CLINICAL AND LABORATORY STANDARDS INSTITUTE®

3rd Edition

POCT13c

Glucose Monitoring in Settings Without Laboratory Support

This guideline focuses on performance of point-of-care glucose monitoring systems, with an emphasis on safety practices, quality control, training, and administrative responsibility.

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

POCT13c, 3rd ed.
June 2018
Replaces POCT13-A2 and POCT13, 3rd ed.

Glucose Monitoring in Settings Without Laboratory Support

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Abstract

Clinical and Laboratory Standards Institute document POCT13—*Glucose Monitoring in Settings Without Laboratory Support* was developed for personnel monitoring glucose levels at sites other than a hospital laboratory. In a question and answer format, the document provides recommendations related to administrative structure, operator authorization, test system selection, QA, and test procedure. Samples of a written evaluation and QC logs are also included.

Clinical and Laboratory Standards Institute (CLSI). *Glucose Monitoring in Settings Without Laboratory Support*. 3rd ed. CLSI guideline POCT13c (ISBN 978-1-68440-000-3 [Print]; 978-1-68440-001-0 [Electronic]). Clinical and Laboratory Standards Institute, 950 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2018.

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Suggested Citation*

CLSI. *Glucose Monitoring in Settings Without Laboratory Support.* 3rd ed. CLSI guideline POCT13c. Wayne, PA: Clinical and Laboratory Standards Institute; 2018.

Previous Editions:

December 1996, June 1999, May 2005, June 2015

ISBN 978-1-68440-000-3 (Print)

ISBN 978-1-68440-001-0 (Electronic)

ISSN 1558-6502 (Print)

ISSN 2162-2914 (Electronic)

Volume 38, Number 11

* POCT13 was corrected in June 2018, and the code was revised to POCT13c.

Contents

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Foreword

This document contains guidelines for performance of point-of-care glucose monitoring systems that emphasize safety practices, QC, training, and administrative responsibility. This guideline was developed for personnel monitoring glucose levels at sites other than a hospital laboratory. **Additionally, personnel must only perform tests that have been authorized by the site coordinator and must meet the personnel qualifications involved in performing point-of-care testing.** In a question and answer format, the document provides recommendations related to administrative structure, operator authorization, test system selection, QA, and test procedure. Samples of a written evaluation and QC logs are also included.

Overview of Changes

This document replaces the second edition of the guideline, POCT13-A2, which was published in 2005. Several changes were made in this edition; chief among them include:

- Safety recommendations in Chapter 2
- Training program recommendations in Subchapter 3.3
- Information related to alternate site testing in Subchapter 5.3.2
- Information related to glucose meter result variations in Subchapter 5.7.3

This document was corrected in 2018 and replaces the original third edition of the guideline, POCT13, 3rd ed., which was published in June 2015. Corrections were made as follows:

- In Subchapter 1.4.2, the definition of lancing device was expanded for clarification.
- In Chapter 2, recommendations regarding the use of lancing devices, lancets, and glucose meters to prevent transmission of bloodborne pathogens were strengthened. Recommendations regarding the use of devices for dispensing insulin were added.
- In Chapter 3, the glucose monitoring program coordinator's responsibilities for infection control were clarified, including training and oversight practices.
- In Chapter 4, the intended use of blood glucose meters (ie, individual vs multipatient use meters) was clarified.
- In Chapter 5, the safety recommendations to prevent the transmission of bloodborne pathogens were improved.

IMPORTANT NOTE:

Personnel must only perform tests that have been authorized by the site coordinator and must meet the personnel qualifications involved in performing point-of-care testing.

IMPORTANT NOTE:

Throughout POCT13, the use of the term "must" was evaluated by the document development committee and deemed appropriate because the uses are either 1) based on a requirement or 2) indicative of a necessary step to ensure patient safety or proper fulfillment of a procedure.

Chapter 1

Introduction

This chapter includes:

- Document scope and applicable exclusions
- Background information pertinent to the document 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 document
- Abbreviations and acronyms used in the document

Glucose Monitoring in Settings Without Laboratory Support

NOTE:

It is assumed that authorized personnel have met the minimum personnel qualifications and training specified by the site coordinator.

NOTE:

This guideline should be used in settings where there is no laboratory support, to be defined by each institution. All areas of use shall be staffed with personnel who are authorized by the institution to use BGMS.

REMINDER:

Operators monitoring glucose levels in acute and chronic care facilities with on-site laboratory support should refer to CLSI document POCT12.[1]

1 Introduction

1.1 Scope

1.1.1 Who Should Use This Guideline?

This guideline was developed for authorized personnel directly involved in the establishment, management, and implementation of a blood glucose (BG) monitoring (BGM) program at sites without support from hospital laboratories. For the purposes of this document, these authorized personnel are referred to as "operators." In settings where there is more than one operator, one individual should be designated to coordinate the testing program. For the purposes of this document, this individual is referred to as the "coordinator." **It is assumed that authorized personnel have met the minimum personnel qualifications and training specified by the site coordinator.**

1.1.2 Where Should This Guideline Be Used?

This guideline should be used in settings where there is no laboratory support, such as those listed below, to be defined by each institution. All areas of use shall be staffed with personnel who are authorized by the institution to use BGM systems (BGMS).

This guideline is **not** intended for use in acute and chronic care facilities with on-site laboratory support. Operators monitoring glucose levels in these types of settings should refer to CLSI document POCT12.[1]

This guideline may be used in a variety of locations, which include but are not limited to:

- Physicians' offices
- Camps attended by people with diabetes
- Mobile emergency medical facilities
- Free-standing dialysis facilities
- Home health care settings (not applicable to individuals with diabetes who do their own testing)
- Visiting nursing programs or home care agencies
- Public health facilities
- Mobile or free-standing clinics (eg, migrant worker clinics, other clinics in remote locations)
- Occupational health facilities
- Pharmacies
- Prisons

REMINDER:

Individuals responsible for sourcing and considering a BGM device may also check publications in peer-reviewed journals on system performance evaluations in accordance with ISO 15197,[12] if applicable.

NOTE:

Consider possible interferences when choosing a glucose monitoring system. For example, the commonly consumed medication acetaminophen is a possible exogeneous interfering substance, which has caused falsely high glucose readings with some glucose meters.

NOTE:

When the patient population needs the option of alternate site testing, ensure that the BGMS instructions for use, from the manufacturer, specifically state that it is intended for that use.

4 What Considerations Should Guide the Choice of a Glucose Monitoring System?

4.1 Glucose Meter Performance

- The performance characteristics of different BGMS available, which include trueness, precision, and diagnostic accuracy of the system, within the critical BG ranges (eg, < 70 mg/dL [< 3.8 mmol/L], 70 to 180 mg/dL [3.8 to 10 mmol/L], > 180mg/dL [> 10 mmol/L])
  - For information on device performance, see the product labeling.
  - Individuals responsible for sourcing and considering a BGM device may also check publications in peer-reviewed journals on system performance evaluations in accordance with ISO 15197,[12] if applicable.
- Impact and number of interferences, assessed by the manufacturer (including medications, abnormal hematocrits, etc.), on the test system
  - For example, the commonly consumed medication acetaminophen is a possible exogeneous interfering substance, which has caused falsely high glucose readings with some glucose meters.
- Whether or not the manufacturer has relevant open compliance issues as cited by regulatory agencies (eg, US Food and Drug Administration in the United States)

4.2 Intended Use

- Individual vs multipatient use meters: If a meter is to be used on more than one person, the meter must be specifically designated by the manufacturer as appropriate for multipatient use,[25] and the manufacturer's instructions for cleaning and disinfection after each use must be followed.
- Range of BG concentrations measured by the system, compared to ranges likely in the patient population
- If the patient population needs the option of alternate site testing, ensuring that the BGMS is intended for that use
- Types of built-in fail-safes the system offers to prevent erroneous readings from being produced or recognized
- Other limitations for use

The device's instructions for use are an additional source of information related to the procedure manual topics listed above.

5.7 What Are the Components of a Quality Assurance Program?

A QA program is a system of multiple checks that assures reliable testing results, taking into consideration specimen collection and patient identification, QC procedures, maintenance and service of meters, recordkeeping, and training. The QA program should meet all regulatory requirements and/or accreditation standards applicable to the site or location.

5.7.1 Quality Assurance Records

QA records, which include QC results, lot numbers and expiration dates of glucose test strips and QC solutions, maintenance and service records, and other relevant documentation, should be maintained for each test system. See Appendixes A and D for examples of potential forms to use for QA records.

QA records should be reviewed by the coordinator or assigned personnel at least once per month, and should be kept for at least two years, or longer than two years if stipulated by the facility's policy.

5.7.2 Quality Control

The use of QC solutions is a critical part of any QA program to assess operator technique and the performance of glucose test strips and meters. All operators must participate in the QC program to demonstrate their competence in the operation of the glucose test strips and meter.

QC solution. Good QA practices dictate routine use of QC solutions to assess system performance. Manufacturers of glucose monitoring systems provide QC solutions specially formulated for optimal performance on their glucose test strips and meters. It is important to use only the QC solutions specifically labeled for use with each particular glucose meter and glucose test strip combination in order to ensure their correct operation. The acceptance ranges for the manufacturer-recommended QC solutions are printed on the glucose test strip vial labels. Generally, a QC program should use more than one QC solution in order to assess system performance at low and high glucose concentrations.

NOTE: There are a number of QC solutions available that are not manufactured by the glucose test strip and meter manufacturer. It is important to check the accompanying package insert to ensure the QC solution is intended to be used with the glucose test strip and meter brands being used. These QC solutions often contain the acceptable ranges in an accompanying package insert. The acceptable ranges for the manufacturer-recommended QC solutions are printed on the glucose test

NOTE:

Components of a QA program:

- Specimen collection and patient identification
- QC procedures
- Maintenance and service of meters
- Recordkeeping
- Training

The QA program should meet all regulatory requirements and/or accreditation standards applicable to the site or location.

NOTE:

QA records should be reviewed by the coordinator or assigned personnel at least once per month, and should be kept for at least two years, or longer than two years if stipulated by the facility's policy.

NOTE:

The use of QC solutions is a critical part of any QA program to assess operator technique and the performance of glucose test strips and meters. All operators must participate in the QC program to demonstrate their competence in the operation of the glucose test strips and meter.

REMINDER:

Each meter should have two logs, one for maintenance and service records and one for recording QC results (see Appendixes A and D, respectively).

IMPORTANT NOTE:

The acceptable limits for QC solutions, as specified by the manufacturer, should be posted so that users can determine if QC results are "in range" or are "out of range." The ranges for the QC solutions and lot number of test strips used should be included on the QC log.

6 Documentation of Quality Control Results and Meter Maintenance

Each meter should have two logs, one for maintenance and service records and one for recording QC results (see Appendixes A and D, respectively). Documentation for QC should include:

- QC test results
- Whether results are acceptable
- Date and time of testing
- Meter recalibration, if indicated by manufacturers' directions
- Glucose test strip lot number and expiration date
- QC solution lot number and expiration date
- Meter identification or serial number
- Initials of the operator performing the test (as well as a key to the identity of the people whose initials are listed)

These logs should be kept for a period of time consistent with regulatory requirements and other legal considerations.

The acceptable limits for QC solutions, as specified by the manufacturer, should be posted so that users can determine if QC results are "in range" or are "out of range." The ranges for the QC solutions and lot number of test strips used should be included on the QC log. All QC results should be recorded in the QC log. In addition, any corrective action taken to restore an "out-of-range" situation (eg, recalibration to a different lot of glucose test strips or the lot of control) should be carefully recorded in the log.

Appendix E. Common Problems With the Use of Glucose Meters

Causes of unreliable results may be individual/sample based or user/device based. Whenever a blood glucose test result is different than expected, ie, different from the person's clinical presentation, the test should be repeated with a fresh blood sample. If the result obtained remains different than expected, a QC solution measurement should be taken and compared to the acceptable range. If the QC solution value is unacceptable, the result should not be acted upon and the point-of-care glucose monitoring system instructions for use should be consulted for the manufacturer's recommended troubleshooting actions. Some common problems and their effects on meter glucose readings are listed in Table E1.

Table E1. Common Problems With Glucose Meters and Recommended Actions

Problem	Results	Recommendation
Glucose test strips not fully inserted into meter	Unreliable result or error code, or meter will not activate	Always be sure glucose test strip is fully inserted in meter.
Glucose test strip inserted upside down or wrong end inserted	Unreliable result or error code, or meter will not activate	Read instructions to learn correct insertion technique.
Display read upside down	Erroneous result (eg, 252 can read as 525)	Review meter use instructions.
Incorrectly coded meter	Unreliable result	Always confirm that the correct "code" has been entered.
Sample site contaminated with sugar (eg, the fingertip)	Unreliable result	Always thoroughly clean and dry test site before sampling.
Not enough blood applied to glucose test strip	Unreliable result or error code	Visually observe glucose test strip when filling to ensure proper filling.
User adds additional sample during reaction	Unreliable result	Review instructions for proper use techniques.
Batteries low on power	Error code	Change batteries and repeat sample collection.
Glucose test strips/controls past expiration date	Unreliable result	Check expiration dates and use within date supplied.
Glucose test strips/controls stored at temperature or humidity extremes	Unreliable result	Store kit and use strips according to manufacturer's directions.
Person dehydrated	Unreliable result	Call for additional assistance.
Person in shock	Unreliable result	Call for additional assistance.
Sites other than fingertips used	Unreliable result	Results from alternate sites may not match fingerstick results (physiological lag). Use fingerstick blood for POCT.
Presence of interfering medications or substances	Unreliable result	Check product insert for list of interfering substances, including disinfectant(s) not recommended by the manufacturer.

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

POCT13 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 page 58.

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				
						EP18			EP18	EP18	EP18
						GP42					
		M29									
			POCT12			POCT12	POCT12				