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POCT06

Effects of Different Sample Types on Glucose Measurements

Sample

This report provides information to assist the clinical and point-of-care staff in result and measurement procedure comparisons of glucose tests.

A CLSI report for global application.

Effects of Different Sample Types on Glucose Measurements

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Abstract

Clinical and Laboratory Standards Institute document POCT06—*Effects of Different Sample Types on Glucose Measurements* provides information to assist the clinical and point-of-care staff in understanding the potential impact of the use of different sample types on results and measurement procedure comparisons of glucose test systems. The information includes preexamination, examination, and physiological considerations. This report will help clinicians understand how to better design evaluation protocols for technology or devices under consideration. Use of this report by clinicians will also help ensure that even those who adopt new technologies early will do so with the knowledge that ensures patient safety. Use of this report by manufacturers will help ensure they can meet and understand customer requirements in their product design for glucose testing systems.

The impacts of sample type, test methodology, calibration, sample transportation or delay in testing, and frequency are reviewed. The influence of metabolic changes was minimally addressed in CLSI document POCT12¹ and will be expanded upon here in order to help clinicians understand how to decide if metabolic changes are influencing result variances noted in a comparison.

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POCT06, 1st ed.

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Foreword

A variety of glucose test methodologies exist today. Processes for glucose testing in the continuum of care can vary by sample type and methodologies. Clinicians today review glucose results obtained using different methodologies even when the patient is in a single unit of the hospital. It is typical for the patient's chart to include glucose meter system results, as well as laboratory analyzer glucose results. The glucose sample could also be drawn from arterial, capillary, or venous blood and performed on whole blood, plasma, or serum. Any or all of these methodological and sample type variations (as well as user technique, reagent stability, sample handling, site of sampling, and testing environment issues, among other contributing sources of variation) can affect glucose test results.

Laboratorians and clinicians may also conduct comparison studies from time to time, either to evaluate a new or novel technology, or to understand how glucose measurement procedures in their facility relate to one another. As care practices evolve, this report will help inform the study investigator of factors that influence glucose measurement procedure comparisons. For example, hospitals are currently experiencing increased testing frequency for bedside (point-of-care) glucose testing. More frequent hospital use of this method of testing is driven by the use of insulin to maintain an inpatient in euglycemia (tight glycemic control). Although these protocols vary in execution, the typical time interval between glucose tests is determined by the patient's response to the insulin administration. This time interval typically varies from 15 minutes to four hours. A need exists to optimize staff efficiency, minimize patient discomfort, and assure the quality and accuracy of the glucose results while executing these protocols. This document can serve to identify possible causes of differences in glucose test results when different measurement technologies, sampling sites, and/or sample types are used.

The authors of this document acknowledge that trueness, repeatability, and reproducibility of glucose methodologies vary. This document provides guidance on the potential sources of error or variation in glucose test results, particularly when the results are obtained with two different measurement procedures using two different sample types (eg, comparing laboratory venous plasma glucose to meter system capillary whole-blood glucose results).

Key Words

Calibration, glucose, glucose monitors, point-of-care testing, sample types, test measurement procedure comparison

Effects of Different Sample Types on Glucose Measurements

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

1.1 Scope

This report is designed to help clinicians, system evaluators, regulators, and manufacturers understand the influence of various parameters on glucose test result comparisons and to understand the clinical challenges that exist when glucose methodologies, sample types, and user techniques differ. This report is intended to help discern whether or not a difference between glucose results is caused by 1) the test measurement procedure(s), 2) patient-specific interferences, 3) the protocol, or 4) by some combination of these factors. It also includes consideration for sample type, fluid compartments, physiology, and calibration of the devices.

The intended users of this report are clinicians, point-of-care teams, pathologists, laboratory directors, and manufacturers of glucose testing devices. The information will help users to understand the clinical challenges that exist within the continuum of care when glucose is measured using different methodologies and sample types.

This report is not intended to be used for measurement procedure validation of new technologies.

1.2 Background

Glucose test result comparisons occur in two distinct types of circumstances: single result-to-result comparisons or test measurement procedure evaluations using multiple sample comparisons. In the single result-to-result scenario, a clinician is interested in determining the accuracy of glucose measurement results of the measurement procedure (eg, blood glucose monitoring system [BGMS]) she/he routinely uses for intervention decisions, by direct comparison to the results obtained using a different measurement procedure (eg, a laboratory serum glucose). In the measurement procedure evaluation study, a glucose measurement system assessment is being conducted to understand the differences between two or more measurement procedures. Several factors influence these comparisons. Taking testing differences into consideration during product development continues to help manufacturers provide new testing solutions that better meet the needs of the clinicians and contribute to improved patient care and confidence.

1.3 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 bloodborne pathogens. The Centers for Disease Control and Prevention (CDC) addresses this topic in published guidelines that address the daily operations of diagnostic medicine in humans and animals while encouraging a culture of safety in the laboratory.² 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 M29.³

1.4 Terminology

1.4.1 A Note on Terminology

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, International Organization for Standardization (ISO), and European Committee for Standardization (CEN) documents; and that legally required use of terms, regional usage, and different consensus timelines are all important considerations in the harmonization process. In light of this, CLSI’s consensus process focuses on harmonization of terms to facilitate the global application of standards and guidelines.

In Subchapter 6.1.3 of this report, the term “system accuracy” is used when discussing the minimum performance criteria for BGMS found in ISO 15197.⁴ The criteria for system accuracy were established from the measurement procedure requirements (precision and trueness) for individual glucose results. The concept of “system accuracy” includes measurement bias and measurement precision. System accuracy describes the ability of a glucose monitoring system to produce measurement results that agree with true glucose values when the system is used as intended. The term “trueness” is also used in this document, as appropriate, when discussing the closeness of agreement between the average value obtained from large series of results of measurement and a true value.

1.4.2 Definitions

accuracy (measurement) – closeness of agreement between a measured quantity value and a true quantity value of a measurand (JCGM 200:2012⁵).

analyte – component represented in the name of a measurable quantity (ISO 17511⁶); **NOTE 1:** In the type of quantity “mass of protein in 24-hour urine,” “protein” is the analyte. In “amount of substance of glucose in plasma,” “glucose” is the analyte. In both cases, the long phrase represents the **measurand** (ISO 17511⁶); **NOTE 2:** In the type of quantity “catalytic concentration of lactate dehydrogenase isoenzyme 1 in plasma,” “lactate dehydrogenase isoenzyme 1” is the analyte (ISO 18153⁷).

bias – difference between the expectation of the test results and an accepted reference value (ISO 5725-1⁸).

calibration – operation that, under specified conditions, in a first step, establishes a relation between the quantity values with measurement uncertainties provided by measurement standards and corresponding indications with associated measurement uncertainties and, in a second step, uses this information to

The Quality Management System Approach

Clinical and Laboratory Standards Institute (CLSI) subscribes to a quality management system (QMS) 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. The QMS approach applies a core set of “quality system essentials” (QSEs), basic to any organization, to all operations in any health care service’s path of workflow (ie, operational aspects that define how a particular product or service is provided). The QSEs provide the framework for delivery of any type of product or service, serving as a manager’s guide. The QSEs are as follows:

Organization	Personnel	Process Management	Nonconforming Event Management
Customer Focus	Purchasing and Inventory	Documents and Records	Assessments
Facilities and Safety	Equipment	Information Management	Continual Improvement

POCT06 addresses the QSE indicated by an “X.” For a description of the other documents listed in the grid, please refer to the Related CLSI Reference Materials section on the following page.

Organization	Customer Focus	Facilities and Safety	Personnel	Purchasing and Inventory	Equipment	Process Management	Documents and Records	Information Management	Nonconforming Event Management	Assessments	Continual Improvement
		GP41 GP43 M29	GP43 POCT12 POCT13	GP41	GP43 POCT13	X EP07 EP32 GP39 GP41 GP42 GP43 GP44 POCT05 POCT12 POCT13	GP43 POCT12 POCT13				GP43

Path of Workflow

A path of workflow is the description of the necessary processes to deliver the particular product or service that the organization or entity provides. A laboratory path of workflow consists of the sequential processes: preexamination, examination, and postexamination and their respective sequential subprocesses. All laboratories follow these processes to deliver the laboratory’s services, namely quality laboratory information.

POCT06 addresses the clinical laboratory path of workflow steps indicated by an “X.” For a description of the other documents listed in the grid, please refer to the Related CLSI Reference Materials section on the following page.

Preexamination				Examination			Postexamination	
Examination ordering	Sample collection	Sample transport	Sample receipt/processing	Examination	Results review and follow-up	Interpretation	Results reporting and archiving	Sample management
GP41 GP43	X GP39 GP41 GP42 GP43 GP44 POCT12 POCT13	GP41 GP43 GP44	GP41 GP43 GP44	X GP41 POCT05 POCT13	X GP41 POCT12 POCT13	X POCT05	POCT12	

Related CLSI Reference Materials*

- EP07** **Interference Testing in Clinical Chemistry. 2nd ed., 2005.** This document provides background information, guidance, and experimental procedures for investigating, identifying, and characterizing the effects of interfering substances on clinical chemistry test results.
- EP32** **Metrological Traceability and Its Implementation. 1st ed., 2006.** This document provides guidance to manufacturers for establishing and reporting metrological traceability.
- GP39** **Tubes and Additives for Venous and Capillary Blood Specimen Collection. 6th ed., 2010.** This standard contains requirements for the materials, manufacturing, and labeling of venous and capillary blood collection devices.
- GP41** **Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture. 6th ed., 2007.** This document provides procedures for the collection of diagnostic specimens by venipuncture, including line draws, blood culture collection, and venipuncture in children.
- GP42** **Procedures and Devices for the Collection of Diagnostic Capillary Blood Specimens. 6th ed., 2008.** This document provides a technique for the collection of diagnostic capillary blood specimens, including recommendations for collection sites and specimen handling and identification. Specifications for disposable devices used to collect, process, and transfer diagnostic capillary blood specimens are also included.
- GP43** **Procedures for the Collection of Arterial Blood Specimens. 4th ed., 2004.** This document provides principles for collecting, handling, and transporting arterial blood specimens to assist with reducing collection hazards and ensuring the integrity of the arterial specimen.
- GP44** **Procedures for the Handling and Processing of Blood Specimens for Common Laboratory Tests. 4th ed., 2010.** This document includes criteria for preparing an optimal serum or plasma sample and for the devices used to process blood specimens.
- M29** **Protection of Laboratory Workers From Occupationally Acquired Infections. 4th ed., 2014.** Based on US regulations, this document provides guidance on the risk of transmission of infectious agents by aerosols, droplets, blood, and body substances in a laboratory setting; specific precautions for preventing the laboratory transmission of microbial infection from laboratory instruments and materials; and recommendations for the management of exposure to infectious agents.
- POCT05** **Performance Metrics for Continuous Interstitial Glucose Monitoring. 1st ed., 2008.** This document provides consensus guidelines for health care professionals, *in vitro* diagnostic (IVD) and medical device manufacturers, and regulatory agencies on how continuous glucose monitor (CGM) data should be: 1) presented; 2) compared between devices; and 3) compared between measurement technologies.
- POCT12** **Point-of-Care Blood Glucose Testing in Acute and Chronic Care Facilities. 3rd ed., 2013.** This document contains guidelines for performance of point-of-care blood glucose meter systems that stress quality control, training, and administrative responsibility.
- POCT13** **Glucose Monitoring in Settings Without Laboratory Support. 2nd ed., 2005.** This document contains guidelines for performance of point-of-care (POC) glucose monitoring systems that stress quality control, training, and administrative responsibility.

* CLSI documents are continually reviewed and revised through the CLSI consensus process; therefore, readers should refer to the most current editions.

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