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2nd 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 current clinical reported results with previously reported results for a given patient, initiating delta check alerts in the laboratory information system, investigating patient samples with delta check alerts, and evaluating the effectiveness of the laboratory's delta check program.

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

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Use of Delta Checks in the Medical Laboratory

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Abstract

Clinical and Laboratory Standards Institute guideline EP33—*Use of Delta Checks in the Medical Laboratory* provides guidance for developing a program for a delta check quality control tool to evaluate the differences between consecutive results for the same patient. The delta check program alerts laboratory personnel to situations in which differences between these consecutive results exceed specified limits. Such changes may indicate changes in patient conditions or sample problems (eg, misidentification, contamination, hemolysis). 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 a patient test result to previous results, investigating samples with delta check alerts, and evaluating the effectiveness of the laboratory's delta check program.

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Foreword

One of the best tools currently available for detecting sample misidentification is the delta check. The term delta check refers to a comparison of two consecutive test results from the same patient, based on quality criteria specified by the laboratory. The difference between two consecutive test results is compared to a limit that is specific for that measurand. When the difference exceeds the set limit, the current result is said to have triggered a delta check alert and should be investigated. Delta checks can be relatively insensitive for detecting sample mix-ups; however, delta checks can be optimized to improve their performance. Additionally, delta checks can be used to detect sample integrity issues and clinically significant changes.

The concept of delta checks was introduced by Nosanchuk and Gottman[1] in 1974 as a quality control technique to identify misidentified samples. 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 test results. In 1975, Ladenson[2] described the first use of computers to compare patients' current and previous test results in real time as results are reviewed. This basic approach to identifying significant delta checks changed little in the ensuing 50 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 50 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.

Overview of Changes

This guideline was revised in 2023 under the Limited Revision Process and replaces the first edition of the guideline, which was published in 2016. Several changes were made in this edition, including:

- Emphasizing validation of the methods and published results for estimates of biological variation, which are important in setting limits for EP33
- Aligning this guideline with recommendations of the European Federation of Clinical Chemistry and Laboratory Medicine (EFLM),[3] which uses a strict methodology to assess the validity of published biological variation estimates:
  - For most measurands mentioned in EP33, EFLM has endorsed updated biological variation estimates for both within-subject biological variation (CV_I) and between-subject biological variation (CV_G). Thus, the calculated indices of individuality shown, which are the ratios of CV_I divided by CV_G, have been modified.
  - FLM does not list valid current estimates of CV_I and/or CV_G for mean corpuscular hemoglobin, partial thromboplastin time, cholesterol (total), or globulins (total). Thus, these measurands were deleted from Table 2.
- Aligning terminology throughout the guideline

NOTE: The content of this guideline is supported by the CLSI consensus process and does not necessarily reflect the views of any single individual or organization.

KEY WORDS

biological variation
delta check
delta check alert
index of individuality
patient safety
reference change value

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Chapter 1

Introduction

Use of Delta Checks in the Medical Laboratory

1 Introduction

1.1 Scope

This guideline provides recommendations for evaluating the changes between consecutive test results for the same patient in the same matrix. These evaluations are called delta checks. This guideline reviews the selection and use of delta checks and provides basic information for laboratories that intend to use delta checks. This document considers several uses, including detection of misidentified samples, contaminated or otherwise compromised samples, and clinically significant changes in patients' test results. This guideline reviews approaches to setting limits for expected differences in consecutive test results, selection of appropriate measurands for use in delta checks, and the types of comparisons that could be used; an approach to evaluating samples 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 an automated delta check program.

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

1.2 Background

Delta check alerts have been used primarily as part of quality improvement in the laboratory.[4] Any delta checking program necessarily detects differences in consecutive test results from causes in four areas (ie, sample misidentification, sample integrity problems, analytical problems, or significant clinical change in a patient), but not all four areas may be deemed important to monitor and act upon. Laboratories should identify their needs and customize their delta check programs accordingly.

Some researchers have concluded that the use of delta checks for identifying mislabeled samples may no longer be useful in some settings.[5,6] With much attention to proper labeling, bar-coded samples, and primary tube sampling, the prevalence of mislabeled samples may be lower in some settings. Delta checks for mislabeled samples may still be useful for laboratories with a higher risk. Also, other uses for delta checks are unaffected by the prevalence of mislabeled samples.

Although QC that uses commercially available control sera helps detect intralaboratory errors (ie, examination errors), patient-based QC techniques, such as delta checks, can detect preexamination, examination, and postexamination differences. Common causes of delta check alerts that occur outside the examination phase include patient misidentification at the time of phlebotomy or sample labeling, sample misidentification in the laboratory, sample contamination (eg, by intravenous [IV] fluids or use of inappropriate additives or preservatives), interferences in samples, and clerical errors. Delta check alerts can also be used to determine if significant clinical changes have occurred in a patient. In Ladenson's original study,[2] few of the delta check alerts were because of sample misidentification. Several other studies have found that most delta check alerts are because of changes in patient conditions.[7,8]