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3rd Edition

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# CLSI POCT04

## Essential Tools for Implementation and Management of a Point-of-Care Testing Program

Sample

This guideline provides direction to users of *in vitro* diagnostic devices outside the medical laboratory on how to ensure reliable results that are comparable to those obtained from medical laboratory instruments.

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

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## Essential Tools for Implementation and Management of a Point-of-Care Testing Program

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### Abstract

Clinical and Laboratory Standards Institute guideline POCT04—*Essential Tools for Implementation and Management of a Point-of-Care Testing Program* provides users of *in vitro* diagnostic devices outside the medical laboratory with information and recommendations for good laboratory practice and for producing reliable test results regardless of where the test is performed. Point-of-care testing (POCT), also known as bedside testing or near-patient testing, is intended to provide more rapid test results than can be achieved in central or satellite laboratory settings. This option is particularly important in critical care areas, such as the intensive care unit, emergency rooms, burn units, emergency transport vehicles, and operating rooms, as well as in skilled nursing facilities and hospices. POCT has also been used to expedite treatment decisions and provide convenience for the patient or client.

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## Foreword

In response to pressures from outside and within, the health care community is re-evaluating the best way to deliver services in a complex system. Part of this examination concerns the delivery of laboratory services to patients and clients.

Medical conditions, physical location of the patient or client, and treatment regimens often need laboratory test results quickly so that appropriate medical care may be administered. Laboratory professionals are challenged by the increasing demands for faster turnaround of results, but at the same time are faced with limitations such as cost constraints in providing these services.

The development of portable testing instruments capable of producing results within minutes has provided one way to meet these demands. Point-of-care testing (POCT), also referred to as near-patient testing or bedside testing, augments dipsticks and other noninstrumented testing systems such as occult blood testing. Because of the enormous consequences stemming from unreliable test results, it is vital that results continue to be trustworthy and of high quality as these tests are transferred from the medical laboratory to the point of care.

POCT is often performed by personnel not trained in medical laboratory practice, and faces similar regulatory and quality management issues as laboratory-based testing. These concerns apply both within and outside the traditional laboratory community. The manufacturer is responsible for providing test systems capable of delivering reliable results when used properly by the testing personnel. Once the decision to offer POCT is made, professionals in laboratory medicine should be involved in supporting and assessing the results of these services.

POCT has been, and will continue to be, implemented in a wide variety of locations. Each hospital, nursing home, emergency service provider, insurance company, home health care delivery network, etc., is responsible for assessing its POCT needs. This guideline provides information on how to assess those needs and how to evaluate and implement POCT.

This guideline provides useful information to locations desiring to perform POCT, written with the assumption that primary users will be nonlaboratory health care personnel. Therefore, this guideline provides definitions, procedures, and recommendations that are both educational and practical. In addition, the format is designed to be user friendly and easy to follow.

### Overview of Changes

Several changes have been made in this edition; chief among them is the introduction of the concept of quality management based on risk assessment (see Subchapter 2.2.3) for POCT sites. This guideline also contains updated recommendations regarding infection control and patient and testing personnel safety (see Subchapter 2.3).

**NOTE:** The content of this guideline is supported by the CLSI consensus process, and does not necessarily reflect the views of any single individual or organization.

### Key Words

Calibration, point-of-care testing, quality control, quality management, safety

# Essential Tools for Implementation and Management of a Point-of-Care Testing Program

## Chapter 1: Introduction

This chapter includes:

- Guideline's scope and applicable exclusions
- Background information pertinent to the guideline's content
- Standard precautions information
- "Note on Terminology" that highlights particular use and/or variation in use of terms and/or definitions
- Terms and definitions used in the guideline
- Abbreviations and acronyms used in the guideline

### 1.1 Scope

Many potential sites are eligible for point-of-care testing (POCT). To achieve producing patient test results comparable with those from the medical laboratory, this guideline provides essential tools for implementing and managing POCT in both clinical and nonclinical settings. Depending on the location, individuals who may perform POCT and for whom this guideline is intended include:

- Nurses and physicians in acute care units in hospitals and emergency rooms
- Cardiac perfusionists in operating rooms
- Visiting home nurses
- Emergency medical technicians
- Nurses in clinics, schools, and colleges
- Pharmacists and pharmacy technicians in pharmacies
- Non-health care professionals at various employment settings, such as drug rehabilitation centers, law enforcement facilities, public screening sites, insurance companies, and physician office laboratories (POLs)

This guideline does not cover patient self-testing and the handling of results generated in this manner. Additionally, this guideline only applies to tests that involve the collection of patient specimens. Thus, examination devices such as breath analyzers, transcutaneous meters, and continuous glucose monitoring devices are outside the scope of this guideline.

## 1.2 Background

Advances in technology and the implementation of microtechniques and portable instruments have made it possible to move laboratory testing closer to the patient/client. POCT is intended to provide more rapid and accessible test results than can be achieved in central or satellite laboratory settings. This is particularly important in critical care areas, such as the ICU, emergency rooms, burn units, emergency transport vehicles, and operating rooms; as well as skilled nursing facilities and hospices. POCT has also been used to expedite treatment decisions and provide convenience for patients/clients. The latter use is significant in ambulatory outpatient settings (eg, physician offices, clinics, geographically remote locations) where POCT has become an important form of diagnostic testing. POCT04 provides information and suggestions for good laboratory practice and for producing reliable test results, regardless of where testing is performed.

A systematic and thorough evaluation is needed to justify the implementation of point-of-care (POC) technology. Each request for POC instrumentation or test implementation can be evaluated by criteria developed collaboratively by the institution and health care providers. The specifications can be developed into a standardized form for use by health care providers considering implementing a POC test or who are requesting the test. A standardized approach allows for a more consistent evaluation process, identifies potential operational issues, aids resource planning, and supports rational implementation. Additionally, consideration should be given to the type, method and invasiveness of sample collection, (eg, a sample collected from a finger using a lancet device may be considered more invasive than one collected by an oral swab).

Identification of the need for, and applicability and selection of POCT should involve an interprofessional approach with POCT stakeholders. An advisory committee consisting of health care providers who request and use POCT results for clinical decision making (eg, physicians) is recommended. POCT management and testing personnel should also be members of the advisory committee. The literature on quality patient care and location of care, as well as technical and clinical performance characteristics (eg, sensitivity, specificity, turnaround time, cost, and risks), should be reviewed and considered.

## 1.3 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. Published guidelines are available that discuss the daily operations of diagnostic medicine in humans and animals while encouraging a culture of safety in the laboratory.<sup>1</sup> 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.<sup>2</sup>

## 1.4 Terminology

### 1.4.1 A Note on Terminology

CLSI, as a global leader in standardization, is firmly committed to achieving global harmonization whenever possible. Harmonization is a process of recognizing, understanding, and explaining differences while taking steps to achieve worldwide uniformity. CLSI recognizes that medical conventions in the global metrological community have evolved differently in different countries and regions, and that legally required use of terms, regional usage, and different consensus timelines are all important considerations in the harmonization process. CLSI recognizes its important role in these efforts, and its consensus process focuses on harmonization of terms to facilitate the global application of standards and guidelines.

## The Quality Management System Approach

Clinical and Laboratory Standards Institute (CLSI) subscribes to a quality management system (QMS) approach in the development of standards and guidelines, which facilitates project management; defines a document structure using a template; and provides a process to identify needed documents. The QMS 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

POCT04 covers 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 page 60.

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		X	X	X	X	X	X				
						EP09 EP18 EP23 EP27 GP16 GP27 GP41 GP42			EP18	EP18	EP18
		GP41 M29		GP41		POCT08 POCT09 POCT12 POCT13				GP27	GP27
			POCT12 POCT13	POCT09	POCT09	POCT12 POCT13	POCT12 POCT13			POCT09	
QMS01	QMS01	QMS01	QMS01	QMS01	QMS01	QMS01	QMS01 QMS02	QMS01	QMS01	QMS01	QMS01
					QMS13				QMS11	QMS12	QMS06
										QMS15	



## Related CLSI Reference Materials\*

- EP09**      **Measurement Procedure Comparison and Bias Estimation Using Patient Samples. 3rd ed., 2013.** This document address the design of measurement procedure comparison experiments using patient samples and subsequent data analysis techniques used to determine the bias between two *in vitro* diagnostic measurement procedures.
- EP18**      **Risk Management Techniques to Identify and Control Laboratory Error Sources. 2nd ed., 2009.** This guideline describes risk management techniques that will aid in identifying, understanding, and managing sources of failure (potential failure modes) and help to ensure correct results. Although intended primarily for *in vitro* diagnostics, this document will also serve as a reference for clinical laboratory managers and supervisors who wish to learn about risk management techniques and processes.
- EP23™**      **Laboratory Quality Control Based on Risk Management. 1st ed., 2011.** This document provides guidance based on risk management for laboratories to develop quality control plans tailored to the particular combination of measuring system, laboratory setting, and clinical application of the test.
- EP27**      **How to Construct and Interpret an Error Grid for Quantitative Diagnostic Assays. 1st ed., 2012.** This guideline describes what an error grid is, why it is useful, and how to construct one and interpret the information. Guidance is provided for manufacturers and for the clinical laboratory.
- GP16**      **Urinalysis. 3rd ed., 2009.** This document addresses procedures for testing urine, including materials and equipment; macroscopic/physical evaluation; chemical analysis; and microscopic analysis.
- GP27**      **Using Proficiency Testing to Improve the Clinical Laboratory. 2nd ed., 2007.** This guideline provides assistance to laboratories in using proficiency testing as a quality improvement tool.
- GP41**      **Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture. 6th ed., 2007.** This document provides procedures for the collection of diagnostic specimens by venipuncture, including line draws, blood culture collection, and venipuncture in children.
- GP42**      **Procedures and Devices for the Collection of Diagnostic Capillary Blood Specimens. 6th ed., 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.
- M29**      **Protection of Laboratory Workers From Occupationally Acquired Infections. 4th ed., 2014.** 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.
- POCT08**      **Quality Practices in Noninstrumented Point-of-Care Testing: An Instructional Manual and Resources for Health Care Workers. 1st ed., 2010.** 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.
- POCT09**      **Selection Criteria for Point-of-Care Testing Devices. 1st. ed., 2010.** This document provides guidance on selection of point-of-care testing devices based on the patient care setting and clinical needs. It is designed as an aid to laboratory and facility management to simplify and facilitate the selection process but also allows evaluation of devices to identify those that are optimal to the patient care setting and population served.

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\* 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)

- POCT12**      **Point-of-Care Blood Glucose Testing in Acute and Chronic Care Facilities. 3rd ed., 2013.** This document contains guidelines for performance of point-of-care blood glucose meter systems that stress quality control, training, and administrative responsibility.
- POCT13**      **Glucose Monitoring in Settings Without Laboratory Support. 3rd ed., 2015.** This guideline focuses on performance of point-of-care glucose monitoring systems, with an emphasis on safety practices, quality control, training, and administrative responsibility.
- QMS01**      **Quality Management System: A Model for Laboratory Services. 4th ed., 2011.** This document provides a model for medical laboratories that will assist with implementation and maintenance of an effective quality management system.
- QMS02**      **Quality Management System: Development and Management of Laboratory Documents. 6th ed., 2013.** 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.
- QMS06**      **Quality Management System: Continual Improvement. 3rd ed., 2011.** This guideline considers continual improvement as an ongoing, systematic effort that is an essential component of a quality management system. A continual improvement program may consist of fundamental processes and common supporting elements described in this guideline.
- QMS11**      **Nonconforming Event Management. 2nd ed., 2015.** Grounded in the principles of quality management, risk management, and patient safety, this guideline provides an outline and content for developing a program to manage a laboratory's nonconforming events.
- QMS12**      **Development and Use of Quality Indicators for Process Improvement and Monitoring of Laboratory Quality. 1st ed., 2010.** This document provides guidance on development of quality indicators and their use in the medical laboratory.
- QMS13**      **Quality Management System: Equipment. 1st ed., 2011.** This guideline provides recommendations for establishing equipment management processes from selection through decommission of equipment used in the provision of laboratory services.
- QMS15**      **Assessments: Laboratory Internal Audit Program. 1st ed., 2013.** This document provides guidance for how a laboratory can establish an internal audit program to enhance the quality of its services through continual improvement. Whereas an audit program defines the "who," "what," "when," "where," and "how" of meeting requirements for internal auditing, the audit process describes the details of how to conduct individual laboratory internal audits.

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