


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.

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 1-56238-867-3 (Print)
ISBN 1-56238-868-1 (Electronic)
ISSN 1558-6502 (Print)
ISSN 2162-2914 (Electronic)

POCT12-A3
Vol. 33 No. 2
Replaces C30-A2
Vol. 22 No. 17

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

Volume 33 Number 2

David B. Sacks, MD
David E. Bruns, MD
Judy Horton, DA, MS, MT(ASCP)
Stellan Lindberg, MSc
John J. Mahoney
Stephen Manzella, PhD
Eugene T. Reilly, MSc
Mitchell G. Scott, PhD

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.

Clinical and Laboratory Standards Institute (CLSI). *Point-of-Care Blood Glucose Testing in Acute and Chronic Care Facilities; Approved Guideline—Third Edition*. CLSI document POCT12-A3 (ISBN 1-56238-867-3 [Print]; 1-56238-868-1 [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



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. *Point-of-Care Blood Glucose Testing in Acute and Chronic Care Facilities; Approved Guideline—Third Edition*. CLSI document POCT12-A3. Wayne, PA: Clinical and Laboratory Standards Institute; 2013.

Previous Editions:

August 1989, June 1991, September 1994, August 2002

Reaffirmed:

September 2018

ISBN 1-56238-867-3 (Print)
ISBN 1-56238-868-1 (Electronic)
ISSN 1558-6502 (Print)
ISSN 2162-2914 (Electronic)

Committee Membership

Consensus Committee on Point-of-Care Testing

Frank M. LaDuca, PhD, FAHA
Chairholder
 ITC
 Piscataway, New Jersey, USA

Ann Chappie, MT(HHS)
 FDA Center for Devices and
 Radiological Health
 Silver Spring, Maryland, USA

Peggy Mann, MS, MT(ASCP)
 The University of Texas Medical
 Branch
 Texas City, Texas, USA

James H. Nichols, PhD, DABCC,
FACB
Vice-Chairholder
 Vanderbilt University School of
 Medicine
 Nashville, Tennessee, USA

Paul D'Orazio, PhD
 Instrumentation Laboratory
 Bedford, Massachusetts, USA

Ann E. Snyder, MT(ASCP)
 Centers for Medicare & Medicaid
 Services
 Baltimore, Maryland, USA

Sheldon M. Campbell, MD, PhD,
 FCAP
 Yale University School of Medicine
 New Haven, Connecticut, USA

Valerio M. Genta, MD
 Sentara Virginia Beach General
 Hospital
 Virginia Beach, Virginia, USA

Marcia L. Zucker, PhD
 ZIVD LLC
 Metuchen, New Jersey, USA

Document Development Committee on Point-of-Care Blood Glucose Testing Systems in Acute and Chronic Care Facilities

David B. Sacks, MD
Chairholder
 National Institutes of Health
 Bethesda, Maryland, USA

Judy Horton, DA, MS, MT(ASCP)
 Suburban Hospital
 Bethesda, Maryland, USA

Staff
 Clinical and Laboratory Standards
 Institute
 Wayne, Pennsylvania, USA

David E. Bruns, MD
Vice-Chairholder
 University of Virginia Medical
 School
 Charlottesville, Virginia, USA

Stellan Lindberg, MSc
 HemoCue AB
 Angelholm, Sweden

Luann Ochs, MS
Senior Vice President – Operations

Richard M. Bergenstal, MD
 International Diabetes Center At
 Park Nicollet
 Minneapolis, Minnesota, USA

Eugene T. Reilly, MSc
 FDA Center for Devices and
 Radiological Health
 Silver Spring, Maryland, USA

David E. Sterry, MT(ASCP)
Staff Liaison

Karen W. Dyer, MT(ASCP) DLM
 Centers for Medicare & Medicaid
 Services
 Baltimore, Maryland, USA

Mitchell G. Scott, PhD
 Barnes-Jewish Hospital,
 Washington University School of
 Medicine
 St. Louis, Missouri, USA

Megan L. Tertel, MA
Editor

Ryan J. Torres
Assistant Editor

Acknowledgment

CLSI, the Consensus Committee on Point-of-Care Testing, and the Document Development Committee on Point-of-Care Blood Glucose Testing Systems in Acute and Chronic Care Facilities gratefully acknowledge the following individuals for their important contributions to the revision of this document:

John J. Mahoney
 LifeScan, Inc.
 Milpitas, California, USA

Stephen Manzella, PhD
 York Hospital
 York, Pennsylvania, USA

Contents

Abstract.....	i
Committee Membership.....	iii
Foreword.....	vii
1 Scope.....	1
2 Introduction.....	1
3 Standard Precautions.....	1
4 Terminology.....	2
4.1 A Note on Terminology.....	2
4.2 Definitions.....	2
4.3 Abbreviations and Acronyms.....	3
5 Policy.....	3
5.1 Administration.....	3
5.2 Persons Who Perform the Tests.....	3
5.3 Measurement Procedure.....	4
5.4 Results.....	4
5.5 Quality Assurance.....	4
6 Appropriate Uses of Point-of-Care Blood Glucose Meter System.....	4
6.1 Applications.....	5
6.2 Limitations.....	5
6.3 Clinical Areas of Use.....	7
7 Administrative Responsibilities.....	8
7.1 Designation of Responsibility.....	8
7.2 Laboratory Service Director Responsibility.....	8
7.3 Coordination of Services.....	8
8 Performance Demonstration of Point-of-Care Blood Glucose Meter Systems.....	9
8.1 Initial Verification.....	9
8.2 Verification of Performance of Additional Glucose Monitors.....	9
8.3 Comparing Results of the Point-of-Care Blood Glucose Meter System and a Laboratory Instrument.....	9
8.4 Verification of Subsequent Lot of Reagent Strips.....	12
9 Quality Assurance Program.....	12
9.1 Quality Assurance Log.....	12
9.2 Quality Control.....	13
9.3 Maintenance and Service.....	13
9.4 External Quality Assessment.....	13
9.5 Data Management.....	13
10 Procedure.....	14
10.1 Procedure Manual.....	14
10.2 Specimen Collection.....	14

Contents (Continued)

10.3 Meter System Calibration18

10.4 Test Procedure18

10.5 Results.....18

11 Institutional Authorization Process19

11.1 Training Program19

11.2 Demonstration of Operator Competency for Point-of-Care Blood Glucose Meter
Systems20

11.3 Continuing Authorization21

11.4 Withdrawal of Point-of-Care Blood Glucose Testing Authorization21

References.....22

Appendix A. Evaluation of Point-of-Care Glucose Meters Using Leftover Human Specimens26

Appendix B. Evaluation of Point-of-Care Glucose Meters Using Capillary Blood36

The Quality Management System Approach46

Related CLSI Reference Materials48

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