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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.

CLINICAL AND LABORATORY STANDARDS INSTITUTE ™

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Providing NCCLS standards and guidelines,
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The Clinical and Laboratory Standards Institute (CLSI, formerly NCCLS) is an international, interdisciplinary, nonprofit, standards-developing, and educational organization that promotes the development and use of voluntary consensus standards and guidelines within the healthcare community. It is recognized worldwide for the application of its unique consensus process in the development of standards and guidelines for patient testing and related healthcare issues. Our process is based on the principle that consensus is an effective and cost-effective way to improve patient testing and healthcare services.

In addition to developing and promoting the use of voluntary consensus standards and guidelines, we provide an open and unbiased forum to address critical issues affecting the quality of patient testing and health care.

PUBLICATIONS

A document is published as a standard, guideline, or committee report.

Standard A document developed through the consensus process that clearly identifies specific, essential requirements for materials, methods, or practices for use in an unmodified form. A standard may, in addition, contain discretionary elements, which are clearly identified.

Guideline A document developed through the consensus process describing criteria for a general operating practice, procedure, or material for voluntary use. A guideline may be used as written or modified by the user to fit specific needs.

Report A document that has not been subjected to consensus review and is released by the Board of Directors.

CONSENSUS PROCESS

The CLSI voluntary consensus process is a protocol establishing formal criteria for:

- the authorization of a project
- 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.

Most documents are subject to two levels of consensus—"proposed" and "approved." Depending on the need for field evaluation or data collection, documents may also be made available for review at an intermediate consensus level.

Proposed A consensus document undergoes the first stage of review by the healthcare community as a proposed standard or guideline. The document should receive a wide and thorough technical review, including an overall review of its scope, approach, and utility, and a line-by-line review of its technical and editorial content.

Approved An approved standard or guideline has achieved consensus within the healthcare community. It should be reviewed to assess the utility of the final document, to ensure attainment of consensus (i.e., that comments on earlier versions have been satisfactorily addressed), and to identify the need for additional consensus documents.

Our standards and guidelines represent a consensus opinion on good practices and reflect the substantial agreement by materially affected, competent, and interested parties obtained by following CLSI's established consensus procedures. Provisions in CLSI standards and guidelines may be more or less stringent than applicable regulations. Consequently, conformance to this voluntary consensus document does not relieve the user of responsibility for compliance with applicable regulations.

COMMENTS

The comments of users are essential to the consensus process. Anyone may submit a comment, and all comments are addressed, according to the consensus process, by the committee that wrote the document. All comments, including those that result in a change to the document when published at the next consensus level and those that do not result in a change, are responded to by the committee in an appendix to the document. Readers are strongly encouraged to comment in any form and at any time on any document. Address comments to the Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, PA 19087, USA.

VOLUNTEER PARTICIPATION

Healthcare professionals in all specialties are urged to volunteer for participation in CLSI projects. Please contact us at customerservice@clsi.org or +610.688.0100 for additional information on committee participation.

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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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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

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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;