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# Glucose Monitoring in Settings Without Laboratory Support; Approved Guideline— Second Edition

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

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



*(Formerly NCCLS)  
Providing NCCLS standards and guidelines,  
ISO/TC 212 standards, and ISO/TC 76 standards*

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*Providing NCCLS standards and guidelines, ISO/TC 212 standards, and ISO/TC 76 standards*

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- the development and open review of documents
- the revision of documents in response to comments by users
- the acceptance of a document as a consensus standard or guideline.

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### Abstract

Clinical and Laboratory Standards Institute document AST4-A2, *Glucose Monitoring in Settings Without Laboratory Support; Approved Guideline—Second Edition* 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, quality assurance, and test procedure. Also included are samples of a written evaluation and quality control logs. The second half of the guideline can be used to create an on-site procedure manual.

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**Contents**

Abstract ..... i

Committee Membership ..... iii

Foreword ..... vii

1 Scope ..... 1

    1.1 Who Should Use This Guideline? ..... 1

    1.2 Where Should This Guideline Be Used? ..... 1

    1.3 What Is Included in This Guideline? ..... 2

    1.4 How Is This Guideline Organized? ..... 2

2 Introduction ..... 3

    2.1 Why Is This Guideline Important? ..... 3

    2.2 How Can This Guideline Be Used? ..... 3

    2.3 Are Blood Glucose Monitoring Systems as Accurate as Laboratory Instruments? ..... 4

3 Standard Precautions ..... 4

4 Definitions ..... 4

5 Information for the Coordinator ..... 7

    5.1 Why Is a Coordinator Needed? ..... 7

    5.2 What Are the Responsibilities of a Coordinator? ..... 7

    5.3 What Should the Coordinator Do to Start a Glucose Monitoring Program? ..... 8

    5.4 What Considerations Should Guide the Choice of a Glucose Monitoring System? ..... 8

    5.5 Why Is a Procedure Manual Needed and What Should It Contain? ..... 9

    5.6 What Are the Components of a Quality Assurance (QA) Program? ..... 10

    5.7 What Should Be Included in a Training Program for Operators? ..... 11

    5.8 How Should the Competence of Operators Be Determined? ..... 15

6 Information for the Operator ..... 16

    6.1 Who Can Perform This Testing? ..... 16

    6.2 What Is Needed to Perform Glucose Monitoring? ..... 18

    6.3 What Should Be Done Before Testing? ..... 19

    6.4 What Should Be Included in Recording Test Results? ..... 21

    6.5 What Are Appropriate Responses to Abnormal Blood Glucose Concentrations? ..... 21

7 Outline for Procedure Manual ..... 22

    7.1 Procedure ..... 22

References ..... 26

Appendix A. Possible Actions When a Person’s Glucose Concentration Is Very High or Very Low ..... 27

Appendix B. New Technologies ..... 30

Appendix C. Common Problems With the Use of Glucose Meters ..... 32

Summary of Delegate Comments and Working Group Responses ..... 34

**Contents (Continued)**

The Quality System Approach.....	38
Related CLSI/NCCLS Publications.....	39



## Foreword

This revision of CLSI/NCCLS document AST4—*Glucose Monitoring in Settings Without Laboratory Support* includes several modifications of the earlier version, which was last published in June 1999:

- Newer technologies have been addressed. Newer devices which measure glucose continuously, as opposed to episodically, may require new approaches. Additionally, some devices measure glucose in interstitial fluid rather than blood.
- Substantial information on appropriate operation of blood glucose monitoring devices has been included, as well as the effects of inappropriate operation of the devices.
- Several new definitions have been included and the terms and definitions have been harmonized with ISO terminology.
- A section has been included that addresses the differences between glucose concentration in capillary and venous blood as well as between plasma and whole blood.
- A comprehensive section on troubleshooting has been included.
- Where possible, the document has been harmonized with a companion CLSI/NCCLS document, C30—*Point-of-Care Blood Glucose Testing in Acute and Chronic Care Facilities*.
- Illustrations of appropriate skin puncture sites have been included.
- The format has been made consistent with other CLSI/NCCLS documents.

A Summary of Consensus Comments on the previous edition of this document (AST4-A) has not been included in the current edition, as all comments were editorial in nature.

### *A Note on Terminology*

Clinical and Laboratory Standards Institute (CLSI), as a global leader in standardization, is firmly committed to achieving global harmonization wherever possible. Harmonization is a process of recognizing, understanding, and explaining differences while taking steps to achieve worldwide uniformity. CLSI recognizes that medical conventions in the global metrological community have evolved differently in the United States, Europe, and elsewhere; that these differences are reflected in CLSI, ISO, and CEN documents; and that legally required use of terms, regional usage, and different consensus timelines are all obstacles to harmonization. Despite these obstacles, CLSI recognizes that harmonization of terms facilitates the global application of standards and is an area that needs immediate attention. Implementation of this policy must be an evolutionary and educational process that begins with new projects and revisions of existing documents.

In keeping with CLSI's commitment to align terminology with that of ISO, the following terms are used in AST4: *Accuracy* refers to the closeness of agreement between a *single test result* and the accepted reference value; whereas *Trueness* is used when referring to the closeness of the agreement between the *average value* obtained from a *large series of test results* and an accepted reference value; and *Precision* refers to the closeness of agreement between *independent test results* obtained under stipulated conditions. See the Definitions section of the guideline.

### **Key Words**

Authorization, blood glucose, coordinator, diabetes, glucose monitoring system, meter, operator, quality assurance, quality control, training, verification



## **Glucose Monitoring in Settings Without Laboratory Support; Approved Guideline—Second Edition**

### **1 Scope**

#### **1.1 Who Should Use This Guideline?**

This guideline has been developed for authorized personnel directly involved in the establishment, management, and implementation of a blood glucose monitoring program at sites without support from hospital laboratories. For the purposes of this document, these authorized personnel will be referred to as “Operators.” In settings where there is more than one Operator, one individual should be designated to coordinate the testing program; and for the purposes of this document, this individual will be referred to as the “Coordinator.”

#### **1.2 Where Should This Guideline Be Used?**

This guideline should be used in settings where there is no laboratory support, such as those mentioned below, to be defined by each institution. All areas of use shall be staffed with personnel who are authorized by the institution to use blood glucose testing meters.

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 the most current edition of CLSI/NCCLS document C30—*Point-of-Care Blood Glucose Testing in Acute and Chronic Care Facilities*.

This guideline for glucose monitoring 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 and surgical centers;
- home healthcare settings (not applicable to individuals with diabetes who do their own testing);
- visiting nursing programs;
- public health facilities;
- mobile or free-standing clinics (e.g., migrant worker clinics, other clinics in remote locations);
- occupational health facilities;
- pharmacies;
- prisons;