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

NOTE: Multiple corrections have been made to the formulae and information in this document. For a listing of all corrections, see page xi.

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.

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

Abstract

Clinical and Laboratory Standards Institute document C54-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.

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Volume 32 Number 11

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Contents

Contents (Continued)

Interim Revision Changes to C54-A

Section 4
- A definition has been added for “standard deviation.”

Sections 8.2.1
- An explanation of the “range test” has been substituted for the “studentized range test” description.

Section 10.3
- A modified protocol for identifying an approximate analyte concentration to be used for the range test has been substituted. The new protocol requires knowledge of both total and within-run precision of the measurement system at the selected analyte concentration.

Section 10.7
- A description of how to calculate the critical difference for the range test has been included.

Sections 10.8
- A protocol for determining both the number of runs and number of replicates per run for the range test has been included.

Appendix A. Worked Examples
- Examples of how to use the document have been revised.

Appendix B. Tables of Runs, Replicates, and Range Rejection Limits
- New tables for use in determining both the number of runs and number of replicates per run for the range test have been included, as well as a description of how to use the tables.

Appendix C. Statistical Concepts
- C4. Range Test—The mathematical basis for the range test replaces Section C4 of the prior version of the document.

- C5. Within-run vs Total Standard Deviation—A description of the components of the precision of a measurement system are provided to elucidate the need for two runs when between-run imprecision makes up a significant proportion of total SD. This replaces Section C5 of the prior version of the document.

- C6. Number of Replicates—This section was eliminated.

- C7. Power Curves—This section was eliminated.

- C8. Comparative Power of Test Procedures—This section was eliminated.

Summary of Consensus and Delegate Comments and Subcommittee Responses

- The Summary of Consensus and Delegate Comments and Subcommittee Responses was removed as part of this interim revision. This summary is on file at the CLSI office and available upon request by contacting CLSI at 610.688.0100 or standard@clsi.org.

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, range test

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

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.

C54 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 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 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 [AMR]), 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

