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.

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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.

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Contents

Abstract i
Committee Membership iii
Foreword vii
Chapter 1: Introduction 1
1.1 Scope 2
1.2 Background 4
1.3 Standard Precautions 5
1.4 Terminology 5
Chapter 2: Infection Control Program 11
Chapter 3: Information for the Coordinator 15
3.1 Why Is a Coordinator Needed? 16
3.2 What Are the Responsibilities of a Coordinator? 16
3.3 Training Program for Operators 17
3.4 How Should the Competence of Operators Be Determined? 20
Chapter 4: What Considerations Should Guide the Choice of a Glucose Monitoring System? 23
4.1 Glucose Meter Performance 24
4.2 Intended Use 24
4.3 Reagents 25
4.4 Manufacturer Support 25
4.5 Testing 25
4.6 Maintenance and Service 26
Chapter 5: What Should the Coordinator Do to Start a Glucose Monitoring Program? 27
5.1 Important Safety Measures 28
5.2 What Is Needed to Perform Glucose Monitoring? 29
5.3 What Should Be Done Before Testing? 30
5.4 What Should Be Included in Recording Test Results? 31
5.5 What Are Appropriate Responses to Abnormal Blood Glucose Concentrations? 31
5.6 Why Is a Procedure Manual Needed and What Should it Contain? 31
5.7 What Are the Components of a Quality Assurance Program? 33
5.8 Information for the Operator 36

Contents (Continued)

Chapter 6: Documentation of Quality Control Results and Meter Maintenance 39
Chapter 7: Proficiency Testing 41
Chapter 8: Conclusion 43
Chapter 9: Supplemental Information 45
References 46
Appendix A. Quality Assurance: Meter Maintenance Log 48
Appendix B. Example of a Procedure Format 49
Appendix C. Blood Glucose Test Result Log (Units of Measure) 50
Appendix D. Example of a Potential Quality Assurance Record: Quality Control Log 51
Appendix E. Common Problems With the Use of Glucose Meters 52
The Quality Management System Approach 56
Related CLSI Reference Materials 58

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.

NOTE: Mandates are occasionally allowed in CLSI guidelines, in cases in which the document development committee feels strongly that a particular action is either required or prohibited, or when a guideline addresses provisions based on regulations. 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.

KEY WORDS

Authorization
Blood glucose
Coordinator
Diabetes
Glucose monitoring system
Meter
Operator
Quality assurance
Quality control
Training

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

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.