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.

Clinical and Laboratory Standards Institute

Setting the standard for quality in medical laboratory testing around the world.

The Clinical and Laboratory Standards Institute (CLSI) is a not-for-profit membership organization that brings together the varied perspectives and expertise of the worldwide laboratory community for the advancement of a common cause: to foster excellence in laboratory medicine by developing and implementing medical laboratory standards and guidelines that help laboratories fulfill their responsibilities with efficiency, effectiveness, and global applicability.

Consensus Process

Consensus—the substantial agreement by materially affected, competent, and interested parties—is core to the development of all CLSI documents. It does not always connote unanimous agreement, but does mean that the participants in the development of a consensus document have considered and resolved all relevant objections and accept the resulting agreement.

Commenting on Documents

CLSI documents undergo periodic evaluation and modification to keep pace with advancements in technologies, procedures, methods, and protocols affecting the laboratory or health care.

CLSI's consensus process depends on experts who volunteer to serve as contributing authors and/or as participants in the reviewing and commenting process. At the end of each comment period, the committee that developed the document is obligated to review all comments, respond in writing to all substantive comments, and revise the draft document as appropriate.

Comments on published CLSI documents are equally essential, and may be submitted by anyone, at any time, on any document. All comments are managed according to the consensus process by a committee of experts.

Appeals Process

When it is believed that an objection has not been adequately considered and responded to, the process for appeals, documented in the CLSI Standards Development Policies and Processes, is followed.

All comments and responses submitted on draft and published documents are retained on file at CLSI and are available upon request.

Get Involved—Volunteer!

Do you use CLSI documents in your workplace? Do you see room for improvement? Would you like to get involved in the revision process? Or maybe you see a need to develop a new document for an emerging technology? CLSI wants to hear from you. We are always looking for volunteers. By donating your time and talents to improve the standards that affect your own work, you will play an active role in improving public health across the globe.

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

Clinical and Laboratory Standards Institute
950 West Valley Road, Suite 2500
Wayne, PA 19087 USA
P: +1.610.688.0100
F: +1.610.688.0700
www.clsi.org
standard@clsi.org

EP33, 1st ed.
March 2016

Use of Delta Checks in the Medical Laboratory

James J. Miller, PhD, DABCC, FACB
Nuria Adem, MT(ASCP)
Raymond D. Aller, MD, FACMI, FHIMSS
Rex Astles, PhD, FACB, DABCC
M. Angeles Cuadrado-Cenzual, PhD, MD
Gerald Davis, MT(ASCP), MPH
D. Robert Dufour, MD
Cammie Fairburn, MS
Corinne R. Fantz, PhD, DABCC
Ana M. Gonzalez
David A. Lacher, MD, MEd
Curtis A. Parvin, PhD
Linda Stang, MLT
Joely Straseski, PhD, DABCC, FACB

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.

Clinical and Laboratory Standards Institute (CLSI). *Use of Delta Checks in the Medical Laboratory*. 1st ed. CLSI guideline EP33 (ISBN 1-56238-927-0 [Print]; ISBN 1-56238-928-9 [Electronic]). Clinical and Laboratory Standards Institute, 950 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2016.

CLINICAL AND LABORATORY STANDARDS INSTITUTE®

Suggested Citation

CLSI. *Use of Delta Checks in the Medical Laboratory*. 1st ed. CLSI guideline EP33. Wayne, PA: Clinical and Laboratory Standards Institute; 2016.

ISBN 1-56238-927-0 (Print)

ISBN 1-56238-928-9 (Electronic)

ISSN 1558-6502 (Print)

ISSN 2162-2914 (Electronic)

Volume 36, Number 3

Committee Membership

Consensus Committee on Evaluation Protocols

James F. Pierson-Perry
Chairholder
Siemens Healthcare Diagnostics, Inc.
USA

Mitchell G. Scott, PhD
Vice-Chairholder
Barnes-Jewish Hospital
USA

Richard Baltaro, MD, PhD, FCAP
College of American Pathologists
USA

Karl De Vore
Bio-Rad Laboratories, Inc.
USA

Robert J. McEnroe, PhD
Roche Diagnostics
USA

James H. Nichols, PhD, DABCC, FACB
Vanderbilt University Medical Center
USA

Gene Pennello, PhD
FDA Center for Devices and Radiological Health
USA

Megan E. Sawchuk, MT(ASCP)
Centers for Disease Control and Prevention
USA

Document Development Committee on Use of Delta Checks

James J. Miller, PhD, DABCC, FACB
Chairholder
University of Louisville Hospital
USA

Raymond D. Aller, MD, FACMI, FHIMSS
Keck Hospital of USC
USA

Rex Astles, PhD, FACB, DABCC
Centers for Disease Control and Prevention
USA

M. Angeles Cuadrado-Cenzual, PhD, MD
Hospital Clínico San Carlos
Spain

Gerald Davis, MT(ASCP), MPH
University of Michigan Hospital
USA

David A. Lacher, MD, MEd
National Center for Health Statistics
USA

Curtis A. Parvin, PhD
Bio-Rad Laboratories, Inc.
USA

Joely Straseski, PhD, DABCC, FACB
ARUP Laboratories
USA

Staff

Clinical and Laboratory Standards Institute
USA

Luann Ochs, MS
Project Manager

Megan L. Tertel, MA, ELS
Editorial Manager

Joanne P. Christopher, MA, ELS
Editor

Alexander B. Phucas
Editor

Acknowledgment

CLSI, the Consensus Committee on Evaluation Protocols, and the Document Development Committee on Use of Delta Checks gratefully acknowledge the following volunteers for their important contributions to the development of this document:

Nuria Adem, MT(ASCP)
Franciscan Health System
USA

D. Robert Dufour, MD
Veterans Affairs Medical Center
USA

Cammie Fairburn, MS
Munroe Regional Medical Center
USA

Corinne R. Fantz, PhD, DABCC
Lab Source, LLC
USA

Callum Fraser, PhD, FAACB
International Federation of Clinical Chemistry
United Kingdom

Ana M. Gonzalez
Beckman Coulter
USA

Linda Stang, MLT
University of Alberta Hospital
Canada

Acknowledgment in Memoriam of our Document Development Committee Chairholder

CLSI, the Consensus Committee on Evaluation Protocols, and the Document Development Committee on Use of Delta Checks gratefully acknowledge the contributions of Dr. James J. Miller, whose guidance and leadership were pivotal to the publication of this, and other, CLSI documents.

Contents

Contents (Continued)

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.

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.

NOTE:

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

KEY WORDS

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

This page is intentionally left blank.

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.