CLINICAL AND LABORATORY STANDARDS INSTITUTE®

2nd Edition

CLSI EP31™

Verification of Comparability of Patient Results Within One Health Care System

CLSI EP31 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.

CLSI EP31-Ed2
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Replaces CLSI EP31-A-IR

Verification of Comparability of Patient Results Within One Health Care System

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Abstract

CLSI EP31—*Verification of Comparability of Patient Results Within One Health Care System* provides guidance on how to verify comparability of quantitative laboratory results for individual patients across a health care system. For the purpose of CLSI EP31, a health care system is defined as a system of physician offices, clinics, hospitals, and reference laboratories, under an administrative entity, where a patient might present for laboratory testing, and whose results might be reviewed by any health care provider within the system for the purpose of providing medical care.

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Foreword

Patients can present for laboratory testing at multiple locations within a health care system. To ensure a consistent level of medical care, it is necessary to regularly confirm that test results from various measurement systems are comparable. CLSI EP31 provides guidance on how to verify the comparability of quantitative laboratory results for analytes tested on different measurement systems.

CLSI EP31 covers the following topics related to the comparability of medical laboratory tests:

- Causes of noncomparability
- Risk assessment of comparability failure
- Frequency of comparison testing
- Concentrations to be compared
- Commutability of comparability testing materials
- Comparability testing protocol
- Acceptance criteria for interpretation of comparability testing

The comparability testing protocol described in CLSI EP31 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 CLSI EP31 to exclude their use.

Overview of Changes

CLSI EP31-Ed2 replaces CLSI EP31-A-IR, published in 2012. Several changes were made in this edition, including:

- Updating terminology and alignment with other changed or new CLSI EP documents
- Providing additional guidance on how to handle noncomparability of methods when detected, with examples in the Appendixes
- Directing readers to CLSI EP46[1] for guidance on determining total allowable error goals or limits for noncommutability
- Providing an additional chapter on the range test, its limitations due to type I error, and its rationale

NOTE: The content of CLSI EP31 is supported by the CLSI consensus process and does not necessarily reflect the views of any single individual or organization.

KEY WORDS

allowable total error
bias
commutability
comparability
imprecision
range test
troubleshooting

Chapter 1

Introduction

Verification of Comparability of Patient Results Within One Health Care System

1 Introduction

1.1 Scope

CLSI EP31 provides recommendations on how to verify comparability of quantitative laboratory results between 2 or more instruments for individual patients within a health care system.

Instruments can vary in several ways:

- Methodologies used by different manufacturers
- Instrument models from the same manufacturer
- Individual instruments of the same model or type

For CLSI EP31, a health care system is defined as a system of physician offices, clinics, hospitals, and reference laboratories, under a single administrative entity, where a patient might present for laboratory testing, and whose results might be reviewed by any health care provider within the system for the purpose of providing medical care.

CLSI EP31 provides a protocol to be used for assessing patient laboratory result comparability across a maximum of 10 instruments using a range test but does include modified strategies when the number of instruments exceeds 10. The CLSI EP31 document committee assumes that a more comprehensive evaluation of quantitative measurement system comparability was undertaken when the measurement systems were initially introduced into the laboratory. The intended users of CLSI EP31 are professionals and administrators within a health care system who are responsible for ensuring the consistency and reliability of laboratory results across different facilities within the system. This includes a broad range of health care professionals such as laboratory technicians, medical laboratory scientists, pathologists, and health care administrators who oversee laboratory services.

CLSI EP31 explores potential reasons for failing a comparability evaluation (either because of error or real repeatable biases) and approaches to mitigate noncomparability through reporting of patient results. Also covered are risk assessments of patient harm because of diagnostic error caused by inappropriate comparability testing frequency, incorrect concentrations being compared, lack of commutability of testing materials, and inappropriate acceptance criteria for interpretation of comparability testing.

The approach described can also be used to verify comparability of patients' results in situations such as instrument component changes or maintenance procedures, alerts from QC, external quality assessment (EQA), proficiency testing (PT) events, or other special-cause events. Comparability after reagent or calibrator lot changes are covered similarly, but more directly applied in CLSI EP26.[2]

Although CLSI EP09[3] provides more rigorous approaches for comparing 2 methods, there is no consensus procedure for demonstrating patient laboratory result comparability for patient samples among more than 2 measurement procedures. The participants involved in revising CLSI EP31 show different approaches for determining the frequency, number/quantity, and types of samples used in testing (eg, random, high, and low concentrations, or concentrations spanning the analytical measuring interval). They also use varying criteria for evaluating and accepting the results of comparison testing and demonstrate ways for dealing with known bias between methods. This approach reflects the complexity of ensuring comparability across multiple methods

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