CLINICAL AND LABORATORY STANDARDS INSTITUTE®

August 2012

EP31-A-IR

Verification of Comparability of Patient Results Within One Health Care System; Approved Guideline (Interim Revision)

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

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

ISBN 1-56238-851-7 (Print)
ISBN 1-56238-852-5 (Electronic)
ISSN 1558-6502 (Print)
ISSN 2162-2914 (Electronic)

EP31-A-IR
Vol. 32 No. 11
Formerly C54-A-IR
Vol. 32 No. 11

Verification of Comparability of Patient Results Within One Health Care System; Approved Guideline (Interim Revision)

Volume 32 Number 11

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

Abstract

Clinical and Laboratory Standards Institute document EP31-A-IR—*Verification of Comparability of Patient Results Within One Health Care System; Approved Guideline (Interim Revision)* 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.

Clinical and Laboratory Standards Institute (CLSI). *Verification of Comparability of Patient Results Within One Health Care System; Approved Guideline (Interim Revision)*. CLSI document EP31-A-IR (ISBN 1-56238-851-7 [Print]; ISBN 1-56238-852-5 [Electronic]). Clinical and Laboratory Standards Institute, 950 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2012.

Suggested Citation

CLSI. *Verification of Comparability of Patient Results Within One Health Care System; Approved Guideline (Interim Revision).* CLSI document EP31-A-IR. Wayne, PA: Clinical and Laboratory Standards Institute; 2012.

Previous Editions:
October 2007, May 2008

Reaffirmed:
January 2017

ISBN 1-56238-851-7 (Print)
ISBN 1-56238-852-5 (Electronic)
ISSN 1558-6502 (Print)
ISSN 2162-2914 (Electronic)

Committee Membership

The changes in this interim revision were approved by the Consensus Committee on Clinical Chemistry and Toxicology as follows:

David G. Grenache, PhD, DABCC, FACB
Chairholder
University of Utah, ARUP Laboratories
Salt Lake City, Utah, USA

Loralie J. Langman, PhD
Vice-Chairholder
Mayo Clinic
Rochester, Minnesota, USA

Julianne Cook Botelho, PhD
Centers for Disease Control and Prevention
Atlanta, Georgia, USA

Yung W. Chan, MT(ASCP)
FDA Center for Devices and Radiological Health
Rockville, Maryland, USA

Corinne R. Fantz, PhD, DABCC
Emory University
Atlanta, Georgia, USA

T. Scott Isbell, PhD, DABCC, FACB
Nova Biomedical Corporation
Chicago, Illinois, USA

Jessie Shih, PhD
Abbott
Abbott Park, Illinois, USA

Graham H. White, PhD
Flinders Medical Centre
Bedford Park, South Australia

Jack Zakowski, PhD, FACB
Beckman Coulter
Brea, California, USA

Staff

Clinical and Laboratory Standards Institute
Wayne, Pennsylvania, USA

Luann Ochs, MS
Senior Vice President – Operations

Ron S. Quicho
Staff Liaison

Megan P. Larrisey, MA
Editor

Ryan J. Torres
Assistant Editor

Acknowledgments

CLSI and the Consensus Committee on Clinical Chemistry and Toxicology gratefully acknowledge James Huntington and Simon Huntington, Co-founders, Analyse-it®, Leeds, United Kingdom, for their unwavering commitment and focused effort on the joint venture partnership with CLSI in the development of software to help laboratories easily implement these CLSI statistical methods.

Special thanks go to the following experts for carefully reviewing the statistics in EP31-A-IR and applying their expert knowledge of statistical analysis for method validation to identify and offer solutions for the discrepancies and errors that have been corrected in this interim revision:

Jeffrey R. Budd, PhD
Beckman Coulter
Chaska, Minnesota, USA

Karl De Vore
Bio-Rad Laboratories, Inc.
Irvine, California, USA

Douglas M. Hawkins, PhD
University of Minnesota
Minneapolis, Minnesota, USA

Christopher M. Lehman, MD
University of Utah Health Sciences Center
Salt Lake City, Utah, USA

Curtis A. Parvin, PhD
Bio-Rad Laboratories
Plano, Texas, USA

The previous version of the document, C54-A (published in May 2008), was approved by the following CLSI committees:

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

Acknowledgments

This guideline was prepared by CLSI, as part of a cooperative effort with IFCC to work toward the advancement and dissemination of laboratory standards on a worldwide basis. CLSI gratefully acknowledges the participation of IFCC experts Ian S. Young, MD, FRCP; and Renze Bais, PhD, on this project.

In addition, CLSI and the Subcommittee on Verification of Comparability of Patient Results gratefully acknowledge the following volunteer for his important contributions to the development and/or completion of this document: Greg Cooper, CLS, MHA, Bio-Rad Laboratories, Inc.

Contents

Contents (Continued)