CLINICAL AND LABORATORY STANDARDS INSTITUTE®

1st Edition

EP33

Use of Delta Checks in the Medical Laboratory

This guideline provides approaches for selecting measurands for which delta checks are useful, establishing delta check limits and rules for comparing them to previous results, establishing delta check alerts in the laboratory information system, investigating specimens with delta check alerts, and evaluating the effectiveness of the laboratory's delta check systems.

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

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For additional information on committee participation or to submit comments, contact CLSI.

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Use of Delta Checks in the Medical Laboratory

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Abstract

Clinical and Laboratory Standards Institute document EP33—*Use of Delta Checks in the Medical Laboratory* provides guidance for developing procedures for delta checking and evaluating the differences between consecutive results for the same patient. Delta check alerts refer to situations in which differences between these consecutive results exceed specified limits. Such changes may indicate changes in patient conditions or specimen problems (eg, specimen misidentification, contaminated specimens, hemolyzed specimens). With the growing use of autoverification, delta checks are increasingly used as one of the tools to identify results that need additional review. This guideline represents a consensus of experts who have reviewed available data on approaches for the use of delta checks. It suggests approaches to establishing delta check limits, selecting measurands for which delta checks are useful, developing rules for comparing them to previous results, investigating specimens with delta check alerts, and evaluating the effectiveness of the laboratory's delta check systems.

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Foreword

The best tool currently available for detecting specimen misidentification is the delta check. The term delta check refers to a comparison of two sets of results from the same patient, based on specified criteria, as a quality improvement effort by the laboratory. The difference between the two sets is compared to a limit that is specific for the measurand. When the difference exceeds the limit, the current result is said to have triggered a delta check alert, and should be investigated. Delta checking can be relatively insensitive for detecting specimen mix-ups; however, delta checks can be optimized to improve their performance for this use. In addition, delta checks can be used to detect specimen integrity issues and clinically significant changes.

NOTE:

The best tool currently available for detecting specimen misidentification is the delta check.

The concept of delta checks was introduced by Nosanchuk and Gottman[1] in 1974 as a QC technique to identify misidentified specimens. In their original description of this approach, the authors used manual checking of a given patient's current and previous results to identify unlikely changes in laboratory procedure results. In 1975, Ladenson[2] described the first use of computers to compare patients' current and previous specimens in real time as results are reviewed. This basic approach to identifying significant delta checks changed little in the ensuing 40 years.

With the widespread use of autoverification, delta checks have become an important component of the tools used to identify results that need additional review before release to the medical record. The purpose of this guideline is to provide approaches for laboratories to use in determining how to apply delta checks.

Although delta checks have been in use in some laboratories for over 40 years, few descriptions exist in the peer-reviewed scientific literature of how delta checks may be used and for what purposes. This guideline provides clarity on the potential uses of delta checks and how to appropriately select measurands for accomplishing those uses.

Because the literature on delta checks is inadequate to develop standards on this topic, CLSI invites comments and feedback from users on the usefulness of this guideline, as well as additional information that may be useful for future revisions of this guideline. Please send comments to standard@clsi.org.

NOTE: The findings and conclusions in this document are those of the authors and are supported by the CLSI consensus process, and do not necessarily reflect the views of the organizations the authors represent.

KEY WORDS

Biological variation
Delta check
Delta check alert
Index of individuality
Patient safety
Reference change value

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

Use of Delta Checks in the Medical Laboratory

1 Introduction

1.1 Scope

This guideline provides recommendations for evaluating the changes between consecutive results for the same patient. These evaluations are called delta checks. The guideline reviews the selection and use of delta checks and provides basic information for laboratories that wish to use delta checks. The document considers several uses, including detection of misidentified specimens, contaminated or otherwise compromised specimens, and clinically significant changes in patients. The guideline reviews approaches to setting limits for expected differences in results, selection of appropriate measurement procedures for use in delta checks, and the types of comparisons that could be used; an approach to evaluating specimens that have delta check alerts; and suggested approaches to evaluate the effectiveness of delta checks once they have been implemented. It also provides guidance for defining appropriate follow-up steps for delta check alerts and for the evaluation of the performance of a laboratory's delta check program.

The intended users of this guideline are medical laboratory management and personnel. This information may also be of interest to hospital or laboratory informatics staff, and software and medical device vendors who need to understand the laboratory's goals when implementing automated delta checking.

This guideline does not directly discuss informatics aspects (computer programming) for establishing delta checks, or methods for determining the precision of the measurement procedures used.

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 using 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

EP33 covers 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 page 64.

Organization	Customer Focus	Facilities and Safety	Personnel	Purchasing and Inventory	Equipment	Process Management	Documents and Records	Information Management	Nonconforming Event Management	Assessments	Continual Improvement
						X					
						C56					
						EP31					
						GP33					
		GP41		GP41		GP41					
						GP44					
		M29									

Related CLSI Reference Materials*

C56 **Hemolysis, Icterus, and Lipemia/Turbidity Indices as Indicators of Interference in Clinical Laboratory Analysis. 1st ed., 2012.** This document provides background information on mechanisms of hemolysis, icterus, and lipemia/turbidity (HIL) interference; intended usefulness of HIL indices; establishment of HIL alert indices; availability of automated HIL detection systems; and interpretation, strengths, limitations, and verification of HIL indices in the clinical laboratory.

EP31 **Verification of Comparability of Patient Results Within One Health Care System. 1st ed., 2012.** This document provides guidance on how to verify comparability of quantitative laboratory results for individual patients within a health care system.

GP33 **Accuracy in Patient and Sample Identification. 1st ed., 2010.** This guideline describes the essential elements of systems and processes required to ensure accurate patient identification. The principles in this document may be applied to manual or electronic systems. Design considerations covered include criteria for accuracy, differences in inpatient vs outpatient settings that impact patient identification, language and cultural considerations, and standardization of processes across the health care enterprise.

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.

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.

* 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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