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1st Edition

POCT06

Effects of Different Sample Types on Glucose Measurements

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

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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 POCT12[1] 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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Contents

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.