C54-P
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Verification of Comparability of Patient Results Within One Health Care System; Proposed Guideline

PLEASE

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This proposed document is published for wide and thorough review in the new, accelerated Clinical and Laboratory Standards Institute (CLSI) consensus-review process. The document will undergo concurrent consensus review, Board review, and delegate voting (ie, candidate for advancement) for 60 days.

Please send your comments on scope, approach, and technical and editorial content to CLSI.

Comment period ends

31 December 2007

The subcommittee responsible for this document will assess all comments received by the end of the comment period. Based on this assessment, a new version of the document will be issued. Readers are encouraged to send their comments to Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, PA 19087-1898 USA; Fax: +610.688.0700, or to the following e-mail address: customerservice@clsi.org

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COMMENT

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®
(Formerly NCCLS)

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International Federation of Clinical Chemistry and Laboratory Medicine

Clinical and Laboratory Standards Institute

Advancing Quality in Health Care Testing

Clinical and Laboratory Standards Institute (CLSI, formerly NCCLS) is an international, interdisciplinary, nonprofit, standards-developing, and educational organization that promotes the development and use of voluntary consensus standards and guidelines within the health care community. It is recognized worldwide for the application of its unique consensus process in the development of standards and guidelines for patient testing and related health care issues. Our process is based on the principle that consensus is an effective and cost-effective way to improve patient testing and health care services.

In addition to developing and promoting the use of voluntary consensus standards and guidelines, we provide an open and unbiased forum to address critical issues affecting the quality of patient testing and health care.

PUBLICATIONS

A document is published as a standard, guideline, or committee report.

Standard A document developed through the consensus process that clearly identifies specific, essential requirements for materials, methods, or practices for use in an unmodified form. A standard may, in addition, contain discretionary elements, which are clearly identified.

Guideline A document developed through the consensus process describing criteria for a general operating practice, procedure, or material for voluntary use. A guideline may be used as written or modified by the user to fit specific needs.

Report A document that has not been subjected to consensus review and is released by the Board of Directors.

CONSENSUS PROCESS

The CLSI voluntary consensus process is a protocol establishing formal criteria for:

- 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.

Most documents are subject to two levels of consensus—"proposed" and "approved." Depending on the need for field evaluation or data collection, documents may also be made available for review at an intermediate consensus level.

Proposed A consensus document undergoes the first stage of review by the health care community as a proposed standard or guideline. The document should receive a wide and thorough technical review, including an overall review of its scope, approach, and utility, and a line-by-line review of its technical and editorial content.

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.

Our standards and guidelines represent a consensus opinion on good practices and reflect the substantial agreement by materially affected, competent, and interested parties obtained by following CLSI's established consensus procedures. Provisions in CLSI standards and guidelines may be more or less stringent than applicable regulations. Consequently, conformance to this voluntary consensus document does not relieve the user of responsibility for compliance with applicable regulations.

COMMENTS

The comments of users are essential to the consensus process. Anyone may submit a comment, and all comments are addressed, according to the consensus process, by the committee that wrote the document. All comments, including those that result in a change to the document when published at the next consensus level and those that do not result in a change, are responded to by the committee in an appendix to the document. Readers are strongly encouraged to comment in any form and at any time on any document. Address comments to Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, PA 19087, USA.

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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Abstract

Clinical and Laboratory Standards Institute document C54-P—*Verification of Comparability of Patient Results Within One Health Care System; Proposed 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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Contents

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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.

Invitation for Participation in the Consensus Process

An important aspect of the development of this and all CLSI documents should be emphasized, and that is the consensus process. Within the context and operation of CLSI, the term “consensus” means more than agreement. In the context of document development, “consensus” is a process by which CLSI, its members, and interested parties (1) have the opportunity to review and to comment on any CLSI publication; and (2) are assured that their comments will be given serious, competent consideration. Any CLSI document will evolve as will technology affecting laboratory or health care procedures, methods, and protocols; and therefore, is expected to undergo cycles of evaluation and modification.

The Area Committee on Clinical Chemistry and Toxicology has attempted to engage the broadest possible worldwide representation in committee deliberations. Consequently, it is reasonable to expect that issues remain unresolved at the time of publication at the proposed level. The review and comment process is the mechanism for resolving such issues.

The CLSI voluntary consensus process is dependent upon the expertise of worldwide reviewers whose comments add value to the effort. At the end of a 60-day comment period, each subcommittee is obligated to review all comments and to respond in writing to all which are substantive. Where appropriate, modifications will be made to the document, and all comments along with the subcommittee’s responses will be included as an appendix to the document when it is published at the next consensus level.

Key Words

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

Verification of Comparability of Patient Results Within One Health Care System; Proposed 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 ten 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 EP9.[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 or external quality assessment (proficiency testing) 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 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

