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Verification of Comparability of Patient Results Within One Health Care System; Approved Guideline

This document provides guidance on how to verify comparability of quantitative laboratory results for individual patients within a health care system.

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

CLINICAL AND LABORATORY STANDARDS INSTITUTE®
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International Federation of Clinical Chemistry and Laboratory Medicine

Clinical and Laboratory Standards Institute

Advancing Quality in Health Care Testing

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- the authorization of a project
- the development and open review of documents
- the revision of documents in response to comments by users
- the acceptance of a document as a consensus standard or guideline.

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Approved An approved standard or guideline has achieved consensus within the health care community. It should be reviewed to assess the utility of the final document, to ensure attainment of consensus (ie, that comments on earlier versions have been satisfactorily addressed), and to identify the need for additional consensus documents.

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VOLUNTEER PARTICIPATION

Health care professionals in all specialties are urged to volunteer for participation in CLSI projects. Please contact us at customerservice@clsi.org or +610.688.0100 for additional information on committee participation.

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Christopher M. Lehman, MD
John Rex Astles, PhD, FACB
Renze Bais, PhD
Sterling Bennett, MD
Ellis Jacobs, PhD, DABCC, FACB
Stan Johnson, MA
W. Gregory Miller, PhD
Jeffrey Vaks, PhD
Harvey Lipman, PhD
Amit R. Phansalkar, MS
Kenneth Sikaris, MD
Dietmar Stöckl, PhD
Greg Cooper, CLS, MHA

Abstract

Clinical and Laboratory Standards Institute document C54-A—*Verification of Comparability of Patient Results Within One Health Care System; Approved Guideline* provides guidance on how to verify comparability of quantitative laboratory results for individual patients across a health care system. For the purpose of this document, a health care system is defined as a system of physician offices, clinics, hospitals, and reference laboratories, under one administrative entity, where a patient may present for laboratory testing, and whose results may be reviewed by any health care provider within the system for the purpose of providing medical care. This document does not provide guidance on how to correct method noncomparability that may be identified.

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Committee Membership

Area Committee on Clinical Chemistry and Toxicology

David A. Armbruster, PhD, DABCC, FACB
Chairholder
Abbott Diagnostics
Abbott Park, Illinois

Christopher M. Lehman, MD
Vice-Chairholder
Univ. of Utah Health Sciences Center
Salt Lake City, Utah

John Rex Astles, PhD, FACB
Centers for Disease Control and Prevention
Atlanta, Georgia

David M. Bunk, PhD
National Institute of Standards and Technology
Gaithersburg, Maryland

David G. Grenache, PhD, MT(ASCP), DABCC
University of Utah
Salt Lake City, Utah

Steven C. Kazmierczak, PhD, DABCC, FACB
Oregon Health and Science University
Portland, Oregon

Linda Thienpont, PhD
University of Ghent
Ghent, Belgium

Jeffrey E. Vaks, PhD
Roche Molecular Diagnostics
Pleasanton, California

Hubert Vesper, PhD
Centers for Disease Control and Prevention
Atlanta, Georgia

Jack Zakowski, PhD, FACB
Beckman Coulter, Inc.
Brea, California

Advisors

Mary F. Burritt, PhD
Mayo Clinic
Scottsdale, Arizona

Paul D'Orazio, PhD
Instrumentation Laboratory
Lexington, Massachusetts

Carl C. Garber, PhD, FACB
Quest Diagnostics, Incorporated
Lyndhurst, New Jersey

Uttam Garg, PhD, DABCC
Children's Mercy Hospitals & Clinics
Kansas City, Missouri

Neil Greenberg, PhD
Ortho-Clinical Diagnostics, Inc.
Rochester, New York

Harvey W. Kaufman, MD
Quest Diagnostics, Incorporated
Lyndhurst, New Jersey

W. Gregory Miller, PhD
Virginia Commonwealth University
Richmond, Virginia

Gary L. Myers, PhD
Centers for Disease Control and Prevention
Atlanta, Georgia

David Sacks, MD
Brigham and Women's Hospital and Harvard Medical School
Boston, Massachusetts

Bette Seamonds, PhD
Mercy Health Laboratory
Swarthmore, Pennsylvania

Dietmar Stöckl, PhD
STT Consulting
Horebeke, Belgium

Thomas L. Williams, MD
Nebraska Methodist Hospital
Omaha, Nebraska

Subcommittee on Verification of Comparability of Patient Results

Christopher M. Lehman, MD
Chairholder
Univ. of Utah Health Sciences Center
Salt Lake City, Utah

John Rex Astles, PhD, FACB
Centers for Disease Control and Prevention
Atlanta, Georgia

Renze Bais, PhD
Pacific Laboratory Medicine Services
Sydney, Australia

Sterling Bennett, MD
LDS Hospital
Salt Lake City, Utah

Ellis Jacobs, PhD, DABCC, FACB
NYU/Bellevue
New York, New York

Stan R. Johnson, MA
Beckman Coulter, Inc.
Brea, California

W. Gregory Miller, PhD
Virginia Commonwealth University
Richmond, Virginia

Jeffrey E. Vaks, PhD
Roche Molecular Diagnostics
Pleasanton, California

Ian S. Young, MD, FRCP
Queen's University Belfast
Belfast, United Kingdom

Advisors

J. David Bessman, MD
Univ. of Texas Medical Branch
Galveston, Texas

Elma Kamari Bidkorpeh
Kaiser Permanente
North Hollywood, California

Harvey B. Lipman, PhD
Centers for Disease Control and Prevention
Atlanta, Georgia

Amit Phansalkar, MS
ARUP Laboratories
Salt Lake City, Utah

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Foreword

Patients may present for laboratory testing at multiple locations within a health care system. Continuity of medical care requires that the comparability of test results produced by different measurement systems be verified periodically. This document provides guidance on how to verify the comparability of quantitative laboratory results for analytes tested on different measurement systems. The document addresses causes of noncomparability, risk assessment of comparability failure, frequency of comparison testing, concentrations to be compared, commutability of comparability testing materials, a comparability testing protocol, and acceptance criteria for interpretation of comparability testing. The comparability testing protocol described in this document is an intuitive, simple approach that balances the need for a statistically valid, clinically relevant methodology with practical limitations on laboratory resources. Other valid procedures for comparability evaluation can be developed by a laboratory, and it is not the intent of this document to exclude their use. This protocol can also be used to validate reagent lot changes.

Key Words

accuracy, bias, coefficient of variation, commutability, comparability, imprecision, studentized range test

Verification of Comparability of Patient Results Within One Health Care System; Approved Guideline

1 Scope

This document provides guidance on how to verify comparability of quantitative laboratory results for individual patients within a health care system. For the purpose of this document, a health care system is defined as a system of physician offices, clinics, hospitals, and reference laboratories, under one administrative entity, where a patient may present for laboratory testing, and whose results may be reviewed by any health care provider within the system for the purpose of providing medical care.

The document provides a simple approach to be used for the assessment of patient laboratory result comparability across a maximum of 10 instruments, and assumes that a more comprehensive validation of quantitative measurement system comparability has been undertaken when the measurement systems were initially introduced into the laboratory. A more comprehensive comparison among measurement procedure results can follow a methodology such as that described in CLSI/NCCLS document EP09.[1] Comparability testing is just one facet of a program for assuring quality laboratory performance and is not intended to be a substitute for other quality monitors. This document does not address corrective action should method noncomparability be identified.

The approach described can also be used to verify comparability of patients' results in situations such as those following reagent or calibrator lot changes, instrument component changes or maintenance procedures, alerts from quality control (QC) or external quality assessment (EQA) (proficiency testing [PT]) events, or other special cause event.

2 Introduction

Out of necessity, or for their own convenience, patients may interface with health care systems for the purpose of laboratory testing in a variety of settings and/or locations. Results of these tests may be compiled and reviewed by providing clinicians at any of the patient care locations. In addition, larger laboratories may have multiple instruments within one location (eg, backup instruments, point-of-care [POC] instruments) that may provide laboratory results for an individual patient during a health care episode. Over time, lots of calibrator and reagents change, calibration and maintenance procedures are performed, and other events may occur that can affect patient test results. The diagnostic value of patient test results is maximized if the measurement systems providing such results are in a state of statistical control (ie, are producing stable and consistent results). Maintaining comparability may involve standardization and calibration of instruments, forced agreement of results among different measurement systems through mathematical transformation, or adoption of different reference intervals and/or therapeutic or diagnostic cutoffs that are clearly indicated in the patient report. Regardless of the approach used to achieve comparable results among different measurement systems, or to accommodate known differences, periodic verification of assay comparability is necessary to provide optimal patient care.

There is no consensus procedure for demonstrating patient laboratory result comparability for patient samples among measurement procedures. A survey of the participants involved in the preparation of this document demonstrated a variety of approaches to testing frequency, number and type of samples tested (eg, random, high and low concentrations, or concentrations spanning the analytical measurement range), evaluation and acceptance criteria for the results of comparison testing, and method of dealing with known bias between methods. The intent of this document is to review the salient issues surrounding verification of comparability of patient results among measurement procedures, and to provide a practical, statistically valid approach that laboratories of varying size and resources can use to satisfy this quality

