need for manual quality tracking for some methodologies, it will always be necessary to train testing personnel and maintain quality assurance (QA) programs.

Sound laboratory principles serve as the foundation for quality laboratory testing. International standards provide overarching guidance[1,2] and other standards-development organizations provide detail-specific guidance for the establishment and implementation of best practices to ensure patient safety and quality of care (see CLSI documents GP02, GP05, GP17, GP18, GP21, GP22, GP26, GP32, and HS01).[3-11]

Accreditation organizations in the United States[12-14] and worldwide[15-17] provide oversight for laboratory testing (which now includes POCT), for all aspects of best practices such as personnel competency requirements, quality control (QC) and QA, and documentation.[18-23]

Before 2005, surveys provided by accreditation bodies in the United States discovered widespread quality problems in POCT, and in response, the US Centers for Disease Control and Prevention (CDC) and Clinical Laboratory Improvement Amendments (CLIA) Advisory Committee (CLIAC) created recommendations for laboratories operating under 'Certificates of Waiver' (see **Appendix A**) for good laboratory practices.[24] Testing personnel are encouraged to understand and adopt best practices based on sound laboratory principles for all laboratory tests, whether they operate under a "Certificate of Waiver" or not.

Because those performing the tests are not specialists in laboratory testing, and because the tests are frequently performed in settings where a lot of other medical and nonmedical activities compete for attention, managing POCT is often challenging. Nevertheless, the risk of patient harm requires that careful quality oversight and assurance be part of setting up and maintaining a POCT operation. When in doubt, consult an expert; pathologists and other doctoral-level laboratory scientists, and clinical laboratory scientists all specialize in laboratory testing, and are critical resources for nonspecialists engaged in testing.

Implementation of good laboratory practice is essential to ensure accurate results and quality patient care, and each testing site must understand and follow applicable local, regional, and national laws and ordinances.

This guideline is an atypical document for CLSI because its target audience includes health care workers who have little or no specific training in laboratory practices, and for whom laboratory testing is only one, and perhaps a minor, component of their work. It is designed to help facilities and individual workers provide accurate, reliable, clinically useful POCT services to improve the speed, accessibility, and quality of patient care. It provides education in basic principles, examples of good practice, and an extensive toolkit of forms and procedures that testing facilities may use as templates, or just as inspiration for their own practices. It is designed to be read as a whole, or consulted in bits for reference, providing an opportunity to learn from it and perform better testing.

How to Use This Document

This informative, user-friendly document provides practical applications of good laboratory practice. The document can be read from cover to cover for a thorough overview or searched by topic to find specific information as needed. Sections 1 through 4 include laboratory definitions and explanations. The remaining sections describe laboratory practice concepts and theories that include examples, checklists, and tools to help with understanding of the ideas and assist with implementation. Icons are used to highlight the ideas and solutions throughout the document. The icons used include the following:

Example

The Example icon is used when an example or scenario is introduced in the document. These are used to help explain a concept or an idea. The examples may not describe laboratory testing exactly as it is performed in your workplace, but the general idea or point can be applied in most settings.

Checkpoint

The Checkpoint icon is used to summarize the important issues or items that should be considered or put into practice. Think of it as a checklist of things that should be done for that section.

Toolbox

The Toolbox icon identifies adaptable tools you can reference and use. Many of the tools are forms, charts, and checklists that can help with implementing the checkpoint items. The Toolbox items are found in the appendixes at the end of the document. Each item is lettered and referenced for easy use.

Key Words

Laboratory errors, noninstrumented testing, point-of-care testing, quality control, testing personnel

Quality Practices in Noninstrumented Point-of-Care Testing: An Instructional Manual and Resources for Health Care Workers; Approved Guideline

1 Scope

This document is designed to provide education in basic concepts of good laboratory practice to a wide audience; to provide tools, protocols, and examples to illustrate and assist in the implementation of good laboratory practices; and to provide templates and other resources to make it easier to build a high-quality point-of-care testing (POCT) program.

The intended audience includes:

- Medical technologists and other laboratory professionals engaged in noninstrumented POCT
- Nurses and other medical personnel without laboratory training or specialization who perform such testing
- Nonmedically trained workers performing such testing
- Laboratory professionals and others engaged in oversight or consultation
- Manufacturers and distributors of noninstrumented point-of-care tests

Organizations that may engage in noninstrumented POCT and that might use this guideline include, but are not limited to:

- Physician office and group practices
- Hospitals and other acute-care facilities
- Long-term care facilities
- Home care organizations
- Outreach and community organizations providing testing
- Other settings where simple laboratory tests may improve disease detection or management

Aspects of good laboratory practice addressed include:

- Roles and responsibilities of the people involved in the testing system
- Selecting, learning, proving, and implementing new tests
- Avoiding errors before, during, and after testing
- Building systems and procedures to maintain test quality
- Recordkeeping to limit risk and document performance

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 known 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.[25] For specific precautions for preventing the laboratory transmission of all known infectious agents from laboratory instruments and materials and for recommendations for the management of exposure to all known infectious diseases, refer to CLSI document M29.[26]

3 Definitions

accuracy – how close a test result for a specific analyte is to how much of the analyte is there; closeness of agreement between a test result and the accepted reference value (ISO 3534-1).[27]

analyte – substance being measured or detected.

competency testing – evaluating a person's ability to perform a test correctly and to use a testing device; **NOTE:** This includes all aspects of testing, from sample collection to result reporting, and it is usually done with samples containing known amounts of the analytes for which the samples are being tested.

control material (control) – a device, solution, or lyophilized preparation intended for use in the quality control process to monitor the reliability of a test system and to maintain its performance within established limits; **NOTE 1:** The expected reaction or concentration of analytes of interest are known within limits ascertained during preparation and confirmed in use; **NOTE 2:** Control materials are generally not used for calibration in the same process in which they are used as controls; **NOTE 3:** Alternate terms include procedural control, internal control, external control, onboard control, and built-in control; **NOTE 4:** For more information, see Section 7.1.1.

external quality assessment (EQA) – see **proficiency testing (PT).**

health care provider – individual authorized to deliver health care to a patient (ISO 17593)[28]; **NOTE:** In ISO 17593, a health care provider is an individual, such as a doctor, nurse, technician, technical specialist, or appropriate assistant that provides instruction to a self-testing patient.

interference (analytical) – the effect of substances in the sample that make the test give wrong results; **NOTE:** Interferences can make a test turn positive when the material to be measured (the "target") is present, keep it from turning positive even though target is present, or make the measured amount of target significantly different from the real value. Interferences may be identified or unidentified substances; some are well known, such as soap added to urine for drug of abuse testing to keep it from turning positive or ethylenediaminetetraacetic acid (EDTA) anticoagulant from a blood collection tube causing extremely low calcium values; others are sporadic and difficult to characterize.

laboratory director – competent person(s) with responsibility for, and authority over, a laboratory (ISO 15189)[2]; **NOTE 1:** This person has final responsibility for the quality and appropriateness of laboratory testing; typically, the laboratory director is a physician or doctoral scientist who can make decisions about the medical and technical aspects of testing; **NOTE 2:** National, regional, and local regulations often apply with regard to qualifications and training (ISO 15189).[2]

lateral flow – a type of antibody-based test ("immunoassay") frequently used at the point of care.

material safety data sheet (MSDS) – technical bulletin providing detailed hazard and precautionary information (ISO 15190)[29]; **NOTE:** The bulletin is provided by a supplier of a hazardous chemical substance in accordance with regulatory requirements and concerns the toxicity, health hazards, physical properties, fire, and reactivity data including storage, spill, and handling precautions.

measuring interval – the upper and lower values, between which the test system will give accurate results; **NOTE:** Alternative terms are reportable range and analytical measurement range.

operator – the person or persons in control of the sample during collection and performance of the test; **NOTE:** An alternative term for operator is testing personnel.

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 CLSI document HS01—*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 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:

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

POCT08-A addresses the QSEs 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.

Documents and Records	Organization	Personnel	Equipment	Purchasing and Inventory	Process Control	Information Management	Occurrence Management	Assessments—External and Internal	Process Improvement	Customer Service	Facilities and Safety
GP02					X	GP02					GP05 GP17 GP18
		GP21							GP22		
GP26	GP26	GP26	GP26	GP26	GP26 GP27 GP29 GP32	GP26	GP26 GP32	GP26 GP27 GP29	GP26 GP27	GP26	GP26
HS01	HS01	HS01	HS01	HS01	HS01	HS01	HS01	HS01	HS01	HS01	HS01 M29

Adapted from CLSI document HS01—*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 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.

POCT08-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 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	GP26	GP26	GP26	GP26	GP26	GP26	GP26	GP26

Adapted from CLSI document HS01—*A Quality Management System Model for Health Care.*

Related CLSI Reference Materials*

GP02-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.

GP05-A2 **Clinical Laboratory Waste Management; Approved Guideline—Second Edition (2002).** Based on U.S. regulations, this document provides guidance on safe handling and disposal of chemical, infectious, radioactive, and multihazardous wastes generated in the clinical laboratory.

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.

GP18-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.

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.

GP22-A2 **Continuous Quality Improvement: Integrating Five Key Quality System Components; Approved Guideline—Second Edition (2004).** This guideline considers continuous quality improvement (CQI) as five integrated quality system components, which include Quality Planning, Quality Teamwork, Quality Monitoring, Quality Improvement, and Quality Review.

GP26-A3 **Application of a Quality Management System Model for Laboratory Services; Approved Guideline—Third Edition (2004).** This guideline describes the clinical laboratory's path of workflow and provides information for laboratory operations that will assist the laboratory in improving its processes and meeting government and accreditation requirements.

GP27-A2 **Using Proficiency Testing to Improve the Clinical Laboratory; Approved Guideline—Second Edition (2007).** This guideline provides assistance to laboratories in using proficiency testing as a quality improvement tool.

GP29-A2 **Assessment of Laboratory Tests When Proficiency Testing Is Not Available; Approved Guideline—Second Edition (2008).** This document offers methods to assess test performance when proficiency testing (PT) is not available; these methods include examples with statistical analyses. This document is intended for use by laboratory managers and testing personnel in traditional clinical laboratories as well as in point-of-care and bedside testing environments.

GP32-A **Management of Nonconforming Laboratory Events; Approved Guideline (2007).** This guideline provides an outline and the content for developing a program to manage a health care service's nonconforming events that is based on the principles of quality management and patient safety.

HS01-A2 **A Quality Management System Model for Health Care; Approved Guideline—Second Edition (2004).** This document provides a model for providers of healthcare services that will assist with implementation and maintenance of effective quality management systems.

K2Q **The Key to Quality (2007).** A high-quality, specialty portfolio, with tabs for quick references, showcases the implementation of all 12 Quality System Essentials (QSEs). This comprehensive portfolio includes essentials, examples, flow charts, cross-references, evaluations, and a CD-ROM.

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.

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

CLINICAL AND LABORATORY STANDARDS INSTITUTE®

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 *e*Learning 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.

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**

ISBN 1-56238-737-5