



POCT09-A

Selection Criteria for Point-of-Care Testing Devices; Approved Guideline

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

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Selection Criteria for Point-of-Care Testing Devices; Approved Guideline

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Abstract

Clinical and Laboratory Standards Institute document POCT09-A—*Selection Criteria for Point-of-Care Testing Devices; Approved Guideline* provides guidance on selection of point-of-care testing (POCT) devices based on the patient care setting and clinical needs. This guidance document is intended to reflect the selection process of instrumented diagnostic systems that can be used at or near the site of patient care. Overall, this guidance document is designed to assist and benefit personnel responsible for the evaluation, negotiation, and selection process including laboratory, management, and information technology. It includes discussions on important factors when considering POCT through clinical and operational needs assessment. In addition, regulatory and accreditation requirements on various POCT or devices are explained, along with the various appendices that serve as a tool for POCT device implementation.

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Foreword

Currently, no consensus guidance is available that can be applied to select an appropriate point-of-care testing (POCT) device for clinical use. This guideline provides an overview of important considerations when comparing POCT devices and includes a draft checklist of criteria that users of the document can employ as a starting point for selecting a new device for clinical use. This can be used by each institution, clinic, or physician's office laboratory to independently develop its own comparisons and rating systems. As with core laboratory devices, the implementation of POCT devices is subject to regulatory and accreditation requirements. Newer devices have a variety of operational features that can assist with clinical management, improve quality of testing, and enhance regulatory compliance, but there are no available consensus criteria for direct comparison of these features.

Overall, this guidance document is designed to assist and benefit personnel responsible for the evaluation, negotiation, and selection process, including laboratory, management, information technology (IT), and end users of the POCT system. Because some vendor sales representatives do not have a laboratory background, the *in vitro* diagnostic industry would also benefit from having a consensus guideline that would assist the sales force with product presentation and encouragement of customer feedback.

Key Words

Instrument, needs assessment, outcomes, point of care, quality control

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1 Scope

This document is designed as an aid for laboratory and facility management to simplify and facilitate the point-of-care testing (POCT) device selection process and allow evaluation of these devices to identify those that are optimal for the patient care setting and population served. The device evaluation process will lead to an increased awareness of the device's testing process and risk associated with use of the device. In addition, long-term benefits can be achieved with improved operational and compliance processes. Thus, patient care, quality, and compliance will be maximized.

This guidance document is intended to reflect the selection process of instrumented diagnostic systems that can be used at or near the site of patient care. Purposely excluded from this discussion are large central laboratory analyzers, noninstrumented testing (eg, dip sticks, visual read lateral flow devices), and handheld glucose meters, which are the subject of other CLSI guidance documents, either already existing (eg, CLSI document C30¹) or in development. Although these classes of diagnostics devices are excluded from specific discussion, many of the processes and concepts discussed herein have widespread utility across device classes.

2 Introduction

Increased robustness and integration capabilities to existing system networks have established POCT devices as comprehensive patient care solutions, expanding their demand beyond conventional health care institutions. The number of available device alternatives for any given analyte, coupled with the devices' examination, operational, and connectivity attributes and associated potential risks can result in a complex selection process that can obscure important factors unique to the facility.

This document provides guidance on selection of POCT devices based on the patient care setting and clinical needs. The breadth of POCT to consider is wide and growing larger every year. Various vendors offer POCT for specific analytes, which include but are not limited to, cardiac markers, coagulation markers (including D-dimer), glucose, drugs of abuse, infectious diseases, occult blood testing, intact parathyroid hormone (iPTH), renal and reproductive function testing, chemistry (eg, bilirubin, lactate, magnesium, sodium, potassium, chloride, and ionized calcium), CO-oximetry (oxygen [O₂] saturation, carboxyhemoglobin, methemoglobin), and blood gas panels (pO₂, pCO₂, pH). There are benchtop and small floor model immunoassay and chemistry analyzers that are promoted as options for POCT. Molecular diagnostics technology is advancing so quickly that it is reasonable to envision POCT for DNA/RNA tests in the near future.

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 blood-borne pathogens. Standard and universal precaution guidelines are available from the US Centers for Disease Control and Prevention.² 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 disease, refer to CLSI document M29.³

4 Terminology

4.1 A Note on Terminology

CLSI, as a global leader in standardization, is firmly committed to achieving global harmonization wherever 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 metrologic community have evolved differently in the United States, Europe, and elsewhere; that these differences are reflected in CLSI, International Organization of Standardization (ISO), and the European Committee for Standardization (CEN) documents; and that legally required use of terms, regional usage, and different consensus timelines are important considerations in the harmonization process. In light of this, CLSI's consensus process for development and revision of standards focuses on harmonization of terms to facilitate the global application of standards and guidelines.

All terms and definitions will be reviewed again for consistency with international use and revised appropriately during the next scheduled revision of this document.

4.2 Definitions

accuracy (measurement) – closeness of agreement between a measured quantity value and a true quantity value of a measurand (ISO/IEC Guide 99).⁴

analytical sensitivity – quotient of the change in an indication and the corresponding change in the value of a quantity being measured (ISO 15193).⁵

analytical specificity – ability of a measurement procedure to determine solely the quantity it purports to measure (ISO 15193).⁵

calibration – operation that, under specified conditions, in a first step, establishes a relation between the quantity values with measurement uncertainties provided by measurement standards and corresponding indications with associated measurement uncertainties and, in a second step, uses this information to establish a relation for obtaining a measurement result from an indication (ISO/IEC Guide 99).⁴

calibration verification – the assaying of materials of known concentration in the same manner as patient samples to substantiate the instrument or test system's calibration throughout the reportable range for patient test results (US CFR 493.2, 24 January 2003).⁶

clinical reportable range (CRR) – the range of analyte values that a method can report as a quantitative result, allowing for specimen dilution, concentration, or pretreatment used to extend the measuring interval (C50).⁷

clinical sensitivity – the ability of a test under study to give a positive result for subjects having the disease/state in question (MM17).⁸

clinical specificity – the ability of a test under study to give a negative result for subjects not having the disease in question (MM17).⁸

corrective action – action to eliminate the cause of a detected nonconformity or other undesirable situation (ISO 9000)⁹; **NOTE 1:** There can be more than one cause for nonconformity; **NOTE 2:** Corrective action is taken to prevent recurrence whereas preventive action is taken to prevent occurrence (ISO 9000).⁹

The Quality Management System Approach

Clinical and Laboratory Standards Institute (CLSI) subscribes to a quality management system approach in the development of standards and guidelines, which facilitates project management; defines a document structure via a template; and provides a process to identify needed documents. The approach is based on the model presented in the most current edition of CLSI 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:

- 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

POCT09-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
C30		C30	X C50	X	X C24 C28 C30 C54 EP05 EP06 EP09 EP15 EP21			X			
GP02	GP11 POCT04	POCT04	POCT04	POCT04	MM17 POCT04	GP02					M29 POCT04

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.

POCT09-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
C54	C30	C54			C30 C50 C54	C50	C30	

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

Related CLSI Reference Materials*

- C24-A3** **Statistical Quality Control for Quantitative Measurement Procedures: Principles and Definitions; Approved Guideline—Third Edition (2006).** This document provides definitions of analytical intervals, planning of quality control procedures, and guidance for quality control applications.
- C28-A3** **Defining, Establishing, and Verifying Reference Intervals in the Clinical Laboratory; Approved Guideline—Third Edition (2008).** This document contains guidelines for determining reference values and reference intervals for quantitative clinical laboratory tests.
- C30-A2** **Point-of-Care Blood Glucose Testing in Acute and Chronic Care Facilities; Approved Guideline—Second Edition (2002).** This document contains guidelines for performance of point-of-care (POC) blood glucose testing that stress quality control, training, and administrative responsibility.
- C50-A** **Mass Spectrometry in the Clinical Laboratory: General Principles and Guidance; Approved Guideline (2007).** This document provides a general understanding of mass spectrometry and the principles that dictate its application in the clinical laboratory. It includes guidance, references, and quality assurance markers that will assist with the implementation and correct operation of a mass spectrometry (MS) system for its many applications. Information on maintaining optimum performance, approaches to ensuring accurate and precise mass measurement, verification of methods, quality control of assays within and between instruments, instrument troubleshooting, sample preparation, interpretation of results, and limitations of the technology is included.
- C54-A** **Verification of Comparability of Patient Results Within One Health Care System; Approved Guideline (2008).** This document provides guidance on how to verify comparability of quantitative laboratory results for individual patients within a health care system.
- EP05-A2** **Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline—Second Edition (2004).** This document provides guidance for designing an experiment to evaluate the precision performance of quantitative measurement methods; recommendations on comparing the resulting precision estimates with manufacturers' precision performance claims and determining when such comparisons are valid; as well as manufacturers' guidelines for establishing claims.
- EP06-A** **Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline (2003).** This document provides guidance for characterizing the linearity of a method during a method evaluation; for checking linearity as part of routine quality assurance; and for determining and stating a manufacturer's claim for linear range.
- EP09-A2** **Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline—Second Edition (2002).** This document addresses procedures for determining the bias between two clinical methods and the design of a method comparison experiment using split patient samples and data analysis.
- EP15-A2** **User Verification of Performance for Precision and Trueness; Approved Guideline—Second Edition (2005).** This document describes the demonstration of method precision and trueness for clinical laboratory quantitative methods using a protocol designed to be completed within five working days or less.
- EP21-A** **Estimation of Total Analytical Error for Clinical Laboratory Methods; Approved Guideline (2003).** This document provides manufacturers and end users with a means to estimate total analytical error for an assay. A data collection protocol and an analysis method that can be used to judge the clinical acceptability of new methods using patient specimens are included. These tools can also monitor an assay's total analytical error by using quality control samples.
- 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.
- GP11-A** **Basic Cost Accounting for Clinical Services; Approved Guideline (1998).** This document provides principles and techniques to help laboratory managers establish a workable cost-accounting system.

*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)

- 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.
- MM17-A** **Verification and Validation of Multiplex Nucleic Acid Assays; Approved Guideline (2008).** This guideline provides recommendations for analytical variation and validation of multiplex assays, as well as a review of different types of biological and synthetic reference materials.
- POCT04-A2** **Point-of-Care *In Vitro* Diagnostic (IVD) Testing; Approved Guideline—Second Edition (2006).** This document provides guidance to users of *in vitro* diagnostic (IVD) devices outside the clinical laboratory, to ensure reliable results comparable to those obtained within the clinical laboratory.

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