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

This document contains guidelines for performance of point-of-care (POC) blood glucose testing that stress quality control, training, and administrative responsibility.

A guideline for global application developed through the NCCLS consensus process.

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

Abstract

NCCLS document C30-A2— *Point-of-Care Blood Glucose Testing in Acute and Chronic Care Facilities; Approved Guideline— Second 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. For facilities where laboratory support is not available, refer to NCCLS document AST4—*Blood Glucose Testing in Settings Without Laboratory Support.*

C30-A2 introduces policy-related issues with respect to administration of the program, persons who perform the tests, selection of methods, reporting of results, and the quality assurance aspects of point-of-care blood glucose testing. Also discussed are the uses of point-of-care blood glucose testing, authorization of operators, instrument verification, and procedural steps.

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Vejle Hospital (Denmark)
Washington Adventist Hospital (MD)
Washoe Medical Center Laboratory (NV)
West Jefferson Medical Center (LA)
West Shore Medical Center (MI)
Wilford Hall Medical Center (TX)
William Beaumont Army Medical Center (TX)
William Beaumont Hospital (MI)
Williamsburg Community Hospital (VA)
Winn Army Community Hospital (GA)
Winnipeg Regional Health Authority (Winnipeg, Canada)
Wishard Memorial Hospital (IN)
Yonsei University College of Medicine (Korea)
York Hospital (PA)

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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. Note, however, that this type of testing supplements, rather than substitutes for, testing in the clinical laboratory.

Designing a POC blood glucose testing service requires the close and active collaboration of many departments within the user 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. The committee believes that a facility must consider all of the recommendations within this document when developing a POC blood glucose testing service. Individual users must demonstrate their ability to operate instruments and perform quality assurance (QA) procedures. Strict adherence to procedures as recommended by the manufacturers must be observed.

Readers of this document are cautioned to monitor changes in laboratory regulations so that POC blood glucose testing procedures can be modified to comply with new requirements.

Standard Precautions

Because it is often impossible to know what might be infectious, all human blood specimens are to be 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 any pathogen and are thus more comprehensive than universal precautions, which are intended to apply only to transmission of blood-borne pathogens. Standard precaution and universal precaution guidelines are available from the U.S. Centers for Disease Control and Prevention (*Guideline for Isolation Precautions in Hospitals*. Infection Control and Hospital Epidemiology. CDC. 1996;Vol 17;1:53-80), (MMWR 1987;36[suppl 2S]2S-18S), and (MMWR 1988;37:377-382, 387-388). For specific precautions for preventing the laboratory transmission of blood-borne infection from laboratory instruments and materials and for recommendations for the management of blood-borne exposure, refer to NCCLS document M29—*Protection of Laboratory Workers from Occupationally Acquired Infections*.

Key Words

Authorization, blood glucose, diabetes, operator, point-of-care (POC) testing, training, verification

The Quality System Approach

NCCLS subscribes to a quality 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 through a gap analysis. The approach is based on the model presented in the most current edition of NCCLS HS1- *A Quality System Model for Health Care.* The quality system approach applies a core set of "quality system essentials (QSEs)," basic to any organization, to all operations in any healthcare service's path of workflow. The QSEs provide the framework for delivery of any type of product or service, serving as a manager's guide. The quality system essentials (QSEs) are:

QSEs

Documents & Records	Information Management
Organization	Occurrence Management
Personnel	Assessment
Equipment	Process Improvement
Purchasing & Inventory	Service & Satisfaction
Process Control	Facilities & Safety

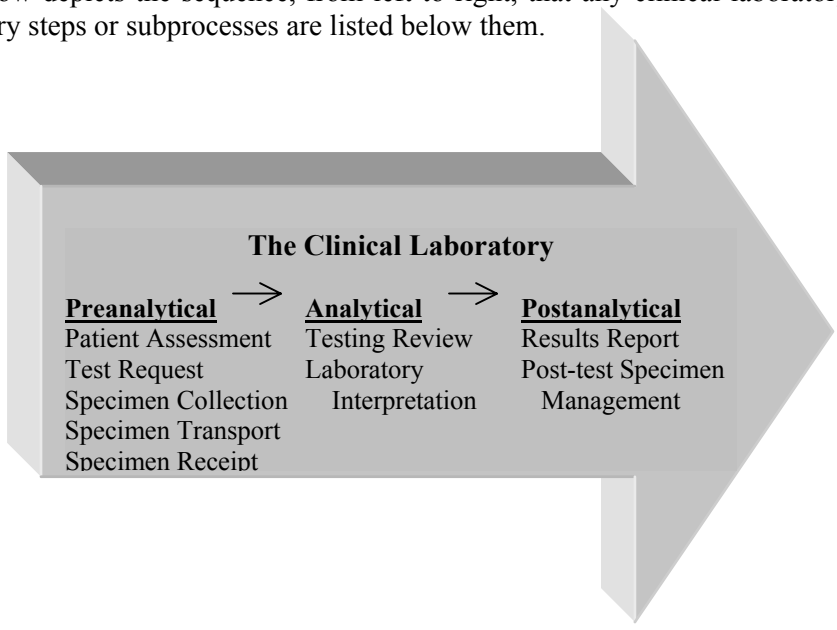
C30-A2 Addresses the Following Quality System Essentials (QSEs)

Documents & Records	Organization	Personnel	Equipment	Purchasing & Inventory	Process Control	Information Management	Occurrence Management	Assessment	Process Improvement	Service & Satisfaction	Facilities & Safety
X		X			X						

Adapted from NCCLS document HS1— *A Quality System Model for Health Care*

Path of Workflow

A path of workflow is the description of the necessary steps to deliver the particular product or service that the organization or entity provides. For example, GP26-A2 defines a clinical laboratory path of workflow that consists of three sequential processes: preanalytical, analytical, and postanalytical. All clinical laboratories follow these processes to deliver the laboratory's services, namely quality laboratory information. The arrow depicts the sequence, from left to right, that any clinical laboratory follows. In addition, the necessary steps or subprocesses are listed below them.



Adapted from NCCLS document HS1—*A Quality System Model for Health Care*

Most of NCCLS's documents relate to the clinical laboratory, so the most common path of workflow will be that depicted above. The path of workflow for other healthcare activities, e.g., respiratory services, imaging services, etc., or for other types of organizations, e.g., medical device manufacturers, will differ from that of the clinical laboratory. All such paths of workflow describe the sequence of activities necessary to produce the organization's or an entity's specific product or services. For those documents that relate to other paths of workflow, the icon will reflect different process steps.

C30-A2 Addresses the Following Steps Within the Clinical Laboratory Path of Workflow

Preanalytical					**Analytical**		**Postanalytical**	
Patient Assessment	Test Request	Specimen Collection	Specimen Transport	Specimen Receipt	Testing Review	Laboratory Interpre-tation	Results Report	Post-test Specimen Management
X		X			X		X	

Adapted from NCCLS document HS1—*A Quality System Model for Health Care*

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

1 Introduction

Point-of-care (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 testing and effective methods for communicating the results to appropriate patient-care providers.

There is a need for specific guidelines and policies for POC blood glucose testing due to the unique characteristics of this activity. POC blood glucose testing often requires the coordination and cooperation of multiple departments, training of operators with limited laboratory training, and use of specimens and technologies that differ from those used by laboratories.

1.1 Scope

This guideline provides instructions and recommendations concerning the administration of POC blood glucose monitoring programs at acute and chronic care facilities where laboratory support is available. POC blood glucose monitoring systems provide rapid results required by medical staff members to make therapeutic decisions. For facilities where laboratory support is not available, refer to NCCLS document AST4—*Blood Glucose Testing in Settings Without Laboratory Support.*

This document applies to quantitative *in vitro* POC whole blood glucose monitoring systems intended for use by healthcare professionals for management of patients with diabetes mellitus and other conditions with perturbations 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 screening for diabetes or diagnosing diabetes mellitus or other disorders of glucose metabolism.

Laboratory clinical chemistry analyzers or dedicated systems 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 Definitions[a]

Authorization, *n* - Recognition of a person who has satisfied the qualification requirements to perform POC blood glucose testing within an institution.

Competency, *n* - Following successful completion of a training program, the assessment of a person's ability to perform POC blood glucose testing.

Director, *n* - The person designated as having primary responsibility for the POC blood glucose testing service.

Instrument verification, *n* - A documented procedure for ensuring that POC blood glucose testing instruments are performing according to the manufacturer's established criteria.

[a] Some of these definitions are found in NCCLS document NRSCL8—*Terminology and Definitions for Use in NCCLS Documents.* For complete definitions and detailed source information, please refer to the most current edition of that document.