CLINICAL AND LABORATORY STANDARDS INSTITUTE®

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POCT12-A3

Point-of-Care Blood Glucose Testing in Acute and Chronic Care Facilities; Approved Guideline—Third Edition

This document contains guidelines for performance of point-of-care blood glucose meter systems that stress quality control, training, and administrative responsibility.

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

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Point-of-Care Blood Glucose Testing in Acute and Chronic Care Facilities; Approved Guideline—Third Edition

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Abstract

Clinical and Laboratory Standards Institute document POCT12-A3—*Point-of-Care Blood Glucose Testing in Acute and Chronic Care Facilities; Approved Guideline—Third Edition* provides information for use by acute and chronic care facilities with laboratory support for structuring a point-of-care (POC) blood glucose testing service intended to ensure quality test results, as well as high-quality patient care.

POCT12 introduces policy-related issues with respect to administration of the program, persons who perform the tests, selection of measurement procedures, reporting of results, and the QA aspects of POC blood glucose testing. Also discussed are the uses of POC blood glucose testing, authorization of operators, meter system verification, and procedural steps.

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Foreword

When rapid results are required for medical staff members to make therapeutic decisions, and the time required to obtain results from the clinical laboratory would compromise patient care, point-of-care (POC) blood glucose testing is appropriate.

Designing a POC blood glucose testing service requires the close and active collaboration of many departments within the operator's institution. The primary focus of responsibility for POC blood glucose testing may vary with the specific needs of each institution.

Guidelines for all aspects of a POC blood glucose testing service are presented in this document. Individual operators must demonstrate the ability to operate meter systems and perform QA procedures. Strict adherence to procedures as recommended by the device manufacturers must be observed.

Operators of POC testing glucose devices are cautioned to monitor changes in laboratory regulations so that procedures for POC blood glucose meter systems can be modified to comply with new requirements. This document does not deal with self-monitoring of blood glucose by persons with diabetes.

Updates in this third edition include the following:

- Implications of POC glucose testing programs that are designed to limit the range of blood glucose levels, or tight glycemic control
- Various limitations to POC blood glucose meter systems, including potential biological and pharmacological interferences
- Responsibilities of the laboratory service director with oversight for POC glucose testing programs
- Considerations for performing blood testing using samples obtained from alternate anatomic sites in acute patient care

Key Words

Glucose, glucose meters, point-of-care, quality assurance, quality control

Point-of-Care Blood Glucose Testing in Acute and Chronic Care Facilities; Approved Guideline—Third Edition

1 Scope

This guideline provides instructions and recommendations concerning the administration of point-of-care (POC) blood glucose monitoring programs at acute and chronic care facilities where laboratory support is available. POC blood glucose meter systems provide rapid results required by medical staff members to make therapeutic decisions.

This document applies to quantitative *in vitro* POC blood glucose meter systems intended for use by health care professionals for management of patients with diabetes mellitus and other conditions with fluctuations in glucose homeostasis. These test systems may be indicated for use with arterial, venous, or capillary whole blood samples obtained from adults, children, or neonates. This guideline does not pertain to glucose measurement for the purpose of self-monitoring of blood glucose, screening for diabetes, or diagnosing diabetes mellitus or other disorders of glucose metabolism.

As criteria for accepting a POC glucose meter are included in this document, manufacturers may wish to refer to this document as an indication of clinical requirements in the marketplace.

Automated clinical laboratory systems or analyzers used to perform routine and stat glucose testing on plasma, serum, whole blood, urine, and cerebrospinal fluid are not included in the scope of this guideline.

2 Introduction

POC blood glucose testing, as performed by trained personnel in acute and chronic care facilities, provides rapid blood glucose results that are used by medical staff members to make therapeutic decisions. In providing this service, the institution assumes a commitment to maintain high-quality POC blood glucose meter systems and effective processes and procedures for communicating the results to appropriate patient care providers.

Optimal use of a POC blood glucose meter system often requires the coordination and cooperation of multiple departments, training of operators with limited or no laboratory experience, and use of specimens and technologies that differ from those used by laboratories. Owing to the unique characteristics of this activity, an update on specific guidelines and policies for POC blood glucose meter systems is pertinent to ensure quality testing and accurate result reporting.

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. The Centers for Disease Control and Prevention (CDC) address this topic in published guidelines that focus on the daily operations of diagnostic medicine in human and animal medicine while encouraging a culture of safety in the laboratory.[1] 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.[2]

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

In addition, the term *"glucose meter systems"* is used throughout the document when referring to glucose monitoring systems and glucose testing systems.

4.2 Definitions

adverse event – untoward incident, therapeutic misadventure, iatrogenic injury, or other adverse occurrence directly associated with care or services provided within the jurisdiction of a medical center, outpatient clinic, or other health care facility; **NOTE:** Adverse events may result from acts of commission or omission (eg, administration of the wrong medication, failure to make a timely diagnosis or institute the appropriate therapeutic intervention, adverse reactions or negative outcomes of treatment).[3]

authorization – recognition of a person who has satisfied the qualification requirements to perform point-of-care blood glucose testing within an institution.

competency – the circumstance to have demonstrated and documented the ability to correctly perform testing using a point-of-care blood glucose meter system.

director – the person designated as having primary responsibility for the point-of-care blood glucose testing service.

informed consent – the process by which a person voluntarily confirms the willingness to participate in a particular medical procedure, after having been informed of all aspects of the procedure that are relevant to the decision to participate; **NOTE:** Informed consent is documented by means of a written, signed, and dated informed consent form.

instrument verification – a documented procedure for ensuring that point-of-care blood glucose meter instruments are performing according to the manufacturer's established criteria.

log book – a document containing information in physical or electronic form.

operator – a person who is authorized to perform point-of-care blood glucose testing.

plasma equivalent (result) – a glucose result obtained from a whole blood glucose meter system that is calibrated to yield a result from the same sample that is equivalent to the result obtained with plasma that has been separated from the cellular components and measured on a laboratory analyzer; **NOTE:** At nominal (43%) hematocrit, this value is approximately 11% higher than the whole blood concentration.[4]

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

POCT12-A3 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, beginning on page 48.

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 C24 C53 EP06 EP07 EP09 EP10 EP15 EP18 EP23	X			EP10 EP18	EP18
GP26	GP26	GP26 H03 H11 M29	GP26 H11	GP26 H03	GP26 H11	GP26 H03 H04 H11 LA04	GP02 GP26 H11	GP02 GP26	GP26	GP26	GP22 GP26 H11

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.

POCT12-A3 addresses the clinical laboratory path of workflow processes 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
	X				X		X	
				EP23	EP23	EP23		
GP26	GP26	GP26	GP26	GP26	GP26	GP26	GP26	GP26
H03	H03	H03	H03	H03	H03			
	H04							
H11	H11	H11	H11					
LA04	LA04	LA04	LA04	LA04				LA04

Related CLSI Reference Materials*

C24-A3 **Statistical Quality Control for Quantitative Measurement Procedures: Principles and Definitions; Approved Guideline—Third Edition (2006).** This guideline provides definitions of analytical intervals, planning of quality control procedures, and guidance for quality control applications.

C53-A **Characterization and Qualification of Commutable Reference Materials for Laboratory Medicine; Approved Guideline (2010).** This document provides information to help material manufacturers in the production and characterization of commutable reference materials, as well as to assist assay manufacturers and laboratorians in the appropriate use of these materials for calibration and trueness assessment of *in vitro* diagnostic medical devices. A CLSI-IFCC joint project.

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.

EP07-A2 **Interference Testing in Clinical Chemistry; Approved Guideline—Second Edition (2005).** This document provides background information, guidance, and experimental procedures for investigating, identifying, and characterizing the effects of interfering substances on clinical chemistry test results.

EP09-A2-IR **Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline—Second Edition (Interim Revision) (2010).** 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.

EP10-A3 **Preliminary Evaluation of Quantitative Clinical Laboratory Measurement Procedures; Approved Guideline—Third Edition (2006).** This guideline provides experimental design and data analysis for preliminary evaluation of the performance of a measurement procedure or device.

EP15-A2 **User Verification of Performance for Precision and Trueness; Approved Guideline—Second Edition (2006).** This document describes the demonstration of method precision and trueness for clinical laboratory quantitative methods utilizing a protocol designed to be completed within five working days or less.

EP18-A2 **Risk Management Techniques to Identify and Control Laboratory Error Sources; Approved Guideline—Second Edition (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-A™ **Laboratory Quality Control Based on Risk Management; Approved Guideline (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.

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.

GP22-A3 **Quality Management System: Continual Improvement; Approved Guideline—Third Edition (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.

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.

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.

Related CLSI Reference Materials (Continued)

H04-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.

H11-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.

LA04-A5 **Blood Collection on Filter Paper for Newborn Screening Programs; Approved Standard—Fifth Edition (2007).** This document addresses the issues associated with specimen collection, the filter paper collection device, and the application of blood to filter paper, and provides uniform techniques for collecting the best possible specimen for use in newborn screening programs.

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.

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