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

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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]